NUREG-1650
Addendum 2

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

April 2005

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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ABSTRACT

This report documents the U.S. Nuclear Regulatory Commission's answers to questions raised by contracting parties during their peer reviews of the Third U.S. National Report for the Convention on Nuclear Safety (NUREG-1650, Rev. 1). Contracting parties to the Convention have two obligations - submit a national report for peer review and review the national reports of other contracting parties. The United States submitted its National Report in September 2004 to the third review meeting of the contracting parties to the Convention for peer review. The meeting was held at the International Atomic Energy Agency in Vienna, Austria, in April 2005. Specifically, the questions and answers resulting from the peer reviews concern the safety of existing nuclear installations, the legislative and regulatory framework, the regulatory body, responsibility of the licensee, priority to safety, financial and human resources, human factors, quality assurance, assessment and verification of safety, radiation protection, emergency preparedness, siting, design, construction, and operation.

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EXECUTIVE SUMMARY

This report documents the U.S. Nuclear Regulatory Commission's (NRC's) answers to questions raised by contracting parties to the Convention during their peer reviews of the U.S. National Report for the Convention on Nuclear Safety (NUREG-1650, Rev.1). Contracting parties have two obligations - submit a national report for peer review and review the national reports of other contracting parties. The United States submitted its National Report in September 2004 to the third review meeting of the contracting parties to the Convention for peer review. This meeting was held at the International Atomic Energy Agency (IAEA) in Vienna, Austria, in April 2005. (The U.S. National Report is also posted on the NRC's Web site at http://www.nrc.gov.)

Upon receiving questions from contracting parties, the NRC staff sorted them according to the article of the U.S. National Report that addressed the relevant material. Technical and regulatory experts at the NRC then answered the questions.

This report follows the format of the U.S. Report for the Convention on Nuclear Safety. Sections are numbered according to the article of the Convention under consideration. Each section begins with the text of the article, followed by an overview of the material covered by the section, and the questions and answers that pertain to that section. The questions and answers in each article are organized alphabetically by country. Specifically, these articles address the safety of existing nuclear installations, the legislative and regulatory framework, the regulatory body, responsibility of the licensee, priority to safety, financial and human resources, human factors, quality assurance, assessment and verification of safety, radiation protection, emergency preparedness, siting, design, construction, and operation.

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

PREFACE

This section describes the purpose and structure of this report and how to obtain documents referenced in the report.

This report documents the U.S. Nuclear Regulatory Commission's (NRC's) answers to questions raised by contracting parties to the Convention during their peer reviews of the U.S. National Report for the Convention on Nuclear Safety (NUREG-1650, Rev. 1). Contracting parties have two obligations - submit a national report for peer review and review the national reports of other contracting parties. The United States submitted its National Report in September 2004 to the third review meeting of the contracting parties to the Convention for peer review. This meeting was held at the International Atomic Energy Agency (IAEA) in Vienna, Austria, in April 2005. (The U.S. National Report is also posted on the NRC's Web site at http://www.nrc.gov.)

Upon receiving questions from contracting parties, the NRC staff sorted them according to the article of the U.S. National Report that addressed the relevant material. Technical and regulatory experts at the NRC then answered the questions.

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

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

This report references a number of documents that are contained in the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is an information system that provides access to all documents made public by the NRC since November 1, 1999. ADAMS permits full searching. Users can view document images, download files, and print locally. To access ADAMS, users must download utility software from the NRC web site http://www.nrc.gov and learn the ADAMS features that permit the searching and retrieval of documents. In addition, documents are available through the NRC's Public Document Room. One may contact the Public Document Room by:

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INTRODUCTION TO U.S. NATIONAL REPORT

This section of the Third U.S. National Report for the Convention on Nuclear Safety described the purpose and structure of the report, the U.S. national policy towards nuclear activities, the main national nuclear programs, and the current nuclear safety issues. It then highlighted major regulatory accomplishments since the previous U.S. National Report was written in 2001. Finally, it referenced the list of nuclear installations in the U.S.

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

Question Number: 01.01

Question: *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.*

Response: 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 the 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.

Question Number: 01.02

Question: *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?*

Response: While the NRC staff is not currently working on additional measures regarding onsite power (emergency diesel generators), recent studies indicate that the reliability of onsite power sources has improved. The reliability of onsite 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.

Question Number: 01.03

Question: *Please give a brief introduction on what measures have been taken to prevent blockage of containment sump by the plants in USA.*

Response: 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.

Question Number: 01.04

Question: *How to deal with reactor vessel head penetration defects in Davis- Besse plant?*

Response: 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.

Question Number: 01.05

Question: *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?*

Response: 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 the applicant's qualifications and a description of operational programs.

Question Number: 01.06

Question: *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.?*

Response: Risk-informed changes to technical specifications (TSs) 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 on evaluating the risk of plant-specific TS changes and on using the five criteria for risk-informed decisionmaking:

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 increase is small and consistent with the intent of the Commission's Safety Goal Policy Statement.
5. The impact of the proposed change is monitored using performance measurement strategies.

RG 1.177 provides the risk acceptance criteria for making plant-specific TS changes:
1. The licensee can 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, the ICCDP contribution should be distributed in time so that any increase associated with conditional risk is small and within normal operating background (risk fluctuations) of the plant. These are called Tier 1 constraints.
2. The licensee can demonstrate that there are appropriate restrictions on dominant risk-significant configurations associated with the change. The restrictions include actions to minimize the likelihood of initiating events and actions to mitigate the risk of the risk-significant configuration if an initiating event occurs. These are called 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. [This is called a Tier 3 constraint.]

Additional information on RG 1.174 can be found on the following link on the NRC public Web site http://www.nrc.gov/reading-rm/doccollections/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/powerreactors/active/01-177/index.html

Question Number: 01.07

Question: *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.*

Response: No response required.

Question Number: 01.08

Question: *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.*

Response: 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 of hydrogen combustion was from beyond design basis accidents. Additional detail is provided in the September 16, 2003 *Federal Register* (Vol. 68, No. 179).

Question Number: 01.09

Question: *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.*

Response: No response required.

Question Number: 01.10

Question: *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?*

Response: One goal is ensuring openness in our regulatory processes. Ways of achieving this goal are spelled out in the agency's strategic plan (http://www.nrc.gov/reading-rm/doccollections/

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 the increasing 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, security and emergency planning issues have become increasingly important to the public and to government officials. The NRC must, therefore, assure the public that its rigorous oversight and defense-in-depth approach ensures adequate protection of the public, and that emergency plans for the facility and the area around 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.

Most important safety information would not be useful to potential terrorists and can be shared with the public. That is not true of security information. The NRC will adopt policies on sensitive security information consistent with the policies of the Department of Homeland Security and other agencies. NRC will withhold a relatively small amount of information that could assist potential terrorists, but 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, and 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 requires 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 of 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 stakeholders with a need to know to participate in NRC decisionmaking on matters involving sensitive unclassified, safeguards, classified, or proprietary information.
6. Obtain early public involvement on controversial issues 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. The activities include the following:

- Enhancing the NRC's communications within the agency and with the public, the media, and Congress (supports Strategies 1, 2, 3, 4, 5, and 6).
- Actively engaging the public, particularly potentially affected local residents, before actions are taken (supports Strategies 1, 4, and 6).
- Holding 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).
- Improving communications about licensee operating events and their significance discussing easily understood risk comparisons, plant features, and regulatory controls to put situations into their proper context. Developing and implementing agencywide guidelines to improve the NRC's ability to communicate with stakeholders regarding risk insights and other health and safety issues (supports Strategy 3).
- Developing communication plans for key program activities (supports Strategies 1 and 4).
- Maintaining and updating NRC's external Web site with timely, user friendly information and continuing to make site enhancements based on input from Web user satisfaction surveys. (supports Strategies 1, 3, and 4).
- Identifying areas that require additional public engagement and dialogue. This may be achieved through independent surveys or other measurement instruments (supports Strategy 2).

Question Number: 01.11

Question: *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?*

Response: 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 to the NRC and the nuclear industry. On September 30, 2002, the task force reported its findings to a senior management review team, including 51 recommendations to the NRC for addressing factors that contributed to the Davis-Besse event.

In its report of November 26, 2002, the senior management review team endorsed all but two of the 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 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-headdegradation/lessons-learned.html for more information.

Question Number: 01.12

Question: *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 preapplication review. Please name these designs under review.*

Response: The NRC is actively reviewing pre-application issues for the ESBWR and ACR-700 designs. The other designs in various stages of preapplication review are EPR, IRIS, PBMR, and SWR-1000.

Question Number: 01.13

Question:

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 onsite 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?*

Response:

1. During the summer of 2004, the NRC staff assessed the licensees' readiness to manage any degradations 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 took effect on April 1, 2005.

2. While the NRC staff is not currently working on additional measures regarding onsite power (emergency diesel generators), recent studies indicate that the reliability of onsite power sources has improved. The reliability of onsite 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 RIS 2004-05. 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 U.S. plants are not designed to switch power to house loads on loss of main load. It is possible to switch to house loads only during a

controlled shutdown.

Question Number: 01.14

Question: *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?*

Response: As stated in the October 17, 2001 *Federal Register* (*66 FR 52657*), "...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." Paragraph (a)(5) of 10 CFR 55.31 requires that 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).

Question Number: 01.15

Question: *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 wellreasoned concept of control systems upgrading that could be performed with no breach of NPP safe operation standards and regulations. Do you have a concept of upgrading NPP safety-related control systems for all operating nuclear plants?*

Response: 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. The several parts to this question will be answered separately.

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. High-quality and high-reliability equipment 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 required safety functions remain the same. NRC requires that each new safety system demonstrate that it 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 cannot be proven, the equipment will not be approved for use in an NPP.

C. "Do you have a concept of upgrading NPP safety-related control systems for all operating nuclear plants?"

The NRC has extensive guidance documents on upgrading safety-related equipment in operating nuclear plants. The documents 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 for meeting NRC regulations.

If the licensee decides to retain the existing equipment and if the existing equipment continues to meet the safety requirements, NRC will not require the replacement of the equipment. NRC does not require upgrading safety-related control systems at operating nuclear plants unless a proposed change meets the requirements of the NRC's backfit rule, 10 CFR 50.109.

Question Number: 01.16

Question: *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?

Response: 1. The nuclear power plants in the U.S. are base-loaded and do not load-follow.

2. Not applicable.

3. U.S. 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 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 degradations 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 took effect on April 1, 2005.

Question Number: 01.17

Question: *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?*

Response: The several parts to the question will be answered separately.

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 substitute one automatic action for a previous automatic action. We know of no instance where manual capability 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. In some non-safety control systems actions that previously required manual action are now done automatically, 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. Therefore, 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 has neither good nor bad experience with justifying the applicability and actual use of digital programmable safety-related protection systems recommended by IAEA and IEC.

NRC has had 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.

Question Number: 01.18

Question: *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?

Response: NRC's Electronic Information Exchange (EIE) allows NRC to exchange material related to official agency business through the Internet with its customers (including licensees) and other Federal agencies. The EIE uses a public key infrastructure and digital signaturing technology to authenticate documents. That is, the system ensures that the exchanged material is secure and verifies the identity of the person submitting the material is.

More information may be found on the NRC web site at http://www.nrc.gov/site-help/eie.htm

Question Number: 01.19

Question: *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 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?

Response: 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 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 reduced 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. The NRC staff monitors fuel performance and is involved in the design and licensing of fuel design changes.

Question Number: 01.20

Question: *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?*

Response: 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. To date, the main impact observed during reviews of extended power uprates is a slight reduction in the timing of 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.

Question Number: 01.21

Question: *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.*

Response: The U.S. 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 U.S. believes that IRRT missions provide a valuable and useful independent review of regulatory authorities.

The IAEA has conducted four OSART missions in the U.S.: at Calvert Cliffs (1987), Byron (1989), Grand Gulf (1992), and North Anna (1999). Next month, May 2005, the IAEA will send an OSART mission to the Brunswick nuclear power plant in Southport, North Carolina. The U.S. is seeking to schedule an OSART mission to a U.S. nuclear power plant at least once every 3 years.

The North Anna OSART report is publicly available 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 predate the implementation of ADAMS and are not readily available.

The United States believes that IRRT missions provide a valuable and useful independent review of regulatory authorities, as evidenced by U.S. 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 2 years. The Commission will determine its next steps with regard to a potential IRRT mission after reviewing the results of the self-assessment.

Question Number: 01.22

Question: *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.*

Response: No response required.

Question Number: 01.23

Question: *All U.S. nuclear power plants have implemented severe accident management guidelines (SAMGs). Are there any periodic emergency exercises/drills which require the use of SAMGs?*

Response: There are no periodic exercises or drills which require the use of severe accident management guidelines (SAMGs). However all licensees have implemented SAMGs. Licensees develop scenarios for emergency exercises and drills that do require the use of the SAMGs, but SAMGs are not required for the exercises and drills. The industry practice is that licensees periodically do a self-evaluation of severe accident response capability. When a licensee develops the plant-specific SAMGs, NRC may do an initial evaluation to ensure the process has been integrated into the licensee's emergency response capability. Periodic tabletop and/or interfacility drills may be used to ensure personnel are familiar with the use of SAMGs, with the objective of training, on testing, and improving severe accident management response capability.

Question Number: 01.24

Question: *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?*

Response: Public Involvement in Licensing Actions

The public can become involved in the licensing of a facility and can make its 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, and 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 citizen 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. Hearing requests and intervention petitions ordinarily must be filed within 60 days of the date of the *Federal Register* publication 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 major new facilities and other major actions. An environmental assessment is usually prepared on the need for a proposed action and to list 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 opinions 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 decisionmaking 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 is used, as appropriate, during the development of the license renewal process. The public, in general, is encouraged to participate in the process through public meetings and public comment periods on rules, license renewal guidance, and other documents. In addition, a party may request a formal adjudicatory hearing if the party would be adversely affected by the renewal.

Question Number: A.01

Question: *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 ?*

Response: 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 for accrediting 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 Systems Approach to Training requirements contained in 10 CFR 50.120 and 10 CFR Part 55.

ARTICLE 6. EXISTING NUCLEAR INSTALLATIONS

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

This section of the U.S. National Report explained how the U.S. ensures the safety of nuclear installations in accordance with the obligations in Article 6. First, it summarized the characteristics of the nuclear industry in the U.S. Then, it explained reactor licensing and discussed the major oversight process in the U.S. - the Reactor Oversight Process - and supporting programs, including the Industry Trends Program and the Program for Resolving Generic Issues. Then, it discussed programs for rulemaking, decommissioning, and research and programs for public participation, handling petitions, resolving allegations, and settling differing professional views and opinions. The Experience and Examples subsections covered nuclear installations for which the NRC's assessments showed that corrective actions were necessary.

The questions and answers pertaining to this section are given below.

Question Number: 06.01

Question: *How to establish the thresholds for performance indicators when NRC evaluates the licensee's performance indicator data?*

Response: 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 3 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% 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% of the technical specification (TS) limit for the green-white threshold and 100% 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 these programs cannot be unacceptable; the NRC would step in to ensure their continued viability.

Question Number: 06.02

Question: *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?*

Response: Licensees have performed inspections of the control rod drive mechanism penetrations and some licensees have replaced or are planning to replace their reactor pressure vessel heads. Alloy 690 material is often used instead of alloy 600 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 to establish 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.

Question Number: 06.03

Question: *Why the trend of precursor occurrence rate in 1999~ 2001 is increasing in Figure 3? How about the trend of 2002 and 2003?*

Response: The NRC has not determined the basis for changes in occurrence rates during these time periods. We are planning to evaluate 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.

Question Number: 06.04

Question: *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?*

Response: The NRC has not modified its criteria for the structural integrity of nuclear power plants. While the requirements for structural integrity depend on 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 affect a safety-related component.

In response to industry experience, the NRC is paying more attention to the flow-induced vibration of safety-related and non-safety-related components. The NRC is monitoring the corrective actions of plants that have experienced problems from flow-induced vibration. The NRC issued generic communications to alert licensees to this issue and 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 the industry are taking steps to ensure that the structural integrity of all components is maintained such that there is no reduction in nuclear safety.

Question Number: 06.05

Question: *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?*

Response: Facility operating licenses and technical specifications specify the maximum power level at which commercial nuclear power plants may be operated. 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 (EPUs) 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 on the specific areas of review.

The review standard also informs licensees of the guidance documents the NRC staff will use when reviewing EPU applications. This helps licensees prepare EPU applications that address topics necessary for a complete application and minimizes the NRC staff's need to issue requests for additional information (RAIs).

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 of the various SRP sections to reviewing EPU applications and developing and revising guidance. During this evaluation, the NRC staff considered the versions of the SRP sections identified in the matrices in Section 2 of the review standard. To determine the need for additional guidance, the NRC staff reviewed (1) safety evaluations for previously approved power uprates, (2) previously approved topical reports for EPUs, (3) various reports on 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 and reviewed RAIs issued for recent EPU applications to ensure that the review standard adequately addressed areas where repeat RAIs have been issued.

The NRC staff reviewed NRC procedural guidance documents to identify documents applicable to processing EPU applications. The review of these documents included the recommendations in various reports on the Maine Yankee experience and the feedback received from internal and external stakeholders.

Question Number: 06.06

Question: *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 U.S. 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 U.S./NRC allows such power output increase doesn't appear obvious. Could U.S./NRC develop the assumptions made or regulation relaxation necessary for acceptance of power uprate?*

Response: There was no regulatory relaxation for power uprates and power uprates are not intended to result in equipment failures or reduce plant safety with respect to component structural integrity, though uprates can reduce the plant's safety margin. That is, the plant may come closer to the limit of what the NRC has determined is safe enough but still remain within the limits. 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 the 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.

Question Number: 06.07

Question: *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?)

Response: 1. No ageing effects are highlighted by the results at this time, but will be covered by the ASP insights study planned for 2005.

2. Because the INES is not a risk-based scale, the ASP results cannot be directly compared to the INES scaling of events.

3. For long-lasting events a maximum of 1 year is defined in the 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.

Question Number: 06.08

Question: *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?*

Response: The Industry Trend Program assesses overall industry performance using industry-level indicators. The program uses a comprehensive set of indicators of known conditions and issues that are compiled from the best available data. However, the staff recognizes that there are limits to what can be tracked and trended by the program. One of the industry trend indicators is the number of "significant events." If a trend is identified in the number of industry-wide significant events, the Industry Trends Program analyzes the trend and takes any necessary actions using established programs (such as the generic communication program or the generic safety issue program). Individual plant issues are also addressed in the reactor oversight program.

Question Number: 06.09

Question: *The third United States of America report gives examples of significant findings resulting from 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?*

Response: These inspection procedures attempt to focus the inspector on risk-significant design and modification issues, not minor issues 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," reviews 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.

Question Number: 06.10

Question: *The significant findings resulting from inspections on the U.S. 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?*

Response: 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 U.S. operating experience is considered in this program. In addition to the Accident Sequence Precursor program, the NRC has established an operating experience staff to perform gathering, screening, and communication functions (see Section 19.7 of the National Report and Section 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession No. ML033350063)). The operating experience staff reviews foreign experience as well as U.S. experience. For issues deemed generic, the staff communicates lessons learned to internal stakeholders, issues generic communications to external stakeholders, and identifies needs for specific inspections.

Question Number: 06.11

Question: *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?*

Response: The trend in the occurrence rate of accident sequence precursors 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 Web site 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.

Question Number: 06.12

Question: *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?*

Response: Several programs are involved in identifying 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 is to issue an information notice to power plant operators (see www.nrc.gov/what-we-do/regulatory/eventassess. 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), which uses a risk-informed approach to monitor 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.

Question Number: 06.13

Question: *The reactor licensing process provides for the review and approval of changes after initial licensing. These provisions address amendments 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.*

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?

Response: The NRC reviews power uprate applications against a licensee's current design and licensing bases. In the review of power uprate applications, the NRC does not intend to impose new criteria or requirements on plants whose design and licensing bases do not include the criteria and requirements in NRC review standard. 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 that the requirements substantially increase 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.

Question Number: 06.14

Question: *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.*

When the color assessed from inspection findings for 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?

Response: 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 will directly define the level of NRC involvement and action. Inspection finding and performance indicator thresholds were developed utilizing expert judgment 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 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.

Question Number: 06.15

Question: *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."*

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?

Response: 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 audits 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 uprate applications to be submitted to the NRC for review and approval will be minimal and that formal guidance for stretch power uprates is not needed.

2. Yes. In developing RS-001, the NRC changed the review standard to reflect experience with steam dryer failures in boiling water reactors. 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 were the result of high-cycle fatigue caused by increased flow-induced vibrations at EPU conditions. The NRC review of the reactor internals for EPU requests will include detailed analyses of the effect of flow-induced vibration and acoustically induced vibration (where applicable) on reactor internal components such as steam dryers and separators and on the jet pump sensing lines that are affected by the increased steam and feedwater flow in 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.

Question Number: 06.16

Question: *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?*

Response: No. We do not perform inspections of supporting organizations such as fuel vendors, engineering analysis companies, etc. under the 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 on reviewing and inspecting licensees and applicants and their vendors, as applicable, to confirm they have an effective system for reporting defects under 10 CFR Part 21, 10 CFR Part 50.73, and 10 CFR 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.

Question Number: 06.17

Question: *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.*

Response: 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 ROP. The staff made these changes to enhance the NRC's ability to detect declining plant performance, including the issues identified at the Davis-Besse plant. The changes completed include modifying the inspection program to help identify negative equipment performance trends, enhance inspector training, and better track and manage 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." The staff established 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 concerns the effects of boric acid corrosion, another is about 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 No. ML043480034).

Question Number: 06.18

Question: *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.*

Response: 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 tests conducted by the licensee, it was determined that Byron, Unit 1 exceeded its licensed power by as much as 2.6%. Comparable overpower values for the other units were estimated to be 1.9% for Byron, Unit 2, 1.1% for Braidwood, Unit 1, and 1.2% for Braidwood, Unit 2. The overpower situations were a violation of the respective licenses and will be addressed through inspection program, but they were not considered safety significant. For accident analyses NRC regulations require that plants be analyzed at 102% reactor thermal power to account for instrument uncertainties. The assumptions of the models result in additional conservatisms in the calculations.

Question Number: 06.19

Question: *It is mentioned that as of August 2004, the NRC has completed more than 100 reviews of power uprates which has contributed 1000e 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?*

Response: 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 the limits. The higher flow rates at power uprate conditions have been evaluated for their effect on major safety-related components. Unfortunately, non-safety-related components, and some safety-related components at the subsystem level such as vent and drain lines and valve subcomponents, were 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 licensees' evaluations of the effects of increased flow in new uprate requests.

Question Number: 06.20

Question: *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?*

Response: Absolutely. The three concerns mentioned are examples of potential areas for improvement in the ROP. The NRC continues to evaluate these suggestions, along with numerous others. The NRC staff continually assesses the ROP to identify and implement potential program improvements through the agency's self assessment program (reference

IMC 0307). The staff reports the results of the self-assessment annually and is in the process of completing the self-assessment for CY 2004. The results of the previous annual assessment were presented in SECY-04-0053, dated April 6, 2004.

Question Number: 06.21

Question:

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 U.S. NPPs?
6. What are the recent trends in the numbers of U.S. NPP accident precursors (2001-2003)?

Response:

1. Plants have performed inspections of the control rod drive mechanism penetrations, and some have replaced or are planning to replace their reactor pressure vessel heads. Alloy 690 material is often used instead of Alloy 600 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, superceding 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 so they can 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, fouling most of the heat exchangers dependent on 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 in the 1989 timeframe. 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 compressed when the approximately 700-pound strainer lid was reinstalled. The compressive force of the lid tore the basket mesh in the area of the weld on the basket's vertical support bracket. This was the initiating event for the 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 took the following the following corrective actions:

(A) All of the Unit 1 and Unit 2 strainers were inspected and the associated baskets were replaced with baskets having stronger bracket support welds.
(B) Nondestructive examinations of the replacement baskets were performed to ensure that critical parameters and welds were satisfactory.
(C) The ESW maintenance procedure for the ESW strainers was revised to ensure the strainers are properly assembled and installed.
(D) Additional revisions to the ESW maintenance procedure for the ESW strainers were implemented to ensure that the proper critical parameters are monitored during subsequent disassembly and to ensure proper repair criteria are in place.
(E) Commercial-grade dedication and/or receipt inspection practices were upgraded to ensure that 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 does statistical analysis of long-term trends. No statistically significant adverse trends have been observed in the accident sequence precursor data from 1993 through 2002. 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 Web site at http://www.nrc.gov/reading-rm/doccollections/commission/secys/2004/secy2004-0210/2004-0210scy.html.

Question Number: 06.22

Question: *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 nonresolved safety issues.*

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?

Response: All unresolved (and resolved) safety issues are documented in NUREG-0933. Beginning in 1983, the staff ranked the priority of issues as HIGH, MEDIUM, LOW, and DROP (see the Introduction of NUREG-0933). The staff pursues the resolution of generic issues that were ranked HIGH and MEDIUM. In 2001, the priority categories were changed to CONTINUE and DROP. Since then, 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 resolution was not pursued; and (3) generic issues that are currently in the resolution process (CONTINUE). NUREG-0933 is accessible on the NRC Web page: http://www.nrc.gov/reading-rm/doccollections/ nuregs/staff/sr0933/. All relevant sources of information, including NRC reviews and evaluations, are used in the screening analysis for prioritizing an issue.

Question Number: 06.23

Question: *The Report lacks information on the storage of radwaste and spent nuclear fuel (SNF) at U.S. NPP sites. For how long will the existing capacities for radwaste and SNF storage be sufficient at U.S. NPP sites?*

Response: 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 the sensitive information screening 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.

Question Number: 06.24

Question: *The Report gives no information on U.S. NPP safety performance indicators. What are the U.S. 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?*

Response: 1. NPP operational events are captured in the Initiating Events cornerstone by three performance indicators(PIs): Unplanned Scrams per 7,000 Critical Hours, Unplanned Scrams With Loss of Normal Heat Removal, and Unplanned Power Changes per 7,000 Critical Hours. See NEI 99-02, Revision 2, pages 11 through 22.

2. Breaches of limiting conditions for operation are not directly reported in the PIs. They are only reported 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 PI Unplanned Scrams per 7,000 Critical Hours.

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.

Question Number: 06.25

Question: *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?*

Response: The U.S. 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 as periodic safety reviews. Periodic safety reviews (PSRs) thoroughly and comprehensively considered and implemented 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 U.S. regulatory framework provide an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, or process improvements and provide confidence that the U.S. civil nuclear power plants can continue to be operated safely.

Considering the U.S. regulatory infrastructure in the aggregate, we believe that the U.S. regulatory process is as demanding and as rigorous as other Contracting Parties' regulatory processes in ensuring safety.

Question Number: 06.26

Question: *How the introduction of the risk-informed baseline inspection program influenced and improved overall safety of NPPs? Can you provide some quantitative information?*

Response: The baseline and supplemental inspection programs verify that nuclear power plants are operating at an acceptable level of safety. The baseline inspection program is very extensive and inspects most of the licensee's major programs. The supplemental program is used to ensured that identified licensee performance deficiencies which are evaluated as greater than green through our significance determination process are corrected adequately 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. One important output of this program is to report to Congress each year on the performance goal measure of "no statistically significant adverse industry trends in safety performance" as part of the NRC's Performance and Accountability Report. Based on the information currently available from the industry-level indicators originally developed by the former Office for Analysis and Evaluation of Operational Data (AEOD) and the Accident Sequence Precursor (ASP) Program implemented by RES, no statistically significant adverse industry trends have been identified through FY 2003. However, three of the industry trend indicators met or exceeded their prediction limits and are discussed in more detail in SECY-04-0052 (available at http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2004/secy2004-0052/2004-0052scy.html).

The staff is continuing to use the AEOD and ASP indicators while it develops additional industry-level indicators that are more risk-informed and better aligned with the cornerstones of safety in the ROP. These additional indicators will be developed in phases and qualified for use in the Industry Trends Program (ITP) and the annual Performance and Accountability Report to Congress. 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 Commission.

Question Number: 06.27

Question: *Have already all license renewal applicants evaluated pressurised thermal shock (PTS) events according to the new PRA methodology?*

Response:	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.
Question Number:	06.28
Question:	*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 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?*
Response:	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.
Question Number:	06.29
Question:	*It is mentioned that the Accident sequence precursor program views U.S. NPP operating experience from a perspective of safety significance. How NRC deals with operating experiences from foreign countries, specifically for U.S. design NPPs (where findings could also be considered as generic issues)?*
Response:	In addition to the ASP, the NRC established an operating experience staff to perform gathering, screening, and communication functions (see Section 19.7 of the National Report and Section 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession No. ML033350063)). The operating experience staff reviews foreign experience as well as United States experience. For 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 communicating 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 Nozzles (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."

Question Number: 06.30

Question: *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?*

Response: 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 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). An inspection for the PI&R area evaluates licensees' corrective action programs. This inspection involves screening all corrective action program issues, performing a semiannual trend review, sampling issues during each inspectible 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.

Question Number: 06.31.

Question: *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 U.S. point of view?*

Response: 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) such tests could at best 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.

Question Number: 06.32

Question: *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?*

Response: 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) of the new IMC, 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.

Question Number: 06.33

Question: *Are there formalised requirements for application of the risk-screening assessment method?*

Response: 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. This approach is used for inspection findings related to licensed operator requalification, emergency preparedness, radiation safety, and physical security. The second approach 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 were developed with the cooperation of internal and external stakeholders. The intent was to be *objective* and *scrutable.*

- Objective: When different individuals use a given SDP tool and the associated decision logic, they will arrive at the same result when using the same input assumptions and conditions.
- Scrutable. The SDP framework facilitates communication of each significance determination and its basis to 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 Web site, http://www.nrc.gov

Question Number: 06.34

Question: *Could more detailed information be obtained on the one-step process of NPP sites licensing?*

Response: The statement in Section 6.2.1 of the U.S. National Report 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."

Question Number: 06.35

Question: *What is the procedure to update a current licence?*

Response: The license amendment procedures are contained in the publicly available document, Office Instruction LIC-101, "License Amendment Review Procedures" (ML040060258).

Question Number: 06.36

Question: *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 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 NRC staff reluctant to report events upwards if the events would worsen 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?*

Response: 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 a trend is not due to noise. All indicators are monitored for trends and improving and declining trends are reported to the Commission annually. Statistically 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, which allow actions to be taken to correct causes of adverse trends. In addition, the industry-level indicators, such as the number of automatic scrams, are objective measures 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 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.

ARTICLE 7. LEGISLATIVE AND REGULATORY FRAMEWORK

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

2. The legislative and regulatory framework shall provide for:

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

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

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

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

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

Questions and answers on this section are as follows.

Question Number: 07.01

Question: *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?*

Response: Yes. Moreover, a license is legally required for the construction of nuclear reactors or production facilities.

Question Number: 07.02

Question: *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?*

Response: The regulations in Title 10 of the Code of Federal Regulations define research and power reactors. A power reactor is a nuclear reactor designed to produce electrical or heat energy and 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.

Reactors that are not power reactors are referred to as nonpower reactors in the regulations. Nonpower reactors include research reactors and test reactors (called testing facilities in some regulations). A nonpower reactor is a research or test reactor licensed under § 50.21(c) or 50.22 for research and development.

A research reactor is 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.

A testing facility is 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 with a 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. The licenses for research and test reactors 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 for 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 light-water 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 Web site under Accession Nos. ML042430048 and ML042430055). The regulatory approach to research and test reactors is graded so that the complexity of the licensing process, the technical safety standards, and the 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 research and test reactors pose a lower risk than power reactors, they are less frequently inspected than power reactors.

The inspection program for operating research and test reactors covers 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. 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.

Question Number: 07.03

Question: *More information would be appreciated regarding the final status of the design approval process for AP1000?*

Response: In September 2004 the NRC granted a final design approval for AP1000 and issued NUREG-1793, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," The proposed rule for certification of the AP1000 design is expected to be issued by April 2005.

Question Number: 07.04

Question: *What is the procedure for hearings of disputes, who conducts/leads them, is participation of lawyers obligatory in hearings?*

Response: Written statements, oral arguments and some triallike procedures are available, depending on the circumstances. See 10 CFR Part 2. Nearly all disputed licensing matters are initiated before a three-person Atomic Safety and Licensing Board. A party may seek review by the Commission, which the Commission grants at its discretion. 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 Appeals. Participation by lawyers is not obligatory, but is usual. However, participation by nonlawyers on their own behalf or on behalf of organizations to which they belong is not infrequent.

Question Number: 07.05

Question: *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?*

Response: At the request of the charged party, a hearing is available to resolve disputes.

ARTICLE 8. REGULATORY BODY

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

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

This section of the U.S. National Report explained the establishment of the U.S. regulatory body, NRC. It also explained how the functions of the NRC are separate from those of bodies responsible for promoting and using nuclear energy (i.e., the U.S. Department of Energy). The update reported on the establishment of a new office, the Office of Nuclear Security and Incident Response, and described NRC's international responsibilities and activities.

Questions and answers pertaining to this section follow below.

Question Number: 08.01

Question: *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?*

Response: 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 has the authority to prevent 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 the Inspector General Act of 1978, as Amended , 5 USC Appendix.

Question Number: 08.02

Question: *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 coordinated by international organisations like the IAEA and the OECD? If possible, please include information about the International Collaboration Research Initiative Addressing Safety Aspects of Advanced Instrumentation and Control initiated by NRC.*

Response: 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 of addressing broader interests represented by the international organizations. With regard to the International Collaboration Research Initiative Addressing Safety Aspects of Advanced Instrumentation and Control, the NRC has terminated this activity because there was not sufficient 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.

Question Number: 08.03

Question: *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?*

Response: 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.

Question Number: 08.04

Question: *How are the benefits utilized in the NRC activities gained from the cooperative research projects like CSARP, CAMP, COOPRA and SGTIP?*

Response: The CAMP project (thermal-hydraulics) and the CSARP project (severe accidents) are programs to exchange information on code applications and maintenance. NRC and its counterparts in about 22 countries have agreements to exchange of information in the form of technical reports, experimental data, correspondence, newsletters, visits, joint meetings, etc. The NRC provides NRC-developed reactor system 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 contributions (data, assessment reports). These exchanges promote worldwide code usage feedback on code attributes which helps improve the codes and validate and verify codes 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 decisionmaking 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.

Question Number: 08.05

Question: *NRC also participates in the Commission on Safety Standards and safety standards committees. 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?*

Response: 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 U.S. 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.

Question Number: 08.06

Question: *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.*

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?

Response: The NRC has the responsibility for emergency planning and response activities, including planning and response for terrorist attacks or natural disasters, at civil nuclear power plants. FEMA is responsible for overseeing the emergency preparedness activities for State and local government decisionmaking with regard to public health and safety. This includes evaluating 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) and the Department of Energy (DOE) have authority over emergencies at nuclear facilities owned or operated by DOD and DOE.

Question Number: 08.07

Question: *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.*

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?

Response: In general, the U.S. Occupational Safety and Health Administration will apply its standards to working conditions involving nonradiological 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 (such as an X-ray machine) not regulated by the NRC.

Because it is not always practical to sharply differentiate between nuclear and radiological safety the NRC regulates and the industrial safety OSHA regulates, a coordinated interagency effort ensures against gaps in the protection of workers and at the same time avoids duplication of effort.

This effort is governed by 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 the problems are significant, the NRC will inform OSHA. Similarly, OSHA will inform the NRC of any significant radiological and nuclear safety problems OSHA identifies 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.

Question Number: 08.08

Question: *The section discusses the budget and funding of NRC, its human resources, and financial management.*

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.

Response: 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, and 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 and scientists, and students.

Question Number: 08.09

Question: *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.)*

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 U.S. 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?

Response: The President submits the NRC budget to the Congress, so 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 the amount recommended by the President.

Question Number: 08.10

Question: *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?

Response: 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 continual 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 called the Government Accounting Office). The NRC is also called on 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. Many mechanisms protect against such conflicts in interest, beginning with the appointment process, which requires confirmation by the Senate. There are also rules prohibiting any financial interests by the Commissioners or agency working staff in any licensees and prohibiting any contact with them by nonagency persons regarding 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 list 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.

Question Number: 08.11

Question: *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?*

Response: The NRC directly administers its fee collection requirements by assessing and collecting its license, inspection, and annual fees. The NRC then sends these funds to the U.S. Department of the Treasury. It does not keep the funds, because it has already received funding directly from Congress for the year. At the end of the fiscal year, the NRC sends the Treasury the fees it has collected for that year to reimburse the Treasury for the funding NRC already received for the year.

Question Number: 08.12

Question: *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?*

Response: 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 for agents of the Secret Service, the 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. (See http://www.opm.gov/fedclass/text/gs-1800.htm and Management Directive 9.8.)

Question Number: 08.13

Question: *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?*

Response: 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, 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 is 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.

Question Number: 08.14

Question: *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 account the existing large number of renewal licence request and the increasing number of new reactor licence request?*

Response: 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 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 -is briefed to ensure that expectations are clear.

Question Number: 08.15

Question: *How the results of inspections in NPPs are evaluated and reviewed?*

Response: 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 according to licensee safety performance. The assessment information and agency response are then communicated to the public. Followup agency actions, as applicable, are conducted to ensure that the corrective actions designed to address performance weaknesses were effective.

Question Number: 08.16

Question: *Do your inspectors work with complex analytical tools and programs to evaluate specific events?*

Response: 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 to assess the risk significance of events: 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 experience at all U.S. nuclear power plants to identify, document, and rank the operating events that are most likely to lead to precursors of inadequate core cooling and severe core damage if additional failures occur. The ASP Program uses specific criteria to define a *significant* precursor. 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 have the capability to performing uncertainty analysis through the propagation of uncertainty distributions at the equipment and human performance levels.

Question Number: 08.17

Question: *What is the role of inspectors in preparation of regulations? Are the inspectors involved in drafting regulations and to which extent?*

Response: 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.

Question Number: 08.18

Question: *What is the reason behind such a huge "Net Appropriated—S&E" increase of expenditure for FY 2004 shown in Table 8.1?*

Response: NRC's net appropriation increased 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% fee recovery (with the exception of the High-Level Waste Program). NRC's FY 2003 budget was based on 94% fee recovery. Therefore, the percentage of NRC's budget (excepting the High-Level Waste Program) reflected in the net appropriation increased by 2% in FY 2004, to 8%. 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.

Question Number: 08.19

Question: *Financial and Human resources: What is the process followed by the U.S.NRC 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 resolve the disagreement?*

Response: 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 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 they may seek legal action against the NRC through the judicial system.

Question Number: 08.20

Question: *The U.S.NRC 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 U.S.NRC 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 U.S.NRC? If not are the regulatory responsibilities of the U.S.NRC clearly dissociated / separated from those related to the development of atomic energy in the Act?*

Response: 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 were 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 to only the Department of Energy, as appropriate.

Question Number: 08.21

Question: *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?*

Response: 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 15 members appointed by the Commission for terms of 4 years each. The Commission also has general authority to establish advisory boards for which the Commission must issue regulations setting forth the scope, procedures, and limitation of the authority of each such board (42 U.S.C. 2201). As the name implies, advisory committees are solely advisory and have no executive authority. They are funded by NRC out of its general appropriations from the Congress.

Question Number: 08.22

Question: *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...*

Response: NRC Regional Offices execute established NRC policies and assigned programs relating to inspection, licensing, investigation, enforcement, emergency response, governmental liaison, and agreement state activities within regional boundaries. In the power reactor area, the Regional Offices conduct most reactor inspections for the NRC using region-based inspectors and resident inspectors stationed at each site. The Regional Offices also take or recommend enforcement action for violations of regulatory requirements, including civil penalties and orders, to the NRC Headquarters Office. They also issue individual licenses to persons who physically manipulate the controls of nuclear power plants or who direct the activities of other individuals who manipulate the controls. However, the NRC Headquarters Office is responsible for issuing licenses authorizing the construction and operation of power reactors, as well as amendments to such licenses. Each Regional Office maintains an Incident Response Center that is activated in response to significant licensee events.

Question Number: 08.23

Question: *Although it is not stated in the document we understand that some of the U.S.NRC 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 U.S.NRC mandate and how is the independence of the U.S.NRC ensured?*

Response: 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-interest statute and its implementing regulation.

Question Number: 08.24

Question: *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?*

Response: 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 program that is addressing operating plant issues is 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.

Question Number: 08.25

Question: *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?*

Response: The Office of Commission Appellate Adjudication (OCAA) participates in every adjudicatory matter that is appealed to the Commission. OCAA analyzes 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 review the petitions, OCAA assists the Commission in framing any questions that need to be addressed and helps 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 consideration. Therefore we cannot discuss particulars. The office has four full-time attorneys who report to the office director.

Question Number: 08.26

Question: *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.*

Response: 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 action program. Recently, the authority created an Organizational Effectiveness Branch, which provides a focal point for quality practices, roles and responsibilities, centralized work planning, and human capital issues. 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.

ARTICLE 9. RESPONSIBILITY OF THE LICENSE HOLDER

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

This section of the U.S. National Report explained how the Atomic Energy Act assigned the prime responsibility for the safety of a nuclear installation to the licensee. The NRC oversees the licensee. This section also discussed the Enforcement Program. The NRC also ensures the safety of nuclear installations through its licensing process (discussed in Articles 18 and 19) and its Reactor Oversight Process (discussed in Article 6).

Questions and answers on this section follow below.

Question Number: 09.01

Question: *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?*

Response: 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 on operating power reactors were challenged. One lawsuit challenged an NRC 2.206 enforcement petition, but it was not successful. During FY 2003, two proposed civil penalties on materials licensees were challenged by licensees. In each case, the NRC reviewed the licensee's response and found no new information to change the NRC's position. In both cases the NRC concluded that a violation had occurred as stated and that there was no 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.

Question Number: 09.02

Question: *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

Response: No response required.

Question Number: 09.03

Question: *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.*

Response: 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 process that is largely built on objective criteria.

ARTICLE 10. PRIORITY TO SAFETY

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

This section of the U.S. National Report focused on probabilistic risk assessment (PRA) and safety culture. The applications of PRA discussed were (1) severe accident issues, (2) evaluating new and existing regulatory requirements and programs, (3) the implementation plan for risk-informed regulation, (4) activities that improve data and methods of risk analysis, (5) industry activities and pilot PRA applications, and (6) activities that apply risk assessment to plant-specific changes to the licensing basis.

Other articles (for example, Articles 6, 14, 18, and 19) also discussed activities undertaken to achieve nuclear safety at nuclear installations. Of particular importance is the discussion of the Reactor Oversight Process in Article 6.

Questions and answers pertaining to this section follow below.

Question Number: 10.01

Question: *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?*

Response: 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 of the evaluation remain valid.

Question Number: 10.02

Question: *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 U.S. NRC applies for intervention aimed at regulation of safety culture at operator organisations?*

Response: 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 Criterion XVII of Part 10 CFR Part 50, Appendix B, the NRC performed special inspections to evaluate the processes used by the Davis-Besse licensee to assess its safety culture and 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 Concerns Program, the safety-conscious work environment (SCWE) at the facility, and tools the Davis-Besse licensee 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 performance of the licensee's corrective action programs in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semiannual 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. 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, in response to SECY-04-0111 entitled "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," the Commission recently issued a Staff Requirement Memorandum (SRM), that directed the staff to undertake a number of activities related to safety culture.

Specifically, the SRM directed the 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 evaluating the licensee's safety culture (for plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed that the staff develop tools so inspectors could rely on more objective findings and that the staff 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) in addressing recent industry issues in this area.

Question Number: 10.03

Question: *Are there any requirements related to for example*
- PRA quality management in general
- up-to-date models
- scope of PRA
- transparency of documentation and analyses
- peer reviews and other reviews
- regulatory review?

Response: Guidance (not requirements) for the cited examples is given 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, documentation, model maintenance and management, and model scope. Finally, risk-informed rules (e.g., 10 CFR 50.69) explicitly include requirements are for these areas.

Question Number: 10.04

Question: *Has NRC staff full access to licensees' PRA computer models?*

Response: Generally, licensees have not been required to submit PRA models for the docket. However, the NRC can obtain full access to the licensee's PRA model for a license application review during a site audit of the PRA model.

Question Number: 10.05

Question: *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)?*

Response: 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).

Question Number: 10.06

Question: *What is an adequate set of PRA quality attributes that has to be fulfilled for decision making and various PRA applications?*

Response: 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.

Question Number: 10.07

Question: *How is it guaranteed that the Risk Informed Decision making is based on adequate and qualified risk insights?*

Response: 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.

Question Number: 10.08

Question: *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?*

Response: Licensees' safety culture activities vary from plant to plant. 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 its plant evaluation process.

Question Number: 10.09

Question: *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?

Response: The industry, including selected NRC staff members, is developing 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. NRC is currently reviewing a topical report on digital I&C. There is also an ongoing expert elicitation effort in the NRC Office of Nuclear Regulatory Research on the initiating event frequency of loss-of-coolant accidents.

Question Number: 10.10

Question: *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?*

Response: The United States does not require individual licensees to apply for changes to their plant-specific technical specifications (TSs) after NRC approves changes to the standard technical specifications (STSs). However, groups of plants of the same 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. Licensees voluntarily adopt plant-specific TS changes using the STSs. However, licensees have to justify the applicability of the STS changes to their plants. This includes evaluating the plant design basis as defined in the final safety analysis report (FSAR).

The review of a proposed generic change to the STSs is a multistaged process designed to ensure that each STS remains internally consistent, maintains coherence among STSs for the nation's nuclear power plant vendors, 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 publicly 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 STS changes proposed by the TSTF and accepts, modifies, or rejects them. Individual licensees may propose to adopt TSTF changes during a license amendment application.

Question Number: 10.11

Question: *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?*

Response: An NRC Safety Culture and Climate Survey was administered to all NRC employees and managers from May 13 through June 7, 2002. The survey defined *climate* 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.

Question Number: 10.12

Question: *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)?*

Response: 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. Licensees may use their expert panel to add inspections or justify why certain issues are not applicable to their plant. Risk-informed inspection programs are considered living programs and new industry experience must be evaluated and addressed in a timely manner.

Question Number: 10.13

Question: *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 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.

Response: The intent of this section is to summarize various activities involving the use of PRA models. Therefore, it is not possible to provide the requested level of detail, though the current text provides a number of examples of how insights from PRAs are being used.

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 changes, which the NEI expects 86 plants to implement.

Operating experience is not integrated into the PRA policy, (i.e., the policy statement does not change) as the previous U.S. National Report explained in more detail.

We have not experienced difficulty in implementing the PRA policy, but specific applications always involve issues that must be addressed, including areas not modeled or modeled simplistically in the PRA, modeling uncertainties, the impact of uncertainties, and model assumptions.

Question Number: 10.14

Question: *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, 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.*

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?

Response: 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 example).

Furthermore, in response to SECY-04-0111 entitled "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," the Commission recently issued a Staff Requirement Memorandum (SRM), that directed the staff to undertake a number of activities related to safety culture.

Specifically, the SRM directed the 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 evaluating the licensee's safety culture (for plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed that the staff develop tools so inspectors could rely on more objective findings and that the staff 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.

Question Number: 10.15

Question: *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. 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?

Response: 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 an 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 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 io 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 peer review team review of the PRA model). The resolutions 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 inservice 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 resolutions 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 an RI-ISI application. An audit includes an audit of the plant-specific failure parameter database as appropriate.

Plant-specific failure parameter databases are based on appropriate generic data updated to the extent possible with plant-specific data (i.e., observed operation and failure data).

Question Number: 10.16

Question: *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.*

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?*

Response: 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 resolutions 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.

Question Number: 10.17

Question: *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.*

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.

Response: 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 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.

Question Number: 10.18

Question: *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. 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 riskinformed applications?*

Response: 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 have evolved as NRC staff has gained experience with these types of applications. Prior to the development of the industry standards and Regulatory Guide 1.200, the staff considered the technical adequacy of licensee PRAs, as documented in each safety evaluation, but this NRC review relied more on the individual NRC staff members' knowledge of and experience with PRA methods and the industry peer reviews. When the NRC staff questioned the adequacy of the licensee's analysis, the staff pursued the question in further detail and occasionally audited the licensee's PRA and supporting documentation.

Question Number: 10.19

Question: *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. 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?*

Response: 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.

Question Number: 10.20

Question: *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.*

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?

Response: 1. The database HERA is being built to support both first and second 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. The database HERA is populated with information obtained from licensee event reports. That is, HERA is not populated with human error probability (HEP) estimates 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 in 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, it has not become available yet for use; however, a HERA beta version will become available to NRC staff for trial applications soon.

Question Number: 10.21

Question: *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.*

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?

Response: The derivation of the subsidiary objectives is presented in Appendix B to Attachment 1 of SECY-05-006.

Question Number: 10.22

Question: *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.*

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.)?

Response: 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.

Question Number: 10.23

Question: *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 riskinforming deterministic requirements.*

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 riskinformed deterministic requirements?

Response: 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.

Question Number: 10.24

Question: *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 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.

Response: 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.

Question Number: 10.25

Question: *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.*

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).

Response: There are no specific evaluation items or methods addressed in the confirmatory order. The only restraints are that the evaluations have to be performed by independent, external organizations, and that the organizational safety culture section had to include an 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 5 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 5 years of assessments include operations performance, the corrective action program, and the engineering program.

Question Number: 10.26

Question: *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 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?

Response: An NRC Safety Culture and Climate Survey was administered to all NRC employees and managers from May 13 through June 7, 2002. The authors of the survey grouped the questions into 18 categories to help organize 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 did not directly correlate with the safety culture indicators in the INSAG-4 guidelines. Similarly, they are not meant to be comparable with the three levels of safety culture from IAEA TECDOC 1329.

With respect to the second part of the question about 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: 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 semiannual trend review, sampling issues during each inspectible 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, in response to SECY-04-0111 entitled "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," the Commission recently issued a Staff Requirement Memorandum (SRM), that directed the staff to undertake a number of activities related to safety culture.

Specifically, the SRM directed the 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 evaluating the licensee's safety culture (for plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed that the staff develop tools so inspectors could rely on more objective findings and 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.

Question Number: 10.27

Question: *Regarding the National Report, Article 10. The following questions are arisen:*
Why the U.S.NRC 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?

Response: 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 risk-informed applications and provide lessons learned from the applications 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 that the implementation of 10 CFR 50.69 is maintained within the supporting analyses. Current operating plants have implemented severe accident management guidelines (SAMGs) through a voluntary industry program. The advanced reactor designs have committed to develop applicable SAMGs. 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 complied with parts of Regulatory Guide 1.200 requirements (e.g., have subjected the plant-specific PRA to industry peer review).

Question Number: 10.28

Question: *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 climate. Please list the 18 categories.*

Response: These categories were given in the Web link in the report http://www.nrc.gov/reading-rm/doc-collections/insp-gen/2003/03a-03.pdf
The categories are:
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, their aability to discuss differing opinions and to openly and confidently raise issues, and whether NRC's climate allows them 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 is 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 of quality of performance and its leniency to 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 whether employees feel their job is worthwhile and important to the NRC, provides a sense of accomplishment, and allows 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 with 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, and 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, deadlines or political constraints, and 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. Opinions are also solicited regarding the differing professional opinion process and risk-informed, performance-based regulation.

Question Number: 10.29

Question: *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?*

Response: The NRC established an operating experience staff to perform gathering, screening, and communication functions (see Section 19.7 of the National Report and Section 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession No. ML033350063)). The operating experience staff reviews foreign experience as well as United States experience. For 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 with 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 U.S. 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."

Question Number:	10.30
Question:	*In the National Report, Section 10.3.6 "Activities that Apply Risk Assessment to Plant-Specific Changes to the 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?*
Response:	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 continue to be expanded into areas that have previously been solely deterministic, but there are no plans to make the regulations solely risk-based and to eliminate the deterministic approaches.
Question Number:	10.31
Question:	*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?*
Response:	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. Two aspects of license renewal are 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. Therefore, risk-informed applications should appropriately consider low-power and shutdown risk contributions, 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.

Question Number: 10.32

Question: *NRC applies PRA technology to resolve severe accident issues, evaluate new and existing requirements and programs, implement riskinformed regulation, and 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?*

Response: 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. With respect to 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 in the regulation.

Question Number: 10.33

Question: *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?

Response: 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 confirmation that the risk of hydrogen combustion was from beyond-design-basis accidents, where the hydrogen generation rate would exceed the effectiveness of the recombiners. Additional detail is provided in the September 16, 2003 *Federal Register* notice (Vol. 68, No. 179).

Question Number: 10.34

Question: *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 reactor 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?*

Response: 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 the application was justified by conservatisms in licensees' analyses (typically conservative analysis of external events such as fires and seismic). This is consistent with the guidance provided in Regulatory Guide 1.174.

Question Number: 10.35

Question: *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?

Response: 1. The results of NRC research are available to the public and may be used by parties in their representations 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-burnup 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 will receive even greater scrutiny.

C. RES may perform prototypical-hardware testing. An operator or designer has access to the test results, but will 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 its research, it does not require its adoption or use. Licensees or applicants need to present their own safety justification, including their analyses and, if applicable, their own research and data.

Question Number: 10.36

Question: *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"?

Response: 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 lessons learned.

Question Number: 10.37

Question: *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?*

Response: 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 to be non-safety-significant.

Question Number: 10.38

Question: *What impact could be expected from your regulation on Risk-Informed Categorization and Treatment of Structures, Systems, and Components?*

Response: Licensees are required by 10 CFR 50.69 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 in the statements of consideration for the rule. In this context, the Commission considers that small changes for plants with a total baseline CDF of 10-4 per year or less, involve CDF increases of up to 10-5 per year. Small changes for plants with a total baseline CDF greater than 10-4 per year involve CDF increases of up to 10-6 per year. The Commission considers that small changes for plants with total baseline LERF of 10-5 per year or less involve LERF increases of up to 10-6 per year, and that small changes for plants with total baseline LERF greater than 10-5 per year involve 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 on why steps should not be taken to reduce CDF or LERF if the licensee wants to reduce special treatment requirements. This approach is consistent with the acceptance guidelines established in Section 2.2.4 of Regulatory Guide 1.174.

Question Number: 10.39

Question: *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 U.S. 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?*

Response: 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 a repair activity.

As the question states, there was 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 occurrences was widely disseminated. Concern over this issue led the NRC to issue Generic Letter 97-01 requesting PWR licensees to inform the NRC of their plans to monitor and manage cracking in VHP nozzles and their intentions, if any, to perform nonvisual, 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."

Question Number: 10.40

Question: *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 U.S. 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?

Response: The current NRC guidance related to decisionmaking based on PRA results is derived from the Commission's safety goals, which are related to risks to the public. Within this context, decisions are not risk-based, but risk-informed, meaning that 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 (see NUREG-1738, "Technical Study of Spent Fuel Pool Accident Risk at Decommissioning Nuclear Power Plants).

Question Number: 10.41

Question: *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 (NRC Reg Guid 1.2000 endorsed industry PSA standard developed by the NRC). Your views on that would be appreciated.*

Response: The 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, NRC's independence of 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 the application's acceptability. 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 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 part, used to support a licensee's risk-informed regulatory application is technically adequate; and (4) documentation to support a regulatory submittal.

Question Number: 10.42

Question: *Regarding safety goals, it is mentioned that NRC has established a subsidiary objective of a core damage frequency of 1x10-4 per reactoryear 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 circumstances which allow a plant modification to result in a CDF greater than 1x10-4 ?*

Response: 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., inadequate defense in depth). The NRC has a regulation, 10 CFR 50.109 (the Backfit Rule), where significant safety improvements can be imposed if certain risk-benefit regulatory analysis criteria are 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 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.

Question Number: 10.43

Question: *"Licensee Safety Culture" Governing Documents and Process, Paragraph 1 What does NRC use as a definition of Safety Culture?*

Response: 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."

Question Number: 10.44

Question: *What are the methods used for safety culture assessment? What are the mentioned methods, concepts, and focus areas accepted by the international nuclear community?*

Response: 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.

Question Number: 10.45

Question: *What is the difference between "organizational safety culture" and "safety culture"?*

Response: 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).

Question Number: 10.46

Question: *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?*

Response: There is currently no formal training for inspectors specifically in the area of safety culture. However, staff members from NRC headquarters with knowledge of 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.

Question Number: 10.47

Question: *Licensee Safety Culture Governing Documents and Process, Paragraph 2 What is the theoretical background for the Attributes to Safety Culture?*

Response: The theoretical background for the attributes of safety culture considered by the NRC is generally drawn from IAEA, INSAG, and some international experts in the field. INSAG-4, 13, and 15 provide further explanation of specific attributes.

Question Number: 10.48

Question: *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?*

Response: 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 on site 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 members from NRC headquarters with experience in those areas have participated on the inspection teams to inspect or evaluate these areas.

Question Number: 10.49

Question: *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?*

Response: The NRC does not have a specific set of detailed criteria for evaluating a licensee's tools for monitoring safety culture. 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 its safety culture, the team inspection reviewed each of the tools to determine which attributes of safety culture the licensee was 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 the assessment. The inspection team also conducted a series of independent interviews and focus groups with target populations to determine if the responses 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 the level of consistency with the licensee's findings. Since all of the Davis-Besse assessments and the NRC's assessment made 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.

Question Number: 10.50

Question: *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 U.S. NPPs?*

Response: 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 the Davis-Besse licensee to assess its safety culture and its 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 Concerns 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:,human performance, SCWE, and problem identification and resolution (PI&R). The PI&R area has an associated inspection that evaluates licensees' corrective action programs' effectiveness in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semiannual trend review, sampling issues during each inspectible 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, in response to SECY-04-0111 entitled "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," the Commission recently issued a Staff Requirement Memorandum (SRM), that directed the staff to undertake a number of activities related to safety culture.

Specifically, the SRM directed the 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 evaluating the licensee's safety culture (for plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed that the staff develop tools so inspectors could rely on more objective findings and 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.

Question Number: 10.51

Question: *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)?*

Response: 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 the programs noted in the question.

Question Number: 10.52

Question: *The reference to a "questioning attitude" in the third paragraph under this subheading 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?*

Response: The NRC acknowledges the importance of licensees having a healthy safety culture and has identified the need to enhance agency 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 plants in the degraded cornerstone column of the ROP Action Matrix)
- To continue to monitor developments by foreign regulators

The SRM directed staff to develop tools so that inspectors 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.

Question Number: 10.53

Question: *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 resolution of corrective actions. Is there not an overreliance 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?*

Response: In regard to the question if there is an overreliance 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 the Salem and Hope Creek plants)

NRC is further enhancing safety culture efforts by:

- Revising the Reactor Oversight Process (ROP) to more fully address safety culture, in accordance with Staff Requirement Memorandum described in more detail under question 10.02.
- Taking significant corrective actions, including the 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.

Question Number: 10.54

Question: *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 subheading "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?*

Response: 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, 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.

ARTICLE 11. FINANCIAL AND HUMAN RESOURCES

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

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

This section of the U.S. National Report explained the requirements regarding the financial resources that licensees must have to support the nuclear installation throughout its life, including the financial resources needed for financing safety improvements made during a plant's operation, for decommissioning, and for handling claims and damages associated with accidents. This section also explained the regulatory requirements for qualifying, training, and retraining personnel.

Questions and answers on this section are as follows.

Question Number: 11.01

Question: *§ 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).

Response: The last shift technical advisor (STA) staffing study conducted by the NRC (5/91) indicated that 79 facilities used dedicated STAs (BS degree, nonlicensed) on shift (Option 2 of the Commission's Policy Statement on Engineering Expertise on Shift). The remaining 25 facilities used dual-role STAs on shift (BS degree, SRO licensed) (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 STA staffing question.

Question Number: 11.02

Question: *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 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?

Response: The NRC does not monitor the licensee's workforce to ensure that personnel meet or maintain position qualification requirements. However, as required during implementation of the Reactor Oversight Process, the NRC will evaluate the training and qualification of licensee personnel.

Question Number: 11.03

Question: *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?*

Response: While the NRC does not routinely conduct financial reviews of power plant licensees (e.g., annual reviews), the NRC is authorized to review licensee financial qualifications during a plant's operating life and during decommissioning, 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 necessary.

Question Number: 11.04

Question: *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?*

Response: At the present the NRC does not have any formal plans to do generic staffing studies of licensee facilities to determine the adequacy of the numbers of appropriately trained staff. However, when required by the Reactor Oversight Process, the NRC will evaluate the adequacy of licensee staffing.

ARTICLE 12. HUMAN FACTORS

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

This section of the U.S. National Report explained the NRC's program on human performance. The seven major areas under the program are (1) human factors engineering issues, (2) emergency operating procedures and plant procedures, (3) working hours and staffing, (4) fitness for duty, (5) the human factors information system, (6) support for event investigations and for-cause inspections, and (7) training. This section also discussed research activities.

The questions and answers on this section are as follows.

Question Number: 12.01

Question: *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?*

Response: 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 on 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 the associated guidance (e.g., NUREG-0711).

The licensee is responsible for training and qualifying contractor personnel. 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 Process, the NRC will evaluate licensee training and qualification programs and, as necessary, the contractor training requirements in those programs.

Question Number: 12.02

Question: *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?*

Response: The regulatory requirements for human factors have their origin in TMI Action Items that were provided to the U.S. 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). The principal sources of NRC guidance on human factors engineering are 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 and human performance. 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). Since the TMI event, the Institute of Nuclear Power Operations (INPO) has continued to support the nuclear industry by preparing programs and guidance on various human factors topics. Most recently, EPRI and the industry have jointly developed a guidance document for licensees to use in upgrading their analog control room instrumentation to digital instrumentation.

Question Number: 12.03

Question: *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?*

Response: 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 procedure covers mainly the human-system interface, the environment, communication, coordination of work and supervision, work practices, and procedure use. The procedure was not intended to focus on staffing levels or safety culture.

With 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, directing 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 doing the evaluation of the licensee's safety culture (for plants in the degraded cornerstone column of the ROP Action Matrix). The SRM also directed the staff to develop tools so that inspectors can rely on more objective findings and to create an enhanced training program. A Safety Culture Response Plan is being developed and will be placed on NRC's Web site in the future.

Regarding staff, paragraph (m) of 10 CFR 50.54, "Conditions of Licenses," specifies the minimum number of licensed operators 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 in 10 CFR Part 50, 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," respectively. In 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 for advanced reactor control room designs and light water reactor control room upgrades. At present, the process for submitting an exemption request is described 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 Regulatory Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m)."

Question Number: 12.04

Question: *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 U.S. NRC adequately prepares/plans for such requests.*

Response: Power Uprates: Since 2002, steam dryer cracking of and flow-induced vibration damage to components and supports of the main steam and feedwater lines have been observed at the Dresden and Quad Cities boiling water reactors, following implementation of extended power uprates.

The NRC staff has determined that 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 systems or reactor plant operation. The NRC has corresponded and met with nuclear industry groups concerning the cracking and vibration damage first observed 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/poweruprates.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 . . . ." The Commission may require additional information from the applicant as needed. Various staff groups in the Office of Nuclear Reactor Regulation (NRR) evaluate different parts of license transfer applications. The Human Performance Section reviews human factors aspects of a transfer (such as changes in the reactor staff and management organizational structure) that could potentially change operating performance and technical safety aspects of the reactor being transferred. The Financial and Regulatory Analysis Section reviews factors that could impact safety, such as the financial qualifications of the proposed transferee to operate the reactor, assurance of adequate decommissioning funding for the reactor being transferred, the adequacy of the reactor liability and property insurance to be provided by the transferee, and whether there is significant 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 evaluated by NRR's Division of Licensing Project Management (DLPM), which incorporates the SER and other information into an order approving or disapproving the application. DLPM then 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 10 years, most of which were wholly or in part related to the deregulation of the electric utility industry in the United States. Examples are 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.

Question Number: 12.05

Question: *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 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).

Response: Under 10 CFR Part 50, "Appendix B, Quality Assurance Criteria For Nuclear Power Plants and Fuel Reprocessing Plants," licensees 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, without NRC review and approval 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 review the acceptability of the licensee's human factors engineering changes. Guidance for implementing 10 CFR 50.59 is given in NRC Regulatory Guide 1.187, "Guidance for the Implementation of 10 CFR 50.59, Changes, Tests and Experiments" (2000).

Question Number: 12.06

Question: *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.*

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."

Response: 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 weeks while the plant is operating. The policy also establishes guidelines to be used on a temporary basis during periods requiring heavy use of overtime, such as plant refueling outages. For these periods the policy is as follows:

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 7 day period (all excluding shift turnover time). A break of at least 8 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 of scheduling personnel at these limits. Similarly, the policy guidance allows 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 how long 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 on a subjective assessment by the licensee.

In SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," the NRC staff 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 on 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

Question Number: 12.07

Question: *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?

Response: 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 "significant regulatory activities in ...seven areas to address human performance under the Human Factors Program." The Report did not mean to discuss each element of NUREG-0711. The Report discusses only elements of the human factors engineering program considered to be "significant regulatory activities." Working hours and shift staffing were included in the National Report because of significant recent NRC initiatives to address these issues.

Question Number: 12.08

Question: *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"?
2. Among 12 elements described in NUREG-0711 Rev.2, what element(s) does the "Human Factors Information System" correspond to?

Response: Licensees and applicants use the HFE Issues Tracking system 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 (HFIS) 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). NRC uses this information to assist in overseeing licensee programs. The information in the HFIS database is not considered all-inclusive but rather indicative of overall performance at an 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 review (NUREG-0800, Chapter 18) of applications for construction permits, operating licenses, standard design certifications, combined operating licenses, and license amendments.

Question Number: 12.09

Question: *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?*

Response: With regard to event investigation, the NRC's inspection program has three levels of investigation. The most significant events are investigated by an "incident investigation team" (IIT). The IIT inspection is an in-depth team inspection with independent root cause analysis, however, this has not been used in the last ten years. The next level of inspection is an "augmented inspection team" (Inspection Procedure 93800), which is somewhat independent but usually does not include independent root cause analysis. The lowest level of event investigation is a "special inspection" (Inspection Procedure 93801), whose primary purpose is to obtain 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 licensees will conduct root cause analyses for risk-significant issues and events. These licensee-generated analyses are then reviewed by NRC inspectors using the guidance in specific NRC inspection procedures. The applicable inspection procedures (Inspection Procedures 95001 and 95002) include the specific attributes that need to be addressed by the licensee's root cause analysis before the NRC can consider the issue closed. The procedures do not favor any one specific root cause methodology, but rather aim to match an appropriate methodology to the issue being assessed. Our experience is that no one methodology is preeminent at U.S. nuclear plants and that the implementation of a methodology chosen is often more important than the type of methodology.

Question Number: 12.10

Question: *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)?

Response: Industry representatives can perhaps better answer the question of which IAEA- and IEC-recommended methods for reducing human-induced failures have proved most effective in the U.S. Licensees are responsible for choosing the methods they believe are most effective in addressing situations that produce human-induced failures at their facilities.

Question Number:	12.11
Question:	*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?*
Response:	1. There are no NRC requirements 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 purpose of updating their PRAs. In Generic Letter 88-20 (issued November 23, 1988), the NRC requested that all licensees conduct an individual plant examination (IPE) using PRA to identify potential vulnerabilities to severe accidents ; 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 information to help assess human performance.

2. The NRC routinely reviews operational events using risk-informed methods to determine the safety significance of the events and to detect worsening performance trends. Human performance issues are considered in these reviews. The NRC's Office of Regulatory Research maintains the Standardized Plant Analysis Risk (SPAR) Model Development Program, which has developed PRAs of all currently licensed NPPs. These PRAs are used to support various 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 uses operational experience for research on human reliability analysis (HRA) methods.

The purpose of NUREG-1764, "Guidance for the Review of Changes to Human Actions," is to provide guidance to the NRC staff on reviewing changes in operator actions that are credited in NPP safety analyses. Changes in credited actions may result from various 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, more risk-significant human actions receive a detailed review and less risk significant human actions receive a less detailed review. NUREG-1764 is not used as guidance for human performance assessments or trend analyses of human-induced NPP operational events.

Question Number: 12.12

Question: *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)?*

Response: 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 (TSs), and these TSs are enforceable requirements. The NRC does not routinely inspect for compliance with these TSs as part of the current reactor oversight process. However, the NRC has on occasion issued violations for licensee failures to maintain compliance with these TSs, 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 TSs, the NRC cannot readily enforce certain provisions. The NRC has developed a draft proposed rule which, if approved as a final rule, will establish clearer, more readily enforceable requirements. 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 give plant managers, or their designees, 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 the authorization is that significant reductions in the effectiveness of operating personnel be highly unlikely. Accordingly, the NRC encourages workers to communicate to their management any concerns they about their ability to safely and competently perform their duties as a result of deviating 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, but workers can bring safety concerns directly to the NRC at any time.

NRC's response to concerns regarding licensee control of work hours has depended 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 about fitness-for-duty self-declarations of fatigue and clarifies the regulatory requirements, including the applicability of NRC's fitness-for-duty requirements (10 CFR Part 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. Enhanced security measures resulted in an increase in working hours for security personnel, causing some individuals to express concern about their ability to perform their duties. A review of the work hours for security personnel indicated that many individuals had been working as many 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.

Question Number: 12.13

Question:

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 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?

Response:

Part 1: Various methods and 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 for licensee safety culture can be found in Section 10.4.2. The NRC does not currently conduct safety culture assessments. The NRC staff had recently sent the Commission 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, directing the staff to undertake several activities related to safety conscious work environment (SCWE) and safety culture:

- Enhance the Reactor Oversight Process (ROP) treatment of crosscutting 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 plants in the degraded cornerstone column of the ROP Action Matrix.
- Continue to monitor industry efforts to assess safety culture.
- Continue to monitor the actions of foreign regulators.

The SRM further directed staff to develop tools so that inspectors could rely on more objective findings and to create an enhanced training program. In carrying out these activities, the staff was directed to follow established processes for revising the ROP, particularly the process for involving stakeholders.

A safety culture response plan is being developed and will be placed on NRC's Web site in the future.

Part 4: Regulatory Guide 1.166 provides NRC guidance on pre-earthquake planning and immediate nuclear power plant operator post-earthquake actions.

Question Number: 12.14

Question: *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?*

Response: There are regulatory requirements only for minimum numbers of licensed staff.

ARTICLE 13. QUALITY ASSURANCE

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

This section of the U.S. National Report explained NRC quality assurance (QA) policy and requirements and guidance for design and construction, operational activities, and staff licensing reviews. It also described QA programs, including QA under the Reactor Oversight Process, augmented QA, and graded QA.

The questions and answers on this section are as follows:

Question Number: 13.01

Question: *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.*

Response: 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 and engineering groups.

Question Number: 13.02

Question: *Is there a special QA program in case of life extension to monitor the ageing of components?*

Response: No. The licensee's existing QA programs, as committed to in the FSAR or in the updated FSAR, are mostly used for plant life extension activities.

Question Number: 13.03

Question: *Does the U.S.NRC 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?*

Response: 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 and ML031490463.

Question Number: 13.04

Question: *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?*

Response: Ultimately, all reductions in commitments to the licensee's existing QA program must comply 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.

Question Number: 13.05

Question: *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?*

Response: No. No separate QA regulations focus on systems, structures and components whose malfunction could only affect the health and safety of workers at the plant. NRC and licensees do not categorize systems in that way. 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.

ARTICLE 14. ASSESSMENT AND VERIFICATION OF SAFETY

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

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

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

This section of the U.S. National Report explained the governing documents and process for ensuring that systematic safety assessments are carried out during the life of the nuclear installation, including the period of extended operation. This section focused on assessments performed to maintain the licensing basis of a nuclear installation. Finally, this section explained the verification of the physical condition and operation of the nuclear installation by analysis, surveillance, testing and inspection.

Other articles (for example, Articles 6, 10, 13, 18, and 19) also discussed activities undertaken to achieve nuclear safety at nuclear installations.

Questions and answers pertaining to this section follow below.

Question Number: 14.01

Question: *In Section 14.1.3 a description is given on how the U.S.NRC 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 [PSR]). Can this be clarified?

Response: It is true that the U.S. approach for ensuring safety is program- and process-oriented. NRC's approach to 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 U.S. regulatory framework provide an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, and process improvements and provide confidence that the U.S. 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 a more comprehensive focused evaluation of safety at individual plants when warranted. The regulatory process will identify the need for more comprehensive reviews in the future.

Question Number: 14.02

Question: *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?*

Response: 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). Generic or plant-specific PRA information may be used in performing the backfit analysis . However, all U.S. nuclear power plants have performed individual plant examinations (IPEs) to search for facility vulnerabilities, and a number of plants have voluntarily made improvements.

Question Number: 14.03

Question: *The report contains additional paragraphs (§14.1.3 p 14-6, 14-7, 14-8) explaining the U.S. 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 U.S. 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 U.S. 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.

Response: The question has 3 parts: the relationship between the U.S. license renewal process and the periodic safety review process, the backfitting process, and additional information on the ISAP and IPE programs.

First, although the license renewal process provides an opportunity for a more comprehensive assessment of plant safety, it is not equivalent to the generally understood periodic safety review process. NRC's approach to 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), provides an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, and process improvements and provides confidence that the U.S. civil nuclear power plants will 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 as periodic safety reviews. Periodic safety reviews thoroughly and comprehensively implemented in the context of a country's regulatory framework can be an effective and necessary element in ensuring continued power plant safety. However, periodic reviews are not the only way to ensure continued plant safety.

Second, with regard to the NRC backfitting process, NRC has imposed requirements on U.S. 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. These requirements have 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 programs 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 U.S. regulatory process as discussed in Section14.1.3. This process allows a more comprehensive focused evaluation of safety at individual plants when warranted and will identify the need for broader reviews in the future.

Section 10.3 does not provided detailed information on the IPE. We regret the error. The following links give additional information on the ISAP and IPE programs:

- http://www.nrc.gov/reading-rm/doc-collections/gen-comm/genletters/1985/gl85007.html
- http://www.nrc.gov/reading-rm/doc-collections/gen-comm/genletters/1988/gl88002.html
- http://www.nrc.gov/reactors/operating/ops-experience/fireprotection/plant-examination.html
- http://www.nrc.gov/reading-rm/doccollections/commission/secys/1996/secy1996-051/1996-051scy.htm

Question Number: 14.04

Question: *This chapter explains that "the U.S. 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?*

Response: While there have been some efforts to establish common guidance and standards for periodic safety reviews, the periodic safety review process is implemented differently and for different purposes in many countries. Consequently, we believe 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. Considered in the context of a countries regulatory framework and thoroughly and comprehensively implemented, periodic safety reviews 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 U.S. regulatory framework provide an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, and process improvements and provide confidence that the U.S. civil nuclear power plants can continue to be operated safely.

The U.S. 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 plant operators, and ensures that adequate protection of public health and safety is provided every day throughout the operating life of a civil nuclear power plant. We currently believe that PSRs are not needed to ensure plant safety in the U.S.

Question Number: 14.05

Question: *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.*

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?

Response: The NRC does not have a specific regulation that requires a periodic NRC safety review of the licensee's PRA or regulates the licensee's baseline PRA. In the context of applying risk-informed regulations, (such as 10 CFR 50.69), which may be voluntarily implemented by licensees as an alternative to or enhancement of other regulations, specific requirements ensure that 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 usually require the submittal of a license application and a review of the licensee's PRA, including the licensee's process for keeping the PRA up to date. However, aging effects are usually treated by aging management programs to ensure that important structures, systems, and components are not susceptible to aging impacts. Thus, aging effects are not usually addressed in PRAs.

Question Number: 14.06

Question: *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.*

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)?

Response: The Atomic Energy Act (AEA) permits the NRC to issue operating licenses with terms up to 40 years, but permits renewal of the licenses. 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 provide and maintain 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 there is sufficient technical understanding of age-related degradation 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 has 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 will, 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 of the nuclear industry (domestic and international) and are not limited to information developed solely by the licensee seeking license renewal. This experience increases year by 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 is gained with licensee performance in managing age-related degradation during the renewal term. If the Commission has sufficient confidence in the adequacy of licensee programs to promptly detect and resolve unforeseen age-related degradation, it may revise the 20-year limit. However, the 40-year limit imposed by the AEA will remain. The Commission can change its own regulations (such as the License Renewal Rule) as appropriate. A change to the AEA would require legislation by Congress.)

Maintenance Rule:
Aging is not explicitly addressed by the Maintenance Rule, 10 CFR 50.65, but the rule requires monitoring performance or condition of systems, structures, and components (SSCs) in 50.65(a)(1) status. Condition monitoring could certainly be construed to account for aging effects. To keep SSCs in 50.65(a)(2) status, the licensee must demonstrate effective control of performance or condition through appropriate preventive maintenance. It seems that appropriate preventive maintenance for effectively controlling performance or condition necessarily accounts for aging in that for SSCs with identified age-related degradation susceptibilities, the affected attributes must be examined periodically and trended so 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.

Question Number: 14.07

Question: *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:*

In the licensing renewal, does NRC utilize the PSA in order to confirm the technical adequacy of the life extension?

Response: In developing the current License Renewal Rule (10 CFR Part 54), the Commission determined that probabilistic safety analyses (PSAs) would be of limited use for determining the scope of systems, structures, and components (SSCs) 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, the Commission 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 the PSA. A PSA may be useful in license renewal on a plant-specific basis to help an applicant assess the relative importance of SSCs and develop an approach for aging management. The use of PSA for license renewal may be revisited in the future as further risk-informed experience is gained.

Question Number: 14.08

Question: *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.*

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"?

Response: The NRC relies on its regulatory process to provide continuous oversight of nuclear power plants and to upgrade requirements as 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 continuing NRC and licensee regulatory activities. These various activities involve implementation of the backfit process and other regulatory processes.

The NRC engages in numerous regulatory activities which, considered together, constitute a regulatory process that provides ongoing assurance that the licensing basis of nuclear power plants provides an acceptable level of safety. This process includes research, inspections (both periodic regional inspections and 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 to modify nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. The NRC also issues operating experience, research, and the results of new analyses in bulletins, generic letters, regulatory information summaries (RISs), and information notices (INs). 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 provides an acceptable level of safety, considering operating experience. This process continues for plants that receive a renewed license.

Question Number: 14.09

Question:

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.

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?

Response:

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 in maintaining safety, improving the 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. After identifying lessons learned, the NRC staff communicates generically with the industry through the Nuclear Energy Institute's License Renewal Task Force using the ISG process. The ISG process captures lessons learned from license renewal application reviews and communicates the lessons to all stakeholders. The process includes early interactions with stakeholders during the development of the ISG, including the 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 issues identified in their applications. If the issues are not addressed, the applicant must address the issues after the renewed license is issued.

2. Applicants for license renewal must address the position in an approved ISG, as applicable, in the 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. The scheduled issue date for the final documents is September 2005.

Question Number: 14.10

Question: *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 and depth of reports.)*

Response: 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)).

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 focuses 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 has 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 40 years.

For license renewal, 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 plants already operating and (2) the environmental impacts of major refurbishment activities that could be required for operation during the 20-year renewal period. The results of this inquiry were published in the Generic EIS (GEIS), NUREG-1437, and the findings of the inquiry were codified in the NRC's rules. Consequently, issues that were generically resolved in the GEIS for all plants (Category 1 issues) 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 (so-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 the applicant may be aware of.

Question Number: 14.11

Question: *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.*

Response: The intent of Article 14 is to summarize the type of information requested, with references to documents containing more detail. Additionally, Regulatory Guide 1.174 provides guidance on considering deterministic and probabilistic information.

Question Number: 14.12

Question: *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?*

Response: Some of the current 104 plants shut down because of performance deficiencies identified by events, licensee reviews, and NRC oversight programs. With the exception of Browns Ferry Unit 1, these plants have restarted and are currently operating (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 of the Code of Federal Regulations states *"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 plants have opted to submit their applications well before the expiration of their operating licenses, which is allowed by the regulations.

Major changes in the licensing bases of plants are not the determining factor for when licensees apply for license renewal. The decision to seek license renewal rests entirely with nuclear power plant licensees, and usually 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 the licensee and situation. 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. Most 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.

The NRC has as of February 2005 issued renewed licenses for 30 reactors at 17 sites.

Question Number: 14.13

Question: *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. U.S. 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 level-4 and level-5 of defense in depth philosophy.*

Response: TVA is performing modifications to Browns Ferry Unit 1 so that the unit will comply with regulatory requirements, codes, and standards when the unit is restarted. TVA is replacing and refurbishing major parts of the facility, based on lessons learned from the recovery of Units 2 and 3 and from Unit 2 and 3 operating experience. 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 its goal is to make the design and licensing bases for Browns Ferry Units 1, 2, and 3 essentially the same.

Question Number: 14.14

Question: *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 U.S. 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.

Response: The integrated plant assessment (IPA) for 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 U.S. comprehensive regulatory process (as discussed in Section 14.1.3), that helps ensure continued safe operation of U.S. nuclear power installations. An IPA will be performed again if a U.S. licensee, once granted a renewed license, seeks to extend the license beyond 60 years.

Question Number: 14.15

Question: *Please explain the typical procedure used by U.S. licensees for internal safety review, of plant modifications, Tech Spec changes etc, before the cases are submitted to NRC for approval.*

Response: Plant modifications are governed by engineering procedures to ensure 10 CFR 50.59 is addressed. Licensees must address a number of questions on the effect the of modification 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 usually have a licensing organization procedure for the process. A licensing engineer is assigned the task of developing the license amendment request. Usually the plant's onsite safety review committee reviews the license amendment request for adequacy. The staff subsequently reviews this document when submitted.

Question Number: 14.16

Question: *It is mentioned that the objectives associated with Periodic Safety Review (PSR) are substantively accomplished in the U.S. 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 U.S. system.*

Response: The NRC inspection and oversight processes help ensure that plants meet current safety standards and practices consistent with NRC rules and regulations. NRC's Reactor Oversight Process is highly transparent. Poor performing plants or plants that are not in compliance with NRC's regulations are identified and compelled to improve performance through various 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, and process improvements and providing confidence that the plant can continue to be operated safely. NRC and U.S. industry resources are most effectively and efficiently utilized by focusing on issues of most safety importance.

With respect to the comment on identifying reasonable safety improvement measures, the NRC can only require reactor licensees 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 may be imposed on U.S. 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 the costs for the facility are justified in view of the increased protection, then the NRC can impose the requirement on power reactor licensees.

The safety improvements imposed by NRC are a subset of the safety improvements implemented at U.S. nuclear power plants. Each U.S. nuclear power plant licensee makes its own decisions on reasonable safety improvements. Many safety improvements at U.S. plants are not initiated or imposed by the NRC. Licensees are principally responsible for the safe operation of their facilities and licensees routinely assess new technologies, off-normal conditions, operating experience, and industry trends to make informed decisions on safety enhancements to their facilities.

Safety enhancements are often self-imposed initiatives motivated by the U.S. industry's self-described pursuit of excellence and the recognition that safety and economics are directly linked in a free-market energy industry . 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 achieve performance levels above the NRC's performance indicator thresholds.

Question Number: 14.17

Question: *The procedure for licence renewal is explained. Please 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?*

Response: 1. When the Commission established the scope of the review for license renewal, it determined that resolution of generic issues that are under current investigation was 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, several approaches 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, the implementation of the resolution can be incorporated in 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 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) will be available to adequately manage the effects of aging. An applicant will have to describe its basis for concluding that the CLB is maintained, in the license renewal application, and briefly describe options that will be technically feasible during the period of extended operation to manage the effects of aging, but will not have to preselect which option will be used. Other approaches are to develop an aging management program which, for that plant, incorporates a resolution of the aging effects issue, or to propose (outside of license renewal) to amend the CLB so 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. In reviewing power uprate applications, the NRC does not intend to impose new criteria or requirements on plants whose design and licensing bases do not include the criteria or requirements 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 the 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 and the common defense and security, the NRC will impose these new requirements on operating reactors. The regulation used to control new requirements is 10 CFR 50.109. The regulation ensures that backfitting of a nuclear power reactor is appropriately justified and documented.

Question Number: 14.18

Question: *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?

Response: All licensees have at least a Level I PRA and simplified Level II (i.e., focused on large early releases) PRA addressing the range of initiating events for full-power operating conditions. Licensees establish their own update requirements for their PRAs, but with the issuance of Regulatory Guide 1.200 and industry standards 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.

Question Number: 14.19

Question: *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?*

Response: The Atomic Energy Act states that the NRC may establish requirements deemed necessary to promote the common defense and security and to adequately protect the health and safety of the public. As discussed in Section 14.1 of the report, the NRC's regulatory approach is to determine before granting a license that a facility satisfies NRC requirements and then to conduct various 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 that programs establish additional requirements. If there is new information (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 licensee activities that are not specifically required by regulation. For instance, the Institute of Nuclear Power Operations conducts various reviews and audits of licensee operations, including "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 improvements. NRC has various reporting requirements with respect to changes without NRC review (see Section 14.1.1.1) or if a licensee identifies "an unanalyzed condition that significantly degraded plant safety" (§ 50.73(a)(2)(ii)(B)).

Question Number: 14.20

Question: *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?*

Response: The NRC does not explicitly require licensees to continually search for ways of improving safety. However, the NRC relies on its regulatory process to continually oversee nuclear power plants and upgrade requirements as 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, and the activities of the licensees.

The NRC engages in numerous regulatory activities which, when considered together, constitute a regulatory process that provides ongoing assurance that the licensing basis of nuclear power plants provides an acceptable level of safety. This process includes research, inspections (both periodic regional inspections and 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 to modify nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. Operating experience, research, and the results of new analyses are also issued by the NRC in 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 bases for the design and operation of all nuclear power plants provide an acceptable level of safety. This process continues to apply to 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 exists for licensee-initiated changes to the licensing basis for a plant 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 (FSAR) is periodically updated to reflect changes to the licensing basis.

Safety enhancements are often self-imposed initiatives above regulation, motivated by the U.S. industry's self-described pursuit of excellence and by the recognition that safety and economics are directly linked in a free-market energy industry. 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.

Question Number: 14.21

Question: *Why is the responsibility of carrying out the cost/benefit analysis that of NRC rather than the licensee?*

Response: NRC is required to conduct regulatory analyses (which contain cost-benefit analyses) for rulemakings to ease burden on licensees. NRC considers the impacts of proposed actions on society. The objective of this regulatory process is to ensure that all regulatory burdens are necessary, are justified, and will achieve the 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 decisions independently. NRC sometimes reviews and approves these changes to the nuclear power facility, but since the licensee has already determined that the changes are justified, NRC's review is focused on the safety aspects of the proposed change and not on the cost/benefit.

Question Number: 14.22

Question: *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?*

Response: 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 the worker protection, emergency preparedness, and security programs. These very important programs are expected to remain in effect during the period of extended operation. The License Renewal Rule distinguishes between programs that are in effect already and programs that need to be enhanced or implemented if the licensee's renewal application is granted (for example, an aging management program).

Question Number: 14.23

Question: *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?*

Response: NRC requirements are adequate for ensuring the safety of nuclear components. The inspections were guided by NRC bulletins and orders. After the 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 to establish inspection requirements for reactor pressure vessel heads at pressurized water reactors. A revised order was issued in 2004, superceding the original order. An ASME Code case is being developed for reactor pressure vessel head inspection requirements.

Question Number: 14.24

Question: *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?*

Response: Background: NUREG-1650, Rev. 1, "The United States of America Third National Report for the Convention on Nuclear Safety," (September 2004). Section 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 set forth in their licenses and enforced by NRC's regulations. 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 licensees' self-described pursuit of excellence and by the recognition that, in the U.S. free-market 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 and regulatory commitments is naturally connected with safety first. However, licensees occasionally undertake safety improvements voluntarily. Nuclear plant site vice presidents and plant managers continually keep their corporate business plans and the bottom line in mind when they consider plant improvements. Licensees usually make expensive changes only if there is some economic advantage (i.e., a resulting cost, efficiency, or capacity

benefit justifies the costs).The following are examples of voluntary safety improvements made at an economic disadvantage:

1. One licensee has replaced older equipment with state-of-the-art devices for improving operations, maintenance, etc. For example, the licensee upgraded leak detection systems with improved digital modules. The changes were not mandated by the NRC. The licensee decided to make the changes for its own reasons. The licensee also installed new suction strainers 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 would eventually have taken some enforcement action if the licensee had not installed new suction strainers.

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 significantly reduced the drywell dose rates and elemental cobalt concentrations measured in the condenser hotwell. The incentive for these changes was partly economic but safety performance was also a factor.

ARTICLE 15. RADIATION PROTECTION

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

This section of the U.S. National Report summarized the authorities and principles of radiation protection, the regulatory framework, regulations, and radiation protection programs for controlling radiation exposure for occupational workers and members of the public. Article 17 of the U.S. National Report addressed radiological assessments for licensing and facility changes.

The questions and answers on this section are as follows.

Question Number: 15.01

Question: *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?*

Response: Regulatory Guides 1.195 and 1.183 provide the details of how the NRC performs design basis accident analyses.

Question Number: 15.02

Question: *The program for occupational radiation control has succeeded in reducing doses.*

More detail information would be appreciated regarding the program for occupational radiation control. What kinds of factor do significantly contribute to this doses reduction?

Response: The "program for occupational radiation control" is the NRC's regulatory program to ensure adequate protection of workers against exposure to radiation from radioactive material during routine nuclear reactor operation. Section 1101 of 10 CFR Part 20 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 Part 20. Furthermore, Section 20.1101 states that the licensee shall use, to the extent practical, procedures and engineering controls based on sound radiation principles to achieve occupational doses and doses to members fo the public that are as low as is reasonably achievable (ALARA). NRC Regulatory Guide 8.8 provides information to licensees on how to maintain occupational radiation exposures ALARA. The NRC reviews the licensees' radiation protection programs and monitors licensees' compliance with the requirements of 10 CFR 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 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 3-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 U.S. LWRs over the past 20 years. In the years immediately following the 1979 accident at TMI, doses at U.S. reactors remained high while plants implemented numerous NRC mandated modifications. As plants completed these modifications, doses at U.S. 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, the doses declined dramatically. Since most of a plant's dose is accrued during outages, the shortening of outages at U.S. plants has led to lower annual collective doses, as have 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.

Question Number: 15.03

Question: *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. Does NRC believe that the present average collective dose level is sufficiently low ? Or the further reduction is needed?*

Response: 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 on sound radiation principles to achieve occupational doses and doses to members to the public that are as low as is reasonably achievable (ALARA). A collective dose that is considered ALARA at one plant may be unobtainable at a plant with a history of a high source term (due to high Stellite levels, inadequate shielding, poor water chemistry, cramped working conditions, etc.). As dose reduction practices improve, it is not unreasonable to expect that plant collective doses at U.S. 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 U.S. 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.

Question Number: 15.04

Question: *According to Section 15, one important constraint that ICRP recommendations are not fully incorporated in U.S. regulations has been the desire to keep 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?

Response: 1. Several large industries in the U.S. utilize special nuclear byproduct and source materials and need to protect their workers and the public from exposure to radiation as 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 industries. At a minimum, such changes require procedure revisions and associated training of workers. The NRC implemented the Backfit Rule to ensure that the costs of any required change are offset by 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 and can be implemented in the U.S..

Question Number: 15.05

Question: *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?*

Response: 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.

Question Number: 15.06

Question: *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?*

Response: 1. 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 mrem (0.10 mSv) to any organ. The NRC does not trend this data. The dose values given above are the NRC's numerical ALARA criteria for radioactive gaseous and liquid effluents. NRC inspects for compliance with these values.

2. 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 on sound radiation principles to achieve occupational doses and doses to members of 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, use of components low in Stellite, remote monitoring techniques, crud control, robotics, and improved outage planning). Dose reduction methodologies which are successful in reducing doses at one plant are shared with the industry so that other plants can benefit from the methodologies. This information sharing has dramatically reduced doses associated with steam generator replacement projects, from approximately 2000 person-rem (20 person-Sv) in 1980 to less than 200 person-rem (2 person-Sv) today.

3. 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.

Question Number: 15.07

Question: *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.*

Response: The U.S. radiation protection regulations are based on International recommendations. However, in some cases, the regulations 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 U.S. 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.

Question Number: 15.08

Question: *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.*

Response: The NRC is currently developing a regulation on 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 preoperational program at least 2 years prior to the initial criticality of the reactor. The preoperational program documents the background radiation levels and variations in the environment around the proposed plant. The NRC staff reviews the applicant's preoperational program for conformance to NRC criteria contained in the 1979 branch technical position "An Acceptable

Radiological Environmental Monitoring Program." The criteria are based on physical and meteorological factors and include 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 the preoperational 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 preoperational 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 levels anticipated in the final environmental statement.

Question Number: 15.09

Question: *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?*

Response: The NRC specifies dose criteria in each nuclear power reactor license. The dose to members of the public living near the reactor from radioactive gaseous and liquid effluents must be ALARA. There are no "source-related" constraints. It is the licensees' responsibility to keep their radioactive effluents below the regulatory requirements. For nuclear power reactors, the regulatory dose limits are as follows: 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.

Question Number: 15.10

Question: *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).*

Response: The ALARA criterion on page 15-2 is the dose in millirem to members of the public from radioactive gaseous effluents. The ALARA criterion on page 15-5 includes additional criteria for the "air dose" for beta and gamma radiation from radioactive gaseous effluents in millirads. The criteria in

Appendix I to 10 CFR Part 50 ALARA 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 mrem (0.10 mSv) to any organ; and the annual air dose from gaseous effluents is below 10 millirads (0.01 cGy) for gamma radiation or 20 millirads (0.02 cGy) for beta radiation.

Question Number: 15.11

Question: *Small mistake: 2000$/rem = 200000$/Sv*

Please describe how the optimization is implemented in the procedures inside NPPs?

Response: ALARA is defined in 10 CFR Part 20 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 the 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. The current industry practice, particularly for power reactors, 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, the availability of replacement labor, and the cost of living. Licensees are encouraged to use such higher values for their own ALARA determinations. Since each licensee establishes its 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.

Question Number: 15.12

Question: *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 "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?*

Response: The U.S. 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 the doses are as low as is reasonably possible (ALARA). The phrase "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 is that the "justification" can be difficult for activities where there is not much relevant experience or there is uncertainty over the ultimate control of the radioactive material. In such cases, there need 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.

Question Number: 15.13

Question: *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.*

Response: That is correct. The conversion from dollars per person-rem to dollars per person-Sv was incorrect. The correct conversion is that 1000 per person-rem is equivalent to $1E5 per person-Sv.

ARTICLE 16. EMERGENCY PREPAREDNESS

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

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

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

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

This section of the U.S. National Report discussed (1) emergency planning and emergency planning zones, (2) offsite emergency planning and preparedness, (3) the emergency classification system and action levels, (4) recommendations for protection in severe accidents, (5) inspection practices and regulatory oversight, (6) responding to an emergency, and (7) international arrangements.

The questions and answers on this section are as follows.

Question Number: 16.01

Question: *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?*

Response: The decision to use potassium iodide (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 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 receiving 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 (within the 10-mile EPZ) is at the greatest risk of exposure to radiation and radioactive materials. When the population has been evacuated from the area and potentially contaminated foodstuffs have been interdicted, the risk from further radioactive iodine exposure to the thyroid gland is essentially eliminated. The National Academy of Sciences (NAS) report published in December 2003 responds to the congressional mandate of Public Law 107-188, Section 127. The NAS report assesses strategies for the distribution and administration of KI in the event of a nuclear incident. The full report may be found at the NAS Web site. The report found that KI is important for protection against thyroid-related health effects due to radioiodine exposure, but the likelihood and extent of a release in the United States cannot be extrapolated from the Chernobyl accident. U.S. reactors have safety features that Chernobyl lacked and the food interdiction policies in the United States would protect the public from ingestion of foods contaminated with I-131, which were the leading cause of thyroid cancers after the Chernobyl accident. In addition, the NAS determined that State and local authorities should make the decision on the implementation and structure of a KI distribution program.

Question Number: 16.02

Question: *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?*

Response: Section 50.47(b)(10) of 10 CFR requires that licensees have a range of protective actions in their emergency plans, including the consideration of evacuation and sheltering. The NRC has provided guidance to assist licensees in 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 ways to achieve dose savings: evacuation and sheltering. Evacuation removes the public from exposure to the plume, and under most conditions, evacuation is preferred. However, in some situations 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. The study will investigate the benefits of sheltering vs. evacuation under certain circumstances.

Question Number: 16.03

Question: *Please give more information on how the public actively participates in these exercises.*

Response: 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 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's and supporting offsite response agencies' capability to implement their emergency plans and involve the participation of the licensee, State and local emergency responders and decisionmakers, 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.

Question Number: 16.04

Question: *What are the emergency reference levels applied for countermeasures (sheltering, iodine tablets and evacuation) in case of an emergency?*

Response: 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 Actions for Nuclear Incidents," May 1992. NUREG-0654, Supplement 3, provides simplified guidance for making protective action recommendations (PARs) based on severe core damage or loss of facility control. The PARs 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 doses radiation in excess of 1 rem. These dose guidelines are set at thresholds well below the values at 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).

Question Number: 16.05

Question: *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.*

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?

Response: 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 decisionmakers. The recommendations 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 on how to best protect the population from exposure to radioactive material. Federal agencies will provide monitoring and assistance to the State, local governments, and the licensee; however, the decision on how to best protect the population rests with the State or local government official authorized to make this decision.

Question Number: 16.06

Question: *NRC generally dispatches a 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?*

Response: In general, the NRC does not use specific, "rapid transportation" methods to respond to a licensee incident. NRC resident inspectors, who work at the nuclear plant, respond with the licensee's emergency response organization, generally within 1 hour, and represent the NRC's "first response" capability. NRC regional personnel make up the NRC site team which responds in a coordinated manner using the easiest mode of transportation available, usually an airplane or automobile. The exception is that 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.

Question Number: 16.07

Question: *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?*

Response: Licensees are responsible for evacuation time estimates. To plan evacuations, licensees develop evacuation time estimates for each nuclear power plant site. These estimates help government authorities 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."

Question Number: 16.08

Question: *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?*

Response: 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, including 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. The protective 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; that immediate life-threatening doses would generally not occur outside the zone in the worst accidents; and that detailed planning within 10 miles would provide a substantial base for expansion of response efforts if necessary. The rationale for the 50-mile IPZ includes the assumptions that detailed planning of control of 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 based on a number of accident descriptions. Thus the planning basis is independent of specific accident sequences. No single accident sequence is singled out as the one for which to plan.

Question Number: 16.09

Question: *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?*

Response: 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 how to protect 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 the public rests with the State or local government officials.

Question Number: 16.10

Question: *This section mentions that if an event were to occur, NRC would coordinate 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?*

Response: 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, like 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.

Question Number: 16.11

Question: *How are the emergency scenarios, like design-basis accident, with the emergency classification system connected?*

Response: Emergency exercises are required by 10 CFR 50.47(b)(14) to 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.

ARTICLE 17. SITING

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

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

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

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

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

This section of the U.S. National Report explained NRC's responsibilities for siting: site safety, environmental protection, and emergency preparedness. First, this section discussed the regulations applying to site safety and their implementation. It emphasized regulations applying to seismic, geological, and radiological assessments. Next, it explained environmental protection. Emergency preparedness was discussed in Article 16, "Emergency Preparedness." International arrangements, which would apply to Contracting Parties in obligation iv above were also discussed in Article 16.

The questions and answers on this section are as follows.

Question Number: 17.01

Question: *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?*

Response: The NRC assumes that the question refers to the U.S. 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 USGS hazard maps, the results from the USGS national hazard mapping project are not directly used in the assessment of NPPs.

Question Number: 17.02

Question: *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.*

Which specific experience or useful experience did NRC gain as lessons learned during the implementation of license renewal reviews?

Response: Background: Since publishing the Third U.S. National Report for the Convention on Nuclear Safety, in August 2004, the Commission finalized its policy statement 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 the environmental inquiry.

Response: For every license renewal action completed to date, the staff has found that the impacts of factors considered in the EJ analysis are generally small. In addition, there have not been distinct community characteristics, for example, subsistence farming or fishing, such that impacts would be borne disproportionately by a particular community. 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.

Question Number: 17.03

Question: *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 facility sites that were (or are) engaged in this procedure, what were(are) the sites and how were(are) the issues resolved?*

Response: 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 (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) were found at or near a nuclear facility (operating or undergoing a license review), then further investigation would be necessary to 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 plant 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 noncapable.

Question Number: 17.04

Question: *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?

Response: 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 a 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.

Question Number: 17.05

Question: *(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)?*

Response: We do not have a written guidance (methods and/or procedure) on 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 NRC 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."

Question Number: 17.06

Question: *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 U.S.?*

Response: 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 of considering SAMAs is to ensure that plant changes (i.e., changes to 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 consist 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.

Not all of the procedures, training, and low-cost hardware changes that were identified have 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 through the backfit process.

Question Number: 17.07

Question: *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"?

Response:

Background: The NRC publishes regulatory guidance in a number of forms. Regulatory guides (RGs) 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 reviewing applications for permits and licenses. RGs are issued in 10 broad divisions, including Division 1, "Power Reactors," and Division 4, "Environmental and Siting."

Standard review plans (SRPs) are issued to provide guidance to NRC staff in implementing regulations to ensure conformance with regulatory and statutory obligations as the staff prepares safety evaluation reports (see NUREG-0800, NUREG-1800) and environmental impact statements (see NUREG-1555). The safety and environmental SRPs evolve with changes in statutory and regulatory frameworks and advances in technology and analytical methods.

Finally, the NRC has recently begun issuing review standards (RSs) which have similar purposes to SRPs, but are intended to consolidate or enhance review guidance on 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) which was developed before utilities expressed interest in the new regulatory framework for early site permits.

Response: The NRC issues all regulatory guidance documents (i.e., regulatory guides, standard review plans, and review standards), 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 in numerous instances (for example, environmental permitting), other agencies at the Federal, State, and Tribal level have separate authorities and must be consulted before the NRC takes regulatory action. The NRC's sister agencies are given the opportunity to share their views on these guidance documents 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 documents the agency's environmental inquiry about the effects of a regulated action on all the radiological, physical, ecological, and sociological aspects of the human environment. Although the applicant may collect some of the data used to assess the impacts 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 consultations with other agencies such as the Fish and Wildlife Service, the Fisheries Service, and State or Tribal Historic Preservation Offices, in accordance with 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.

Question Number: 17.08

Question: *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.*

Response: Background: In the site evaluation phase the staff considers a wide range of environmental issues that affect the design of the plant. These "site safety" issues include severe natural phenomena such as earthquakes and manmade hazards such as airports or pipelines. Other siting issues involve "environmental protection" (how the plant would interact with the human environment), and "emergency planning" (how the public would still be protected if plant design features did not function as designed). Demographics is one that cuts across the three siting areas (site safety, environmental protection, and emergency planning). The staff recognizes that population distribution changes over time.

The NRC performs the environmental protection review to comply with the agency's obligations under the National Environmental Policy Act. The NRC performs the site safety and the emergency planning reviews to fulfill its obligations under the Atomic Energy Act (AEA).

Response: Both the NRC and the license holder have certain obligations for keeping informed of demographic changes during the operational phase of a nuclear power plant. An important element in the licensing basis of the facility is the maintenance of its final safety analysis report (FSAR); the license holder is responsible for updating the FSAR periodically to ensure that the FSAR contains the latest information (see 10 CFR 50.71(e)). This responsibility is readily achieved by modifications that result from design changes at the facility, but is equally applicable to changes in the vicinity of the facility which may be outside of the control of the operator. If the latest information could have a bearing on the safe operation of the facility (for example, placement a natural gas pipeline close to the facility), the licensee must update the FSAR. The NRC reviews the updated FSAR.

The essential regulatory concern with respect to 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, the NRC takes action regarding emergency preparedness. In certain cases, the Commission may determine whether a shutdown or another enforcement action is appropriate (see 10 CFR 50.54(s)). Population growth beyond the projected demographics considered in the initial licensing of the reactor is in itself 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, for the evaluation of the duration (around 1 month) of postulated design basis accidents, is the low-population zone (LPZ) (see 10 CFR 50.2). The LPZ is a function of the population center distance, which is the distance from the nearest boundary of a population center containing 25,000 residents. Therefore, if urban sprawl extends the population center distance beyond the distance considered in the initial licensing of the facility, then the LPZ may change and should be reflected in the updated FSAR as described above.

Current NRC regulations do not dictate the update of evacuation time estimates (ETEs) in licensee emergency plans. However, NRC has encouraged licensees to update 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 on 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 on updating 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 evacuating 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, decisionmakers 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 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 keep the emergency plan and its implementing procedures up to date and properly maintain emergency equipment and supplies. Since the emergency plan is contained in the Final safety analysis report in accordance with 10 CFR Part 50, Appendix E, Section III, the updating requirements of 10 CFR 50.71(e) apply. Updating evacuation time estimates is not be considered a decrease in the effectiveness of the emergency plan under 10 CFR 50.54(q) and licensees may update the estimates without prior Commission approval.

Question Number: 17.09

Question: *In the Review Standard RS-002, there is no any guidance for evaluation of an application that includes a "plant parameter envelope (PPE)". 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?*

Response: The NRC issued Review Standard (RS)-002, "Processing Applications for Early Site Permits," on May 3, 2004. Paragraph (1) of Section 4.6 of this document provides general guidance on reviewing 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 guidance for the NRC staff on an applicant's use of a PPE in specific technical 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 must show that the chosen design falls within the PPE, or must otherwise demonstrate that the NRC's regulations are met.

ARTICLE 18. DESIGN AND CONSTRUCTION

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

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

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

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

This section of the U.S. National Report explained the defense-in-depth philosophy, and how it is embodied in the general design criteria of U.S. regulations. It explained how applicants meet the defense-in-depth philosophy, and how the NRC reviews applications and conducts inspections before issuing licenses to ensure that this philosophy is implemented in practice. Next, this section discussed measures for ensuring that the applications of technologies are proven by experience or qualified by testing or analysis. Article 14 also addressed this obligation under "Verification by Analysis, Surveillance, Testing and Inspection." Finally, this section discussed requirements regarding reliable, stable, and easily manageable operation, specifically considering human factors and the man-machine interface. This obligation was also addressed in Article 12, "Human Factors."

The questions and answers on this section are as follows.

Question Number: 18.01

Question: *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.*

Response: The consideration of the defense-in-depth principle relies on the knowledge, understanding, and expertise of the NRC staff. A simple example of reliance on programmatic activities is the establishment of a fire watch to support maintenance activities when a fire barrier is inoperative. 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 or replacing the defective fire barriers.

Question Number: 18.02

Question: *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.*

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"?

Response: 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 the failure to identify the problems in a more timely manner. Therefore, on the basis of Criterion XVII of Part 10 CFR 50, Appendix B, the NRC performed special inspections to evaluate the processes used by Davis-Besse to assess its safety culture and corrective action plans. The areas evaluated in the Davis-Besse inspections were: the internal and external safety culture self-assessments and monitoring tools, the status of the Employee Concerns Program, the safety-conscious work environment (SCWE) at the facility, and the 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, (human performance, SCWE, and problem identification and resolution (PI&R)). An inspection procedure for the PI&R area evaluates licensees corrective action programs in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semiannual 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 for human performance and (2) to independently assess the extent of condition of the identified human performance root causes.

The Commission has directed the staff to undertake a number of activities related to safety culture.

Question Number: 18.03

Question: *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?*

Response: The NRC approach to using 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," and by 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." These documents describe acceptable realistic analysis methods for thermal-hydraulic analysis of loss-of-coolant accidents and operational transients. A basis for the acceptability of the methods is assessment against a qualified database which adequately represents the important parameters for each accident and transient being analyzed. Both Westinghouse and General Electric utilized experimental program databases derived from a series of separate-effects, component, and integral-system tests, including full-scale tests of 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 reviewing the above-mentioned designs have proven successful and will continue to be followed by the NRC.

Question Number: 18.04

Question: *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)?*

Response: 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 (10 CFR 54.21(d)). The final safety analysis report supplement must contain a summary description of the programs and activities for managing the effects of aging and evaluating 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 Regulatory Guide 1.188, "Standard Format and Content for Applications To Renew Nuclear Power Plant Operating Licenses." Guidance for the NRC staff on license renewal 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.

ARTICLE 19: OPERATION

Each Contracting Party shall take appropriate steps to ensure that:

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

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

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

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

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

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

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

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

This section of the U.S. National Report stated that the NRC relies on regulations in Title 10, "Energy," of the *U.S. Code of Federal Regulations* (10 CFR) and internally developed programs in granting the initial authorization to operate a nuclear plant and in monitoring the plant's safe operation throughout its life. The material discussed under this article described the more significant regulations and programs corresponding to each obligation of Article 19.

The questions and answers on this section are as follows.

Question Number: 19.01

Question: *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.*

Response: Although relocation of an LCO and associated requirements is contingent on 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 to 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 on 10 CFR 50.36(c)(2)(ii), which lists the four criteria needed for including LCOs in the technical specifications can be found at http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0036.html Information on 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/doccollections/cfr/part050/part050-0059.html

Question Number: 19.02

Question: *The majority of the U.S. 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?*

Response: 1. The foremost benefit is the reduction in the number of limiting conditions for operation that will be retained in the plant-specific TSs. Other benefits that licensees of NPPs gain through adopting improved TSs 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 (NPPs) that 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 interacting with NRC licensing and inspection staff.

2. The basis for the TSs of all U.S. NPPs is 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, including the analyses of radiological consequences, and insights from a probabilistic risk assessment. However, the differences between the NPPs that adopt the STS and NPPs that 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 the STS in developing their plant-specific TSs, including a standard approach to surveillance requirements, actions, and completion times.

3. The 10 CFR 50.90 process for approving a change to an NPP's TSs, is the same regardless of whether the NPP has adopted improved TSs. 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 Web site at http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0090.html

Question Number: 19.03

Question: *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?*

Response: In the past, the NRC exclusively used the "deterministic" risk approach to evaluate technical specifications (TSs). This approach is based on defense-in-depth requirements and engineering judgment. In recent years, the NRC has adopted a probabilistic risk approach, including 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) ("Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," (60 FR 42622), August 16, 1995), encourages greater use of PRA techniques to improve safety decisionmaking and increase regulatory efficiency. More information on this policy is found on the NRC Web site at http://www.nrc.gov/reading-rm/doccollections/commission/policy/60fr42622.pdf.

Question Number: 19.04

Question: *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?

Response: During the first 2 to 3 years, the PIs worked as designed. However, we have learned from past experience with PIs that their effectiveness decreases over time . This occurs for several reasons. Licensees (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) find arguments not to count an event. At present, an increasing number of issues falls 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 continually 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.

Question Number: 19.05

Question: *Could the United States of America indicate if risk-informed decisionmaking has led, up to now, to restrictive changes in operational technical specifications? If any, could the USA provide some examples?*

Response: In using the risk-informed approach to improving current regulations for technical specifications (TSs), 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, licensees have established TS-allowed outage times that consider only the specific TS system 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 rely on the requirements in licensee Maintenance Rule programs. Information on 10 CFR 50.65 can be found on the NRC Web site at http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0065.html.

Question Number: 19.06

Question: *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?*

Response: The criteria and reporting schedule are specified in Title 10 of the Code of Federal Regulations, Sections 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 No. ML003762595 or http://www.nrc.gov/reading-rm/doccollections/nuregs/staff/sr1022/r2/sr1022r2.pdf).

The required timing for Emergency Notification System (ENS) reporting is specified 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 the event's 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.

Question Number: 19.07

Question: *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.*

What is the basic reason why the public hearing is conducted by the Atomic Safety and Licensing Board member, not by NRC staff?

Response: Public hearings are typically held to resolve contested NRC staff licensing decisions. The Atomic Safety and Licensing Board is independent of the staff and thus can fairly hear and decide such disputes.

Question Number: 19.08

Question: *NRC encourages licensees to use the improved standard technical specifications as the basis for plant-specific technical specifications. 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.*

Response: The benefits of using the improved TSs include: (1) ease of understanding and interpretation by an NPP's operators, licensing and engineering staff, and management, and by the NRC staff; (2) reduction in regulatory burden because of less need for TS interpretations and relief, 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).

Question Number: 19.09

Question: *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.*

Please explain the reason, background and justification for revisions of 10CFR50.72 and 10CFR50.73 in 1992 and 2000.

Response: 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) to make changes consistent with NRC actions to improve integrated plant assessments. Additional information is provided in a *Federal Register* Notice dated October, 25 2000 (65 FR 63786). 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.

Question Number: 19.10

Question: *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.*

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?

Response: The Reactor Operating Experience Task Force evaluated all items in the NRC operating experience program. This task force no longer exists, but various groups of NRC staff are permanently assigned to implementing the operating experience program.

Question Number: 19.11

Question: *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.*

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.

Response: 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 the items. Occasionally, the group reviews NPP events that involve 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. The following information notices (INs) have been issued to address human factors events. (All generic communications are available on the NRC Web site 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 to the core spray isolation logic. The electricians believed that removing these fuses would provide the nearest local blocking-point protection needed while they performed the modification. However, the fuses that were removed were considerably "upstream" of the local blocking point, and this improper action had several unexpected consequences.

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 high-high intermediate range scram signal when the operator withdrew rods to increase reactor pressure without recognizing the need to follow the normal procedures for reestablishing 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.

Question Number: 19.12

Question: *(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?*

Response: The operating experience clearinghouse performs the gathering, screening, and communication functions described in Sections 19.7 and 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession No. ML033350063). The clearinghouse began operating on January 1, 2005.

Question Number: 19.13

Question: *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 onsite repositories for long-term SNF storage?
4. Do they practice SNF shipments away from the site?

Response: 1. NRC considers spent fuel to be outside the scope of the Convention on Nuclear Safety. It plans to include spent fuel issues at nuclear plants in the 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.

Question Number: 19.14

Question: *The report is very comprehensive. All the activities of the article are regulated or coded. The report could elaborate more on the responsibility of the licensee in terms of the OE process.*

Response: In the United States, licensee responsibility in the operating experience process includes (1) reporting of events, use of corrective action programs, and review of operating experience , (2) support of NRC inspection activities, (3) communication of operating experience to industry and the public, 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 stated: "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 ."

Question Number: 19.15

Question: *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.*

Response: No response required.

Question Number: 19.16

Question: *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?

Response: Risk-informed improvements to technical specifications rely 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.

Question Number: 19.17

Question: *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.*

Response: No response required.

Question Number: 19.18

Question: *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.*

Response: No response required.

Question Number: 19.19

Question: *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?*

Response: 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-encumbering selected positions (i.e., filling a position for a designated length of time with two people to allow for knowledge transfer)
- Utilizing entry-level and mid-level technical development programs for succession planning
- Offering recruitment and retention bonus incentives for specialists
- Utilizing senior-level and mid-level executive leadership development programs for succession planning in leadership positions
- Establishing Web-based information forums for knowledge transfer
- Providing internal and external training opportunities to develop critical skills
- Updating the standard review plan for technical guidance
- Reemploying annuitants (i.e., recent retirees) for knowledge transfer

Question Number: 19.20

Question: *Good Practice: Regulations are in place requiring timely reporting of safety significant incidents to the regulator.*

Response: No response required.

Question Number: 19.21

Question: *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.

Response: 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 stated: "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." (Section 5 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession No. ML033350063).

Question Number: 19.22

Question: *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?*

Response: Per Article 19.8, the NRC regulatory scheme contains provisions to minimize 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 19 viii refers to the minimization of waste, not minimization of concentration. If a waste material is minimized, the unit concentration often 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.

Question Number: 19.23

Question: *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"?*

Response: 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 the records can be used for the historical site assessment at the time of decommissioning (see 10CFR 50.75(g)).

Section 50.75(g)(4)(iii), "Recordkeeping," refers to 10 CFR 50.83, "Partial Site Release." Section 50.75(g)(4)(i) requires the licensee to keep records of property transfers into and out of the originally licensed site area.

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 of keeping records of property released for unrestricted use before the plant is decommissioned is to assure that all radioactive material is accounted for in demonstrating compliance with the radiological criteria for license termination.

Note that transfers for restricted use are not allowed under 10 CFR 50.83, the partial site release provision. Partial site release 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.

Question Number: 19.24

Question: *Are there formalised requirements for the simulator-based training programme and criteria for admission of personnel to independent or supervised work?*

Response: 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 supervising workers or letting them work independently (without supervision). However, as required and necessary during implementation of the reactor oversight process, the NRC will evaluate the licensee's program for determining whether workers can work independently.

Question Number: 19.25

Question: *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?*

Response: Many scenarios that can jeopardize and/or terminate recirculation operation of these systems. Most of these scenarios are addressed by design provisions. For example, 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 whip 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 by debris in the fluid.

The United States has an open generic safety issue (GSI-191) to reexamine some of the previous design provisions for assuring recirculation sump performance. The principal scenarios being revisited are 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 at http://www.nrc.gov/reactors/operating/ops-experience/pwr-sumpperformance.html.

Question Number: 19.26

Question: *Could more detailed information be obtained on procedures and regulations for extension of the reactor lifetime and licence renewal?*

Response: Current, detailed information on the U.S. license renewal process and license renewal applications is available on the NRC Web site. The Fact Sheet on Reactor License Renewal at http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/licenserenewal.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.

Question Number: 19.27

Question: *What U.S. authority determines the need to close access to information related to physical protection of nuclear installations?*

Response: 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 withheld from the public.

Question Number: 19.28

Question: *Could more detailed information be obtained on the specificity of the combined licence, in particular, its special terms and granting procedure?*

Response: 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 the license conditions, such as the technical specifications, are also similar.

Question Number: 19.29

Question: *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?*

Response: Since deregulation, the grid has been 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 the 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 loss of offsite power (LOOP) frequencies during critical operation have decreased significantly in recent years, while LOOP durations have increased. Studies also indicate that the reliability of onsite power sources has improved. Overall, the studies show a decrease in the risk of core damage from a LOOP.

Question Number: 19.30

Question: *Is there interrelation or impact of the reactor operating experience on the existing energy market?*

Response: Reactor operating experience has several impacts on existing energy markets.

- 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 (currently one of the least expensive sources of electric power on a cost per kilowatt basis in U.S. markets), the greater the price competition in energy markets and the lower the average costs and prices in those markets.
- 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.

Question Number: 19.31

Question: *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?*

Response: There is no need to revise the SAR for 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.

Question Number: 19.32

Question: *Could more detailed information be obtained on the integrated approach implemented for qualification of foreign-manufacture equipment?*

Response: The NRC staff does not differentiate between the qualification of domestic or foreign suppliers to U.S. licensees and thus does not have an integrated approach for qualifying foreign manufactured equipment. Licensees, through the Nuclear Procurement Issues Committee (NUPIC), perform audits of domestic and foreign suppliers, as necessary, to qualify suppliers of parts and equipment to the QA requirements of Appendix B to 10 CFR Part 50.

APPENDIX A: ACKNOWLEDGMENTS

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APPENDIX B: LIST OF ACRONYMS

AARM	Agency Action Review Meeting
ACR	Advanced CANDU Reactor
ADAMS	Agencywide Documents Access and Management System
AEA	U.S. Atomic Energy Act
ALARA	as low as reasonably achievable
AOT	allowed outage time
ASME	American Society of Mechanical Engineers
ASP	Accident Sequence Precursor program
BWR	boiling water reactor
CFR	*Code of Federal Regulations*
CLB	current licensing basis
CNS	Convention on Nuclear Safety
CP	construction permit
CRDM	control rod drive mechanism
CY	calendar year
DBLLTF	Davis-Besse Lessons Learned Task Force
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
EDG	emergency diesel generator
EDO	Executive Director of Operations
EIE	Electronic Information Exchange
EIS	environmental impact statement
EJ	environmental justice
ENS	Emergency Notification System
EPA	U.S. Environmental Protection Agency
EPR	European Pressurized Reactor
EPRI	Electric Power Research Institute
EPU	extended power uprate
EPZ	emergency planning zone
ER	environmental report
ESBWR	New Simplified Boiling Water Reactor
ESP	early site permit
ESW	essential service water
ETE	evacuation time estimates
FEMA	U.S. Federal Emergency Management Agency
FR	*Federal Register*
FY	fiscal year
FSAR	final safety analysis report
GALL	Generic Aging Lessons Learned
GDC	general design criterion
GSI	generic safety issue
HERA	Human Event Repository and Analyses
HRA	human reliability analysis
IAEA	International Atomic Energy Agency
ICCDP	incremental conditional core damage probability
ICLERP	incremental conditional large early release probability
ICRP	International Commission on Radiological Protection

IEC	International Electrotechnical Commission
IIT	Incident Investigation Team
IMC	Inspection Manual Chapter (also MC)
IN	information notice
INES	International Nuclear Event Scale
INPO	Institute of Nuclear Power Operations
INSAG	International Nuclear Safety Advisory Group
IP	inspection procedure
IPE	individual plant examination
IPZ	ingestion exposure pathway zone
IRIS	International Reactor Innovative and Secure
IRRT	International Regulatory Review Teams
ISO	International Standards Organization
ITP	Industry Trends Program
LCO	limiting conditions for operation
LER	licensee event report
LHGR	linear heat generation rate
LOCA	loss-of-coolant accident
LOOP	loss of offsite power
LPZ	low-population zone
LR	license renewal
NEI	Nuclear Energy Institute
NEPA	National Environmental Policy Act
NERC	North American Electric Reliability Council
NRC	U.S. Nuclear Regulatory Commission
NPP	nuclear power plant
NRR	Office of Nuclear Reactor Regulation
NUPIC	Nuclear Procurement Issues Committee
OCAA	Office of Commission Appellate Adjudication
OE	operating experience
OECD	Organization for Economic Co-operation and Development
OGC	Office of the General Counsel
OL	operating license
OMB	U.S. Office of Management and Budget
OSART	Operational Safety Review Teams
OSHA	U.S. Occupational Safety and Health Administration
PAG	protective action guide
PBMR	Pebble Bed Modular Reactor
PBPM	Planning, Budgeting, and Performance Management
PI	performance indicator
PI&R	problem identification and resolution
PPE	plant parameter envelope
PRA	probabilistic risk assessment
PSA	probabilistic safety analysis
PSR	periodic safety review
PTS	pressurized thermal shock
PWR	pressurized-water reactor
QA	quality assurance
RADS	reliability and availability database

RAI	request for additional information
RES	Office of Nuclear Regulatory Research
RG	regulatory guide
RIS	regulatory information summary
ROP	Reactor Oversight Process
RPV	reactor pressure vessel
RS	review standard
SAMA	severe accident mitigation alternative
SAMDA	severe accident mitigation design alternative
SAMG	severe accident management guidelines
SCWE	safety-conscious work environment
SDP	significance determination process
SER	safety evaluation report
SPAR	Standard Plant Analysis Risk
SRM	staff requirement memorandum
SRP	standard review plan
STA	shift technical advisor
STS	Standard Technical Specifications
TI	temporary instruction
TS	technical specifications
TSTF	Technical Specifications Task Force
TVA	Tennessee Valley Authority
USC	*United States Code*
VHP	vessel head penetration
WANO	World Association of Nuclear Operators
WOG	Westinghouse Owners Group

NRC FORM 335 (9-2004) NRCMD 3.7 U.S. NUCLEAR REGULATORY COMMISSION **BIBLIOGRAPHIC DATA SHEET** *(See instructions on the reverse)*	1. REPORT NUMBER (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.) NUREG-1650 Addendum 2
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Same as Item 8, above

10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

This report documents the U.S. Nuclear Regulatory Commission's answers to questions raised by contracting parties to the Convention on Nuclear Safety in their peer reviews of the U.S. Third National Report for the Convention on Nuclear Safety (NUREG-1650, Rev. 1). Contracting parties have two obligations - submit a national report for peer review and review the national reports of other contracting parties. The U.S. Third National Report was submitted for peer review in September 2004 for the third review meeting of the Convention, which was held at the International Atomic Energy Agency in Vienna, Austria in April 2005. Specifically, the questions and answers resulting from the peer reviews concern the safety of existing nuclear installations, the legislative and regulatory framework, the regulatory body, responsibility of the licensee, priority to safety, financial and human resources, human factors, quality assurance, assessment and verification of safety, radiation protection, emergency preparedness, siting, design, construction, and operation.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*	13. AVAILABILITY STATEMENT unlimited
Convention on Nuclear Safety (CNS) nuclear safety, plants, installations legislation, regulation, licensing, license renewal, enforcement probabilistic risk analysis, performance-based, risk-informed quality, siting, design, construction, operations radiation protection, emergency preparedness financial, human resources, human factors periodic safety reviews, safety culture, international agreements reactor oversight process, assessments deregulation, new reactors	14. SECURITY CLASSIFICATION *(This Page)* unclassified *(This Report)* unclassified
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