

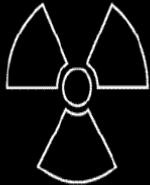
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**Answers to Questions From the  
Peer Review by Contracting Parties  
On the United States of America  
Fourth National Report for the  
Convention on Nuclear Safety**

**April 2008**

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

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**ANSWERS TO QUESTIONS  
FROM THE PEER REVIEW BY CONTRACTING PARTIES  
ON THE  
UNITED STATES OF AMERICA  
FOURTH NATIONAL REPORT FOR THE  
CONVENTION ON NUCLEAR SAFETY**



**APRIL 2008**

**U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON DC 20555-0001**

## **ABSTRACT**

This report documents the U.S. Nuclear Regulatory Commission's answers to questions raised by contracting parties during their peer reviews of the Fourth U.S. National Report for the Convention on Nuclear Safety (NUREG-1650, Rev. 2). 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 2007 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 2008. 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.

# TABLE OF CONTENTS

Executive Summary	1
Introduction	2
Introduction to U.S. National Report	4
Article 6. Existing Nuclear Installations	16
Article 7. Legislative and Regulatory Framework	34
Article 8. Regulatory Body	38
Article 9. Responsibility of the License Holder	50
Article 10. Priority to Safety	54
Article 11. Financial and Human Resources	68
Article 12. Human Factors	77
Article 13. Quality Assurance	86
Article 14. Assessment and Verification of Safety	91
Article 15. Radiation Protection	109
Article 16. Emergency Preparedness	117
Article 17. Siting	126
Article 18. Design and Construction	131
Article 19. Operation	138
Appendix A: Acknowledgements	153
Appendix B: List of Acronyms	154

## **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.2). 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 2007 to the fourth 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 2008. (The U.S. National Report is also posted on the NRC's website at <http://www.nrc.gov>.)

Upon receiving questions from contracting parties, the NRC staff categorized them according to the article of the U.S. National Report that addressed the relevant material. 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 are organized within each article 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 also has two appendices. Appendix A identifies contributors, and Appendix B identifies and defines the acronyms used.

# INTRODUCTION

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. 2). 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 2007 to the fourth 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 2008. (The U.S. National Report is also posted on the NRC's website at <http://www.nrc.gov>.)

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This report also has two appendices. Appendix A identifies contributors, and Appendix B identifies and 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 and the ability to view document images, download files, and print locally. To access ADAMS, users must download utility software from the NRC web site 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 (PDR). One may contact the PDR 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 2005. 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:** I-1

**Question/Comment:** The U.S. is commended on including as Part 3 of the U.S. 4th National Report a contribution from Institute of Nuclear Power Operations (INPO) to explain how the nuclear industry maintains and improves nuclear safety.

**Response:** Your comment is appreciated.

**Question Number:** I-2

**Question/Comment:** Good Practice – It was effective to include a table summarizing changes to the U.S. 4th National Report as compared to its 3rd report. It helped the reader to focus on issues of interest or on updates specific to certain topics.

**Response:** Thank you for your comment.

**Question Number:** I-3

**Question/Comment:** Please give more information about Wolf Creek pressurize dissimilar metal butt weld cracking event. Are there any regulatory requirements for the other similar nuclear power plants from NRC?

**Response:** In the U.S., we are relying on the industry initiative, MRP-139, as a short term (2-3 years) approach to managing primary water stress corrosion cracking (PWSCC) in dissimilar metal butt welds. This initiative involves an inspection and mitigation strategy, prioritized on the basis of temperature and size of welds. The title of MRP-139 is “Materials Reliability Program: Primary System Piping Butt Weld Inspection and Evaluation Guidelines,” and it is available on the NRC Agencywide Documents Access and Management System (ADAMS) under Accession Number ML060170529. Please refer to Section 1.2 on baseline examinations and Chapter 6 to see how welds are categorized for inspection based on the mitigation strategy for any given weld. The non-proprietary version which is the only version that is publicly available does not provide the inspection frequencies but there are similarities between MRP-139 inspection frequencies and Section 5 of NUREG-0313 (ADAMS Accession Number ML031470422) written by the NRC staff to address boiling water reactor intergranular stress corrosion cracking problems in the 1980s. The NRC staff has developed a Temporary Instruction (TI)

which is an inspection procedure that the NRC Regional offices will use to verify implementation of MRP-139 by licensees. TI 2515-172 was issued on February 21, 2008 (ADAMS Accession No. ML073330037).

The NRC staff is also working on a long term approach to address PWSCC through the American Society of Mechanical Engineers (ASME) Code. In late 2005 the NRC staff requested ASME to develop inspection requirements. ASME is developing Code Case N-770 and it is receiving good support from industry participants at the ASME Code meetings. NRC staff is participating in the development of the Code Case. We expect completion of the Code Case in 2008 and incorporation of the Code Case in Title 10 of the Code of Federal Regulations, Part 50, Section 55a by 2010.

**Question Number:** I-4

**Question/Comment:** Do the potential adverse flow effects discovered in Dresden NPP ask the NRC to review the new certified reactor designs (for example AP1000) again?

**Response:** Potential adverse flow effects are part of design certification reviews. Specifically, the AP1000 design certification includes requirement for preoperational vibration assessment measurement testing for flow-induced vibration of reactor internals and for piping and supports. In addition, in the review of the combined licenses referencing the AP1000, the NRC is giving attention to implementation of this program and how it accounts for the more recent experience.

As with other operating experience information, NRC reviews how it may be applicable to specific facilities and designs, and makes decisions as to whether additional review of a design or additional requirements may be necessary.

**Question Number:** I-5

**Question/Comment:** The USA has provided a comprehensive and informative report. The introduction includes important topics mentioned at the Third Review Meeting and the corresponding measures taken by the USA. [Contracting Party] considers this to be good practice.

**Response:** Your comment is appreciated.

**Question Number:** I-6

**Question/Comment:** "On November 22, 2004, the NRC amended 10 CFR Part 50 to provide an alternative approach for establishing the requirements for treatment of SSCs for nuclear power reactors using a risk-informed method of categorizing SSCs according to their safety significance. The 10 CFR 50.69 rule revises requirements with respect to "special treatment," that is, those requirements that provide increased assurance (beyond normal industrial practices) that SSCs perform their design-basis functions. This amendment permits licensees and applicants for licenses to remove

SSCs of low safety significance from the scope of certain identified special treatment requirements and revises requirements for SSCs of greater safety significance.”

What are the U.S. NRC experiences with respect to the Risk-Informed Categorization and Treatment of SSCs for Nuclear Power Reactors? How the 10 CFR Part 50.69, as a new amendment was accepted by the nuclear industry? How many US nuclear power plants (NPPs) follow this new alternative approach? How this alternative approach contributes to better focus on the priority to safety (see Part 2 Article 10., 10.1 Background)?

**Response:** No plant has yet applied for a license amendment to adopt the new regulation using its current implementation guidance. The NRC is currently considering an industry proposal for an alternative method for categorizing components based on the safety significance of the pressure boundary (i.e. passive) functions they perform. This alternative methodology will provide greater flexibility for those plants which may wish to implement 10 CFR 50.69. The industry is planning pilot applications of 50.69 when the methodology for categorization of the passive functions has been finalized.

The NRC expects that adoption of 10 CFR 50.69 will provide better focus on safety-significant components by applying risk insights available from a plant-specific analysis, rather than treating all components as equally significant from a safety perspective.

**Question Number:** I-7

**Question/Comment:** The observation of material degradation in several reactors has led to increased quantum of in service inspection. What is the increase in the inservice inspections to be conducted by the licensees? Excessive inspections burden has the potential to adversely affect the quality of inspections. How this is guarded against.

**Response:** Pages 15 through 19 address reactor materials degradation issues concerning the following; Wolf Creek Pressurizer Dissimilar Metal Butt Weld Cracking, Duane Arnold Jet Pump Riser Safe End Cracking Event, Unanticipated Equipment Problems from Power Uprates, PWR Post-LOCA Chemical Formation, Davis-Besse Nuclear Power Station Reactor Vessel Head, and South Texas Instrumentation Penetrations. The changes to inservice inspections performed by licensees to address these issues are within the following documents which are publicly available through ADAMS; Materials Reliability Program: Primary System Piping Butt Weld Inspection and Evaluation Guideline (MRP-139) (ADAMS No. ML052150196), First Revised NRC Order EA-03-009 dated February 20, 2004 (ADAMS No. ML040220181), and NRC Bulletin 2003-02: Leakage from Reactor Pressure Vessel Lower Head penetrations and Reactor Coolant Pressure Boundary Integrity dated August 21, 2003 (ADAMS No. ML032320153). In addition for the Wolf Creek Pressurizer Dissimilar Metal Butt Weld Cracking issue, individualized Confirmatory Action Letters (CAL) were issued to licensees which increased their inservice

inspection requirements. The CALs were individually tailored for each plant's specific plant configuration. A listing of the CALs can be found at the following public web address;

<http://www.nrc.gov/reactors/operating/ops-experience/pressure-boundary-integrity/weld-issues/cal.pdf>.

Additional information can be obtained for all of these items at the following publicly available web addresses:

<http://www.nrc.gov/reactors/operating/ops-experience/pressure-boundary-integrity.html>

<http://www.nrc.gov/reactors/operating/ops-experience/pwr-sump-performance.html>.

Inspection burden is considered when performing backfit analysis. NUREG-1409, Backfitting Guidelines (ADAMS No. ML032230247), is a good resource regarding backfit analysis. NRC expects no decrease in quality due to the quality assurance requirements for the personnel and procedures utilized to perform the inspections.

**Question Number:** I-8

**Question/Comment:** It is said in your report "a joint NRC/ industry integrated chemical effects testing programme was started and concluded." How did you ensure the separation from industry?

**Response:** This joint research program was conducted under a memorandum of understanding (MOU) between the NRC and the Electric Power Research Institute (EPRI), who was the nuclear industry representative. Terms were included in MOU to ensure that the NRC retains sufficient independence from the industry in the use and interpretation of results from this program. Specifically, the MOU stipulated that NRC and EPRI would jointly produce data for this program, but would not reach conclusions as to the application of this data to regulation. Conclusions as to the application of the data to regulation were performed independently by the NRC and industry.

**Question Number:** I-9

**Question/Comment:** It is important that licensees go beyond compliance with regulations in terms of licensee's primary responsibility. Please show typical examples where licensees go beyond compliance.

**Response:** Recognizing the unique aspects of nuclear plant operation and the consequences of a core-damaging or other significant event, nuclear plant managers strive to identify and adopt best industry practices to improve plant safety and reliability and reduce the potential for such events. Through INPO, the U.S. nuclear industry establishes performance objectives and goals that are intended to push performance beyond that required by regulation, thus improving performance and increasing

margins to regulatory compliance. For example, there are established regulations that clearly prescribe when safety-significant events are required to be submitted to the NRC. The industry has established additional detailed guidance on reporting operating events at a much lower threshold to INPO for the purpose of sharing precursor-type events. The result is that while many stations are only required to submit a few event reports to the NRC each year, on average each U.S. nuclear station reports over 30 events to INPO. This greatly increases the amount of sharing among the industry. Another example is in the area of fuel performance. The U.S. industry has adopted an aggressive goal of every plant operating with zero fuel defects by 2010. While current fuel performance at each station is well within technical specifications, safety analyses, and regulatory requirements, the U.S. industry is combining efforts with INPO, EPRI, the fuel vendors, and the international community to meet the standard of excellence that it has set for itself.

**Question Number:** I-10

**Question/Comment:** Reference section "Risk-Informed Categorization and Treatment of SSCs for Nuclear Power Reactors" Pg. No.22, which regulatory guide has been issued to provide guidance and recommendations for the implementation of 10 CFR part 50.69 rule?

**Response:** Regulatory Guide (RG) 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," Revision 1, was issued in May 2006. This RG provides guidance for the risk-informed categorization aspects of 10 CFR 50.69.

**Question Number:** I-11

**Question/Comment:** The flaws (in pressurizer surge line) could have caused the welds to fail in less than three years. A number of those analyses indicated | that the failure could have occurred without any prior leakage, which would serve as a warning of | impending failure. This is a very important statement. How does it influence acceptability of Leak Before Break approach, especially as applied in EPR where the instantaneous Large Break LOCA has been excluded from the design basis? This question can be answered by NRC since as stated in page 51 "In Stage 1 of the MDEP, the NRC is cooperating with the regulatory authorities in Finland and France on the design reviews of the AREVA EPR." (in chapter 8.1.4 International Responsibilities and Activities)

Since NRC asked the licensee to inspect the pressurizer surge, spray, safety, and relief nozzle welds by December 31, 2007, (page 16) it would be appreciated to learn further NRC conclusions on the subject.

**Response:** The citation in the beginning of Question 13 relates to a scoping fracture mechanics evaluation of indications found by ultrasonic examination of dissimilar metal butt welds in the pressurizer nozzle at Wolf Creek Nuclear Power Plant. These nozzle welds were constructed with Alloy 82/182 which is known to be susceptible to primary water stress corrosion

cracking (PWSCC). The scoping fracture mechanics evaluation was performed in the Fall of 2006.

The NRC Staff position on Leak Before Break (LBB) criteria that is outlined in NUREG-0800 Standard Review Plan Section 3.6.3 continues to be applicable to new applications to utilize LBB in piping systems that contain weld material such as Alloy 52/152, which is more resistant to stress corrosion cracking than previously used alloys.

By a letter dated February 14, 2007, the Nuclear Energy Institute indicated that the Electric Power Research Institute Materials Reliability Program would be undertaking a task to refine the crack growth analyses pertaining to the Wolf Creek pressurizer dissimilar metal butt weld ultrasonic indications. These additional analyses were performed to address the NRC staff's concerns from the scoping evaluation regarding the potential for rupture without prior evidence of leakage from circumferentially oriented PWSCC in pressurizer nozzle welds. The goal of these studies was to demonstrate, through reduction of conservatism and uncertainties in the previous evaluation, that PWSCC in pressurizer dissimilar metal butt welds will progress through-wall and exhibit detectable leakage prior to causing a possible rupture event.

Industry completed these analyses and documented the results in MRP-216, Revision 1, "Advanced FEA [Finite Element Analysis] Evaluation of Growth of Postulated Circumferential PWSCC Flaws in Pressurizer Nozzle Dissimilar Metal Welds: Evaluations Specific to Nine Subject Plants." The NRC staff assessment of this MRP report concluded that there is reasonable assurance that the nine plants addressed by this evaluation can operate safely until their next scheduled refueling outages in the Spring of 2008. The NRC staff safety assessment can be found through the NRC Agencywide Documents Access and Management System under Accession Number ML072400199. This safety assessment provided the basis for the licensees of the nine plants to conduct the inspection of the pressurizer nozzle dissimilar metal butt welds in the Spring of 2008 rather than by December 31, 2007, as previously committed. This study pertained to the narrow issue of whether licensees needed to schedule mid-cycle outages to complete the pressurizer nozzle weld inspections or could continue to operate until their planned Spring 2008 outages to conduct inspections. The concern also arose from a narrow but potentially significant concern that if circumferential PWSCC cracking existed in the pressurizer nozzle welds it could lead to rupture prior to evidence of leakage. The results of the study are not intended to be applied to any broader PWSCC concerns nor imply that it is appropriate to manage potential PWSCC by leakage. The NRC staff's approach to addressing PWSCC in the short term is based on an industry initiative, known as MRP-139, which involves an aggressive inspection and mitigation strategy, prioritized on the basis of temperature and size of welds. The NRC staff is also working on a long term approach to address PWSCC through the American Society of Materials Engineer (ASME) Code. In late 2005 the NRC staff requested ASME to develop inspection

requirements. ASME is developing Code Case N-770 and it is receiving good support from industry participants at the ASME Code meetings.

**Question Number:** I-12

**Question/Comment:** To address concerns about the potential for chemical precipitates and corrosion products to significantly block a fiber bed and increase the head loss across an emergency core cooling system sump screen, a joint NRC/industry Integrated Chemical Effects Testing Program was started in 2004 and concluded in August 2005. (page 17)..... Most of the testing is expected to occur in summer and fall 2007. The staff will consider the test results in the licensees' final strainer designs, and in demonstrations that their strainer designs are adequate.

As the issue is of the high importance both to the designers of PWRs and to nuclear representatives conducting public discussions about NPP safety, it would be highly appreciated if the US delegation could provide further details on the results during the IV CNS meeting.

**Response:** NRC will discuss this issue as part of its presentation.

In addition, we understand the question to refer to research performed to provide a technical basis for resolution of the PWR sump performance issue, as well as to testing undertaken or sponsored by licensees to address the issues on a plant-specific basis.

A compendium of technical information associated with the PWR sump clogging issue can be found on the NRC's PWR Sump Performance web page at:

<http://www.nrc.gov/reactors/operating/ops-experience/pwr-sump-performance/tech-references.html>

Included on this web page are links to the following information:

- Reports which summarize NRC-sponsored research related to PWR sump performance (i.e., NUREG series publications),
- Test reports which contain interim research results, technical reports, and planning information related to past integrated chemical effects testing,
- Trip reports which document NRC's observations of industry-sponsored testing that has been conducted to provide the basis for any needed ECCS modifications, Audit reports which document the NRC's review of selected plant evaluations of sump clogging and planned mitigation strategies, Miscellaneous documents pertaining to PWR sump clogging including industry guidance for evaluating sump clogging, summaries of industry research and staff review, and historical information.

Summaries of public meetings at which industry and NRC-sponsored testing methods and results were discussed can be found at:

<http://www.nrc.gov/reactors/operating/ops-experience/pwr-sump-performance/public-meetings.html>.

In the future, the web site will also include copies of licensee submittals that address the PWR sump performance issue. As reports on results of this testing become available, they will be posted on the sump performance web site.

**Question Number:** I-13

**Question/Comment:** The NRC is considering an approach that, in addition to the ongoing effort to revise some specific regulations to be risk-informed and performance-based, would establish a comprehensive set of risk-informed and performance-based requirements applicable for all nuclear power reactor technologies as an alternative to current requirements.(page 65) On May 4, 2006, the NRC issued an Advanced Notice of Proposed Rulemaking seeking stakeholder input and currently is evaluating that input.

As the risk informed approach has been recently strongly advocated by the NRC and seems to offer significant advantages, it will be appreciated if NRC could provide further information on the evaluation of the proposed rulemaking during the IV CNS meeting.

**Response:**

As a result of the ANPR, in SECY-07-0101, "Staff Recommendations Regarding a Risk-Informed and Performance-Based Revision to 10 CFR Part 50," dated June 14, 2007, the staff recommended that the Commission approve deferring rulemaking for risk-informed and performance-based 10 CFR Part 50 reactor requirements for advanced reactors until after the development of the licensing strategy for the Next Generation Nuclear Plant (NGNP) or receipt of an application for design certification or a license for the Pebble Bed Modular Reactor (PBMR). In addition, the staff would provide the Commission a recommendation on initiating rulemaking 6 months after the licensing strategy for the NGNP is finalized. The basis for the staff recommendation is as follows:

In evaluating stakeholder input in response to the ANPR, in general, all stakeholders were supportive of the plan to develop risk-informed and performance-based requirements for future reactors but indicated that the NRC should not begin rulemaking immediately. Most stakeholders also suggested that before initiating rulemaking, draft requirements using the NUREG-1860 as the technical basis should be developed and made available for discussion and that the draft requirements should be tested against the licensing of a non-light-water reactor (LWR) under 10 CFR Part 50 and Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," as a pilot. Most stakeholders stated that the NRC needs to maintain a high priority on completing the licensing of the next generation of near-term LWRs and review of design certifications.



Almost all stakeholders supported completing current rulemaking efforts to risk inform 10 CFR Part 50. Regarding initiating new rulemakings, many stakeholders indicated that the best candidates for risk-informed rulemaking had already been revised.

The staff agreed with the stakeholders that new rulemakings are not warranted at this time. For LWRs, the staff agreed that the NRC should not undertake new risk-informed and performance-based revisions of 10 CFR Part 50 until specific rules are identified as needed. This approach would allow industry and the NRC to focus resources on maintaining the safety of existing reactors and on the expedient licensing of new reactors to existing requirements. The staff would propose candidate rulemakings after the staff and industry have had time to identify appropriate candidates. For non-LWRs, the staff believes that the results of the development of the licensing strategy for the NGNP and the PBMR pre-application review will help determine how to proceed to rulemaking. The staff believes this approach is appropriate, in part, because rulemaking is not needed for the near-term LWR licensing applications expected in the 2007-2010 time frame.

In its September 19, 2007, staff requirements memorandum to SECY-07-0101, the Commission approved the staff's recommendation to defer rulemaking for risk-informed and performance-based 10 CFR Part 50 reactor requirements for advanced reactors until after the development of the licensing strategy for the NGNP, or receipt of an application for a PBMR design certification or combined license. The Commission also noted that the staff should publish the technology neutral framework and that it should be tested on an actual design indicating that the PBMR design review would be a logical choice to test this approach. The framework, NUREG-1860 ("Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing, Volumes 1 and 2"), has been published.

NUREG-1860 documents one approach to establish the feasibility for development of a risk-informed and performance-based process for the licensing of future nuclear power plants. Criteria are provided for the identification and selection of the licensing basis events and safety classification of structures systems and components, and for the development of an alternative set of risk-informed and performance-based requirements to 10 CFR Part 50. A potential set of example requirements is provided in the NUREG. The report also identifies the programmatic, policy and technical issues that would need to be developed for implementation of such an approach (as documented in NUREG-1860).

**Question Number:** I-14

**Question/Comment:** It is stated that that “the staff did not identify any safety concerns nor compliance issues as a result of its review of GL 2006-02”. Could you please specify if there are any measures that have been taken by the licensees as an outcome of their own review of GL 2006-02?

**Response:** Stronger contractually-binding Transmission Protocol Agreements have been created. The formation of required North American Electric Reliability Council Standards provide assurance that these contracts are two-way agreements (i.e., require notifications between Transmission and Generator Operators).

**Question Number:** I-15

**Question/Comment:** It is stated on page 16 of sub-section Reactor Materials Degradation Issues, that in 2007, through ultrasonic testing of eight Inconel 82/182 welds at Duane Arnold revealed evidence of two flaws in welds between low-alloy steel reactor vessel nozzles and stainless steel jet pump riser pipe safe which are approximately 55–75 percent through wall. Upon reevaluating data from 1999 and 2005 ultrasonic testing examinations, the licensee determined that these flaws had been evident at the time of those examinations, but had not been identified.

Have the analysis of results confirmed the presence of actual stress – corrosion flaws? What was the reason for failure to reveal these flaws by using ultrasonic test from 1999 to 2005? What was the root cause for these stress-corrosion cracks, what kind of corrective measures were taken to provide for a more reliable detection of such flaws and preventing their occurrence in future?

**Response:**

- 1) Although no metallurgical examination of the flaws was performed, multiple, independent evaluations of the ultrasonic testing (UT) data from 2007 have all concluded that the flaws identified at Duane Arnold were due stress corrosion cracking (SCC) based on the characteristics of the UT signal.
- 2) The failure of the 2005 inspection, which was of principle interest to the NRC staff as that was an American Society of Mechanical Engineers Boiler and Pressure Vessel Code (ASME Code), Section XI, Appendix VIII, Supplement 10 examination, was attributed to a mechanical failure of the automated UT system employed for that examination. Specifically, it was concluded that the UT transducer had pulled away from the pipe surface during the inspection of the bottom side of the pipe (i.e., the location of the flaw) such that only intermittent contact was achieved. However, this was not recognized at the time of the 2005 examination. The failure of prior examinations was most closely related to the lack of adequate surface preparation (i.e., the existence of weld crowns) at the locations in question.
- 3) The root cause of these SCC flaws was that this susceptible material (Inconel 82/182) had been in service at Duane Arnold for some period of

time prior to the initiation of protective hydrogen water chemistry control and/or mechanical stress improvement. Improvements in weld surface preparation, greater industry sensitivity to the quality of inspection data, and the general continued implementation of ASME Code, Section XI, Appendix VIII, Supplement 10 qualified examinations are expected to improve the reliability of future examinations.

**Question Number:** I-16

**Question/Comment:** In sub-section devoted to discussion of Unanticipated Equipment Problems from Power Upgrades, it is mentioned, that the higher main steamline flow can create an acoustic resonance which can cause adverse flow effects. In this connection, as indicated on page 17 the NRC has updated relevant sections of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants". Could you, please specify numbers of these sections and provide brief comments on the main idea of revising relevant sections of NUREG-0800?

**Response:** The NRC staff completed the update of Standard Review Plan Sections 3.9.2 and 3.9.5, which provide guidance for review of potential adverse flow effects in current operating nuclear power plants requesting power upgrade, and as part of the review of the design and construction of new nuclear power plants.

The NRC staff has also completed the revision to Regulatory Guide 1.20, Comprehensive Vibration Assessment Program for Reactor Internals During Preoperational and Initial Startup Testing, on vibration assessment programs for reactor internals to address potential adverse flow effects. The staff included helpful information in the Regulatory Guide on the consideration of potential flow effects on other plant systems and components.

**Question Number:** I-17

**Question/Comment:** The safety issue of containment sump performance during LBLOCAs which may result in LP ECCS failure is being solved practically for all modern NPP's units. The decision is connected with implementation of filtration systems with high cleanup factor of coolant from particles and other debris. It provides even catching of small particles from colloidal solution of broken insulation in coolant. However, NRC identified an additional aspect of the issue, i.e. the potential for chemical effects on strainers and downstream components, which has turned out to be particularly challenging:

The issue in conjunction with chemical precipitates in the containment sump, is it specific only to PWR of the U.S. design and weather it is associated, for example, with the reactor plant water chemistry? Would it be possible to get familiarized with research tasks (issues) and results of associated tests?

Are the issues of containment sump clogging addressed in NUREG-0933 "Prioritization of Generic Safety Issues"?

**Response:**

1) Issues regarding chemical effects and their impact on emergency core cooling system (ECCS) performance are plant-specific. These effects and their impact are dependent on reactor water chemistry, plant design, materials in containment, and ECCS design and operation. The use of a containment sump buffer, and the particular buffer chosen, also has been shown to strongly affect the magnitude and nature of chemical reactions that could occur. Absence of a buffer does not eliminate chemical effects, but merely changes the type of effects which occur. Based on information the NRC has obtained about reactors in the United States, as well as discussions with regulatory staffs from other countries, the NRC believes that there is potential for chemical effects at all pressurized water reactors (PWRs), and that such effects should be evaluated. The NRC is currently evaluating whether additional actions are needed to address the potential for chemical effects in suppression pools of boiling water reactors (BWRs).

2) See response to Question I-12.

3) Yes. Generic Safety Issue 191, discussed in NUREG-0933, addresses PWR sump performance in the presence of LOCA-generated debris.

## 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 explains how the United States ensures the safety of nuclear installations in accordance with the obligations in Article 6. This section covers the reactor licensing and major oversight processes in the United States. This section also discusses programs for rulemaking, fire protection regulation, decommissioning, research, and programs for public participation. The NRC posts the major results of assessments on the agency's public Web site at <http://www.nrc.gov>. This update includes expectations about early site permits and design certification applications, current experience, and revised details about programs.

**Question Number:** 6-1

**Question/Comment:** The report notes that the most notable enhancement to the NRC's assessment and inspection programme was in the area of safety culture. We would be grateful for some further information relating to the main features of this safety culture assessment and inspection enhancement.

**Response:** A complete description of the enhancements to the Reactor Oversight Process (ROP) in the area of safety culture is provided in Regulatory Issue Summary 2006-13, "Information on the Changes Made to the Reactor Oversight Process to More Fully Address Safety Culture." The NRC staff is currently performing a lessons learned evaluation of the first 18 months implementation of the ROP safety culture enhancements. Following the completion of the lessons learned evaluation, further enhancements will be made to the ROP in the area of safety culture.

The Regulatory Issue Summary can be found on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200613.pdf>.

**Question Number:** 6-2

**Question/Comment:** The fourth measure presented in the report consists in the use of safety indicators. Implementation of indicators significant for safety is difficult to perform.

Could United States give examples of safety indicators making it possible to find out trends concerning the safety performance of the installations?

**Response:** The Industry Trends Program (ITP) provides a means to assess whether the nuclear industry is maintaining the safety performance of operating reactors, and to identify significant trends in safety performance. Its specific objectives are:

- Collect and monitor industry-wide data that can be used to assess whether the nuclear industry is maintaining the safety performance of operating plants and to provide NRC feedback to its nuclear reactor safety inspection and licensing programs;
- Assess the safety significance and causes of any statistically significant adverse industry trends, determine if the trends represent an actual degradation in overall industry safety performance, and respond appropriately to any safety issues that may be identified;
- Communicate industry-level information to Congress and other stakeholders in an effective and timely manner; and
- Support the NRC's performance goal of ensuring safety while enhancing openness in the agency's regulatory processes.

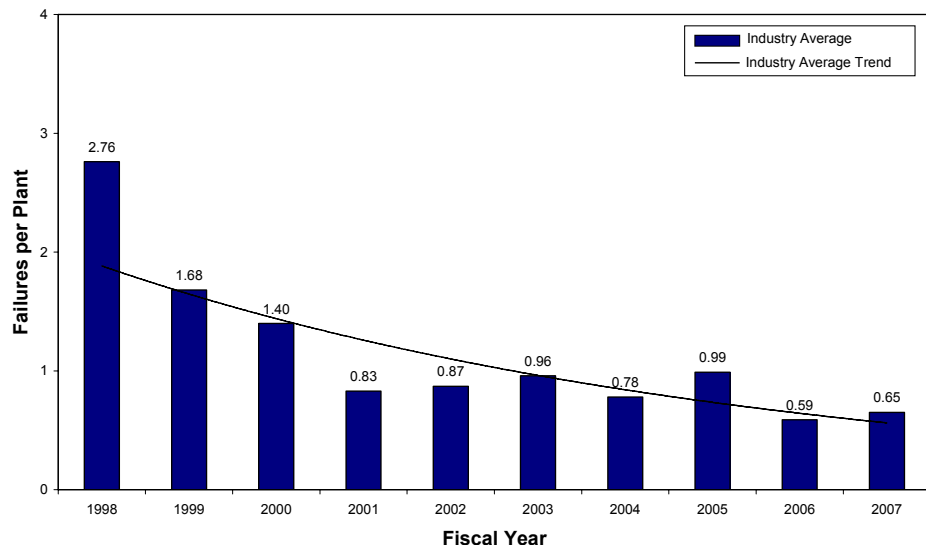
The NRC staff used information currently available from existing NRC programs to develop an initial set of 14 indicators for identifying adverse industry trends in safety performance. The current industry performance indicators are:

- **Automatic Scrams While Critical:** The number of unplanned automatic scrams that occurred while the affected reactor was critical.
- **Safety System Actuations (SSA):** Safety system actuations are manual or automatic actuations of the logic or equipment of either certain Emergency Core Cooling Systems (ECCS) or, in response to an actual low voltage on a vital bus, the Emergency AC Power System.
- **Significant Events:**
  - A Yellow or Red Reactor Oversight Program (ROP) finding or performance indicator
  - An event with a Conditional Core Damage Probability (CCDP) or increase in core damage probability ( $\Delta$ CCDP) of  $1 \times 10^{-5}$  or higher
  - An Abnormal Occurrence as defined by Management Directive 8.1, "Abnormal Occurrence Reporting Procedure"
  - An event rated two or higher on the International Nuclear Event Scale
- **Safety System Failures (SSF):** Safety system failures are any events or conditions that could prevent the fulfillment of the safety function of structures or systems.

- **Forced Outage Rate (FOR):** The number of forced outage hours divided by the sum of unit service hours and forced outage hours.
- **Equipment Forced Outages per 1000 Commercial Critical Hours (EFO):** The number of forced outages caused by equipment failures per 1000 critical hours of commercial reactor operation.
- **Collective Radiation Exposure (CRE):** The total radiation dose accumulated by unit personnel.
- **Accident Sequence Precursors (ASP):** Events with a CCDP or increase in  $\Delta$ CDP that is greater than or equal to  $1 \times 10^{-6}$ .
- **Unplanned Power Changes:** Total unplanned power changes at all plants each year multiplied by 7000 hrs, divided by the total critical hours for all plants each year.
- **Reactor Coolant System (RCS) Specific Activity:** Sum of maximum percentage of Technical Specification RCS specific activity within each year at all plants, divided by the total number of plants with data.
- **Reactor Coolant System Leakage:** Sum of maximum percentage of Technical Specification RCS leakage within each year at all plants, divided by the total number of plants with data.
- **Drill/Exercise Performance:** Total number of classifications at all plants each year multiplied by 100, divided by the total number of classification opportunities at all plants each year.
- **Emergency Response Organization (ERO) Drill Participation:** Total number of key ERO members participating in drills at all plants each year multiplied by 100, divided by the total number of key ERO members at all plants each year.
- **Alert and Notification System Reliability:** Total number of successful alert and notification system tests at all plants each year multiplied by 100, divided by the total number of tests at all plants each year.

An example of the long term-trend data for Safety System Failures obtained in the ITP is shown in the following graph.

**Safety System Failures**



The NRC also developed a new indicator to provide a risk-based index to assess overall industry performance with regard to the frequency of selected initiating events. The Baseline Risk Index for Initiating Events (BRIIE) monitors a number of risk-significant initiating events, assigns an importance measure to each event according to the relative contribution of the event to industry core damage frequency, and calculates an integrated, industry-level, risk-based indicator.

**Question Number:** 6-3

**Question/Comment:** USA indicates that the number of higher risk precursors is significantly decreasing over the period FY 2001-2005. Could USA indicate how many high risk precursors (CCDP higher than  $10^{-4}$ ) were identified during the last three years and give examples?

**Response:** No precursors with a  $CCDP/\Delta CDP \geq 10^{-4}$  have been identified in the past three years. The table below provides a brief description of all the high-risk precursors identified since FY 2001.

Plant	Discovery Date	Precursor Description	$\Delta CDP$	Condition Duration
Oconee 1	12/4/00	RPV head leakage due to PWSCC of five thermocouple nozzles and one CRDM nozzle	$3 \times 10^{-4}$	~1 year
Oconee 3	02/18/01	RPV head leakage due to PWSCC of nine CRDM nozzles	$3 \times 10^{-4}$	~1 year
Oconee 2	04/28/01	RPV head leakage due to PWSCC of four CRDM nozzles	$1 \times 10^{-4}$	~1 year
North Anna 2	11/13/01	RPV head leakage due to PWSCC of one CRDM nozzle	$2 \times 10^{-4}$	~1 year
Point Beach 1 & 2	11/29/01	This condition involved a design deficiency in the air-operated minimum-flow recirculation valves of the AFW pumps which could potentially lead to common-mode failure of the pumps.	$7 \times 10^{-4}$	Original Design Deficiency (~30 years)
Davis Besse	02/27/02	Cracking of CRDM nozzles, RPV head degradation, potential clogging of the emergency sump, and potential degradation of the HPI pumps	$6 \times 10^{-3}$	~1 year
Point Beach 2	10/29/02	This condition involved a design deficiency in the flow-restricting orifices in the recirculation lines of the AFW pumps. Because of this design deficiency, the orifices are vulnerable to debris plugging when the suction supply for the AFW pumps is switched to its safety-related water supply (the service water system). Blocked flow in the recirculation lines of the AFW pumps, combined with inadequacies in plant emergency operating procedures, could potentially lead to pump deadhead conditions and a common-mode, non-recoverable failure of the pumps. The mean $\Delta CDP$ was $6 \times 10^{-5}$ for Unit 1.	$4 \times 10^{-4}$	Re-design Deficiency (~1 year)



**Question Number:** 6-4

**Question/Comment:** United States has performed thorough investigation concerning the sump clogging. In the frame of the Operating experience Program could the United States clarify how the clearinghouse addresses the recent events (e.g. electrical system failure in Sweden, earthquake in Japan)?

**Response:** The Operating Experience (OpE) Clearinghouse meets regularly to review various OpE data inputs and make decisions based on safety significance to determine if further evaluation is warranted. The Clearinghouse reviews, or “screens” new 10 CFR Part 50.72 reactor event notifications, preliminary notifications, 10 CFR Part 21 notifications of defects and non-compliance, plant status information, 10 CFR Part 50.73 licensee event reports (LERs), NRC inspection report findings, and international events. The intent of the OpE program is to determine which issues are potentially safety significant and generic, evaluate those issues, and make recommendations for any further actions the agency should take.

In making a screening decision, the Clearinghouse considers the potential safety significance using a systematic process that applies both quantitative (i.e., risk) and qualitative (i.e., potential generic implications, adverse trends, new phenomena) factors to the decision making process.

After OpE information is “screened in” as safety significant and communicated to various stakeholders, it is then evaluated to clearly determine the extent of its impact on plant operation, safety and generic applicability. The evaluation of OpE information has two objectives. The first is to assess the significance of the issue and to glean important OpE lessons learned. The second is to make recommendations on what further actions, if any, the NRC should take to apply the lessons learned from the issue. Such actions may consist of: (1) communicating OpE lessons learned to various internal and/or external stakeholders through reports, briefings, email listservs or generic communications, (2) taking a regulatory action through a generic communication to require responses from the licensees or issuing orders for actions, and (3) influencing agency programs such as inspection, oversight, licensing, incident response, security, rulemaking, and research. Application of OpE lessons learned always involves communication of the issue to internal stakeholders. Less common outcomes of operating experience issue recommendations are rulemaking or transfer to the agency generic safety issues program.

Recent events such as the electrical system failure in Sweden and the earthquake in Japan were treated the same way as other events. In this case, both of these events were determined to be safety significant, and screened in for further evaluation. The issues were communicated internally to various technical staff, and several staff provided support for the evaluation of the issues. These evaluations led to multiple applications of lessons learned, both internal and external to the NRC and

included two information notices that were issued regarding the event in Sweden.

**Question Number:** 6-5

**Question/Comment:** The report states that NRC has been able to substantiate between 25 % and 30 % of the allegations of the public. Is there any type of follow up given to the remaining 70-75% allegations?

**Response:** The NRC encourages individuals to come forward and identify safety concerns to their employers or to NRC. It is the policy of the NRC to expeditiously determine the validity and safety significance of all allegations concerning NRC-regulated activities and, where appropriate, require corrective action. The NRC reviews and resolves 100% of allegations where sufficient information is available to allow follow-up and communicates its results appropriately with known allegers. The NRC substantiates between 25-30% of the total number of allegations. For the 70-75% of allegations that are NOT substantiated, the NRC will not perform any further follow-up.

**Question Number:** 6-6

**Question/Comment:** “The NRC communicates the results of its oversight process by posting plant-specific inspection findings and performance indicator information on the NRC’s public Web site. The NRC also conducts public meetings with licensees to discuss the results of the NRC’s assessments of licensee performance.”

Are there signs and if yes what are those of how the U.S. NRC Reactor Oversight Process is understandable for the public, and how it contributes to strengthening public acceptance of nuclear energy?

**Response:** As noted in the NRC’s Strategic Plan for Fiscal Years 2008-2013 (NUREG-1614, Vol. 4), one of the NRC’s organizational excellence objectives is to ensure openness in the regulatory process. The NRC staff focuses on stakeholder involvement and continues to improve various aspects of the ROP as a result of feedback and lessons learned. The NRC has issued an annual survey of external stakeholders each year since the ROP was first implemented. Several of the questions in this survey are related to perceptions of whether the ROP is understandable and whether there is ample opportunity for public participation. The results of the annual surveys have been generally favorable for these elements and can be found on the NRC’s external web page at: <http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/program-evaluations.html>.

**Question Number:** 6-7

**Question/Comment:** “The NRC conducts reactor safety research to support its mission of ensuring that its licensees safely design, construct, and operate nuclear reactor facilities. The agency carries out this research programme to identify, evaluate, and resolve safety issues; to ensure that an

independent technical basis exists to review licensee submittals; to evaluate operating experience and results of risk assessments for safety implications; and to support the development and use of risk-informed regulatory approaches. In conducting the Reactor Safety Research Program, the NRC anticipates challenges posed by the introduction of new technologies.”

And Part 2, Article 8, 8.2 Separation of Functions of the Regulatory Body from Those of Bodies - Promoting Nuclear Energy “The NRC was established as an independent authority to regulate the possession and use of nuclear materials as well as the siting, construction, and operation of nuclear facilities.”

How is it ensured that the U.S. NRC Reactor Safety Research Program serves for identification, evaluation and resolving safety issues and not for the promotion of application of nuclear energy for peaceful purposes? Are there requirements in place in relation to the research organizations providing technical support to the U.S. NRC for their independence of the research organizations providing technical support to the nuclear industry?

**Response:**

The Energy Reorganization Act of 1974 specifically assigns the responsibility for development of nuclear energy to an agency other than the NRC. The development and promotion of nuclear energy, and other sources of energy, is a function of the Department of Energy. The Energy Reorganization Act clearly gives the NRC responsibility for licensing and regulatory functions, as opposed to development and promotion. Section 205 of the Energy Reorganization Act establishes the Office of Nuclear Regulatory Research with the charge of recommending and engaging in research necessary for the performance of the Commission’s licensing and related regulatory functions. This mandate to license and regulate without promoting is diligently and carefully adhered to.

There are requirements for independence of the organizations supporting the NRC and the nuclear industry. The Federal Acquisition Regulations and the NRC Acquisition Regulation require that organizations supporting the NRC avoid conflicts of interest. Information about conflicts of interest is provided in 48 CFR 2009.570. A conflict of interest is present when a contractor has interests related to the work to be performed under an NRC contract which:

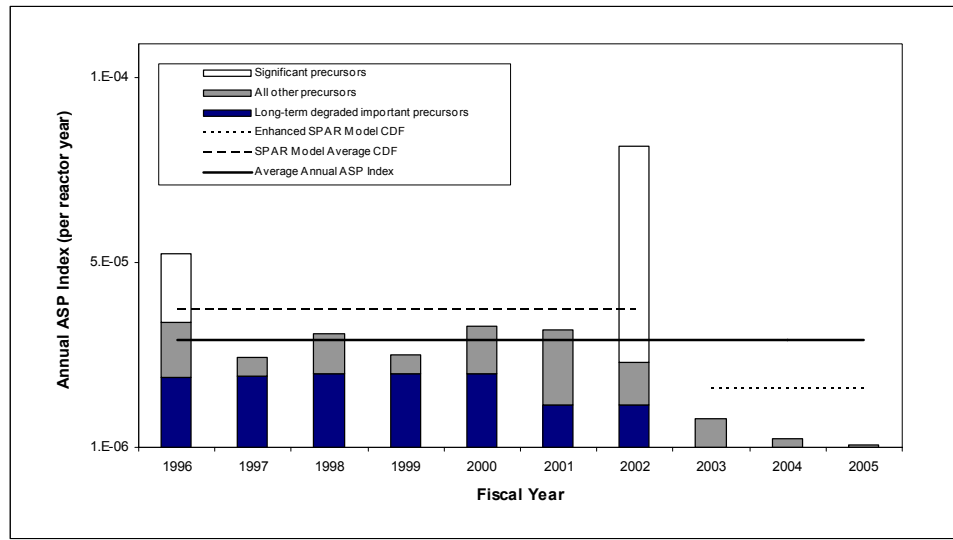
(1) May diminish its capacity to give impartial, technically sound, objective assistance and advice, or may otherwise result in a biased work product; or

(2) May result in its being given an unfair competitive advantage.

**Question Number:** 6-8

**Question/Comment:** It is reported that the risk contribution from precursors was generally constant during 1996–2003 period and has decreased during 2003–2005. Please indicate whether any reasons could be identified for this observed improvement.

**Response:** The integrated ASP index shows the risk contribution of precursors per fiscal year.



The risk contribution due to precursors is dominated by long-term, high-risk precursors ( $CDPs/\Delta CDPs \geq 10^{-4}$ ) and *significant* precursors (events with a  $CDP/\Delta CDP \geq 10^{-3}$ ). Therefore, the main reason for the decrease in risk contribution from precursors during FY 2003–2005 is no long-term, higher-risk precursors or significant *precursors* were identified during this period.

**Question Number:** 6-9

**Question/Comment:** It is mentioned that the agency would conduct research to address technical issues that it anticipates will arise during its review of advanced reactor designs.

Normally, the designers are expected to conduct research, analysis and testing or a combination there of to address the technical issues that are raised during review of the design by the regulators. Why the agency has taken it on itself to conduct such research and how does it “anticipate” the technical issues for advanced reactor design.

**Response:** As stated in the question, the designers must conduct research and analysis to support their design and any associated improved technologies. The NRC conducts research to confirm that the methods and data generated by the industry ensure that adequate safety is maintained. For advanced reactor designs, some technical issues are obvious, such as behavior of materials at high temperatures for gas

reactors. Other issues will not be obvious and may not surface before the design review process. As the advanced reactor designs mature and the application process is initiated, the agency will invest more resources in the identification and evaluation of technical issues for advanced reactors.

**Question Number:** 6-10

**Question/Comment:** It is said INPO conducts Plant Evaluations focusing on plant safety and reliability. On the other hand, the NRC performs ROP (Part 1, p32 ROP). Those give quantitative assessment for licensee's safety activities. Are there any correlations between results of those assessments? If there are any conflicts between those assessments, how are those resolved?

**Response:** INPO uses a different assessment tool than the NRC. INPO's mission is to promote the highest levels of safety and reliability -- to promote excellence -- in the operation of nuclear electric generating plants. In addition, the INPO process is not specifically driven by probabilistic risk; therefore, INPO may view an event that occurs at a plant as a discrete event and factor it broadly into the context of overall performance.

The ROP assessment program evaluates the overall safety performance of operating commercial nuclear reactors and communicates those results to licensee management, members of the public, and other government agencies. Generally, NRC and INPO assessment ratings for a given plant and time period compare well, however, if they differ significantly, the NRC will review the situation.

**Question Number:** 6-11

**Question/Comment:** Related to the implementation of the ROP,

- 1) How many inspectors are involved in the inspection for one unit except resident inspectors?
- 2) How much man power is needed for one unit?
- 3) How many inspection items is an inspector responsible for?
- 4) Do you have a meeting before and after every inspection?

**Response:** 1) With respect to the ROP, the man-hours spent per reactor site are recorded and reported to the Commission, not the number of inspectors. Theoretically, doubling the number of inspectors would complete the inspection in ½ the time, but maintain the same number of man-hours for inspection completion.

Most non-resident reactor inspectors come from one of the NRC regional offices. Each regional office has 70-100 reactor inspectors, and each of those inspectors will visit each reactor site in their region at least once in a three year period.

2) The average number of man-hours per site in Fiscal Year 2007 (October 2006-September 2007) was 6540 man-hours, which is approximately equal to 6 full-time inspectors. A site can have one, two, or three reactors, but the number of reactors is an insignificant factor in the number of man-hours expended per site.

3) Resident and region-based inspectors are assigned and held accountable to complete specified inspection procedures. An inspector must complete all inspection requirements for a minimum number of items i.e., samples, which are identified within the inspection procedure. The actual number of inspection procedures and samples per inspector fluctuates because each inspection procedure contains varying time and sample requirements.

4) An entrance meeting is required for non-resident inspectors to discuss the coming inspection with licensee managers and staff. An exit meeting is required for both Resident and non-resident inspectors to discuss the inspection findings and other relevant issues before the departure of the non-resident inspectors from the site. See Inspection Manual Chapter 2515 Section 12.01 for additional information.

**Question Number:** 6-12

**Question/Comment:** Reference section "New Reactor Licensing" page No.9 of the report, how much time did NRC take to review early site permit applications for the Illinois and Mississippi sites before issuance of early site permits ? Please highlight the safety issues which were encountered during the review process.

**Response:** Exelon Generation Company (EGC) submitted its application for the EGC ESP site (Illinois) on September 25, 2003; the NRC issued the Early Site Permit for the EGC ESP site on March 15, 2007. System Energy Resources, Inc. (SERI) submitted its ESP application for the Grand Gulf site (Mississippi) on October 21, 2003; the NRC issued the Early Site Permit for the Grand Gulf site on April 5, 2007. Therefore, for each of these reviews, the length of time the NRC took to review the early site permit application and issue a permit was approximately 3.5 years.

In general, safety reviews of early site permit applications focus on site characteristics such as seismology, geology, meteorology, and hydrology. The staff also assesses the risks of potential accidents, aspects of emergency planning, whether the site would support adequate physical security measures, and the applicant's quality assurance measures.

One area of our safety review that was unique and specific to the EGC ESP site (Illinois) included an extensive review of a proposed alternative method for estimating the seismic hazard at the proposed site as well as the applicant's assessment of the local seismic hazard. An area of our safety review that was unique and specific to the SERI ESP site (Mississippi) included an extensive review of the applicant's probabilistic evaluation of the possibility that an accidental barge explosion on the Mississippi River could prove to be a hazard to a plant located on the site.

For both ESP reviews, our detailed safety findings may be in NUREG-1844, dated May 2006 (for the Illinois site) and in NUREG-1840, dated April 2006 (for the Mississippi site).

**Question Number:** 6-13

**Question/Comment:** Reference section “Unanticipated Equipment Problems from Power Upgrades” page No. 16 of the report. Does NRC require the plants to install vibration monitoring equipment before permitting power uprate operation in order to address the problem of damage of steam lines components?

**Response:** NRC has not imposed any additional requirements for specifically monitoring piping movements associated with power uprate operation. Start-up testing procedure includes monitoring of steam and feedwater piping movement and vibration. American Society of Mechanical Engineers O&M Standard 3 is the standard used to determine the acceptability of piping vibration movements.

**Question Number:** 6-14

**Question/Comment:** Reference section 6.3.10, what type of analysis is performed by NRC to support its Reactor Safety Research Program and to support review of licensee’s submittals and licensing decision making? What is the scope of the analysis and the tools used?

**Response:** As a result of operating experience, emergent technologies, and advancements in the state-of-the-art, the staff identifies areas for new research that can directly impact the agency’s missions of safety and security. Such research needs are vetted through technical advisory groups and agency management to define the scope with due consideration to the regulatory application, the significance of the safety response being evaluated and the available margin. The Office of Nuclear Regulatory Research (RES) is then charged with developing the data, methods and tools needed by licensing offices. Examples of tools used to audit applicant’s calculations are the TRACE code for thermal-hydraulic response, FRAPCON for fuel behavior, CONTAIN for containment parameters, and MELCOR for beyond design bases analyses. Licensing offices establish the scope of individual confirmatory calculations. On occasions, RES assists licensing offices with analyses that require specialized expertise.

**Question Number:** 6-15

**Question/Comment:** Background:

...evaluates U.S. nuclear power plant | operating experience to identify, document, and rank the operating events that are most likely to | have led to inadequate core cooling and severe core damage (precursors), accounting for the likelihood of additional failures. (page 34)

...The NRC issued Revision 2 to NUREG-1022, "Event | Reporting Guidelines, 10 CFR 50.72 and 50.73," in October 2000, concurrently with the rule changes. (page 137)

Comment:

Several countries, e.g. Spain or Mexico, used US guidance as the basis for their systems of reporting safety related events. It would be of interest to perform a comparison of INES (which is focused on radiological exposures) with the US Accident Sequence Precursor Program and NUREG 1022 Event Reporting Guidelines, and possibly with the recent modifications of reporting system introduced in Spain or Germany, to identify the system which will be best suited to prevent accidents in NPPs.

**Response:** The NRC would like to clarify that the reporting systems mentioned in this question are not meant to prevent accidents in NPPs (as stated in the question). The NRC currently does not have plans to compare reporting systems or to determine which system might be best suited to prevent accidents in NPPs.

**Question Number:** 6-16

**Question/Comment:** In 2005 [Contracting Party] put the following question: 1) "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." In the response it was mentioned inter alia that 2) "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 provides confidence that the U.S. civil nuclear power plants can continue to be operated safely". Could U.S. provide updated information on the experiences in applying risk informed regulatory framework?

**Response:** After license renewal, plant operations are subjected to the same risk-informed regulatory processes and oversight applicable during both the initial (40-year) license period and the extended license period, including 10CFR50.65 (maintenance rule), reactor oversight process, as well as risk-informed license amendment processes.

See the response to question 10-10 for additional information on risk-informed regulation.



**Question Number:** 6-17

**Question/Comment:** In 2005 [Contracting Party] requested info on pressurized thermal shock (PTS). It was mentioned that “the PTS methodology development activities are still under way.” What is the recent situation in the development?

**Response:** NRC has completed its updated study of the PTS phenomena in the current, operating U.S. pressurized water reactor (PWR) fleet. As a result of this work, NRC has concluded that the provisions of the PTS rule, Title 10 of the Code of Federal Regulations 50.61, are more conservative than necessary. Subsequently, NRC has published for public comment a proposed voluntary PTS rule, 10 CFR 50.61a, in the Federal Register in October 2007 (72 FR 56275) as an alternative to the PTS rule.

**Question Number:** 6-18

**Question/Comment:** The NRC has an active fire research program that develops the technical bases for ongoing and future regulatory activities in fire protection and fire risk analysis.

Could you please explain in more detail the NRC fire research program?

**Response:** The NRC RES does have a very active fire research program. Current risk studies indicate that approximately 50% of the risk for core damage accidents from internal events is a result of fire. Approximately five years ago, RES decided to create a group within NRC to address this specialized area of research. This group is currently the Fire Research Branch (FRB) within the larger Division of Risk Analysis (DRA). The FRB is made up of approximately 9 dedicated members with expertise in Fire Protection, Nuclear, Electrical, Mechanical, Industrial and Chemical Engineering along with expertise in the area of physics. Fire Research projects are typically initiated one of two ways; 1) with a “User-Need” letter, or 2) as a RES initiative. The User-Need letter originates in another NRC office and RES is asked to solve a specific problem. An example of this would be the “Verification and Validation of Selected Fire Models for Nuclear Power Plant Applications,” NUREG-1824. In this case, the Office of Nuclear Reactor Regulations (NRR) identified a need for RES to verify and validate fire models for use in the Risk-Informed, Performance-Based Fire Protection Rule, National Fire Protection Association (NFPA) 805 (10CFR50.48c). An example of a RES initiated project would be the Fire PRA work. However, after this project was started, NRR identified the user-need and the project was completed as a user-need request. This process is referred to as anticipatory research, i.e., RES attempts to identify future needs of other NRC Offices and begins the project. The results of the Fire PRA project were reported in NUREG/CR-6850. The FRB also establishes strong professional working relationships with other groups. For example, RES has a Memorandum Of Understanding (MOU) with the Electric Power Research Institute (EPRI) to work on joint technical projects. Both NUREG-1824 and NUREG/CR-6850 were joint projects. The FRB also works with other United States Federal Agencies with similar missions. For example, the National Institute of Standards

and Technology (NIST) collaborated with RES and EPRI on NUREG-1824. The NRC has no testing laboratories and relies on contracting the services of the U.S. National Laboratory System. An example of this is the recently completed Cable Response to Live Fire (CAROLFIRE) program to examine the phenomena of cable hot shorting and subsequent spurious actuation of equipment. This work was performed under contract in the facilities of Sandia National Laboratories (SNL). The FRB currently has fire research projects on-going in the areas of fire model improvement, fire PRA, fire Human Reliability Analysis (HRA), fire testing and fire-electrical system/cable interactions.

**Question Number:** 6-19

**Question/Comment:** Sources of candidate generic issues include safety evaluation, operational events and suggestion from individual staff members, outside organization or members of general public?

How do you evaluate importance of sources of candidate generic issues and how do you estimate their safety relevance?

Could you please give us some suggestion examples coming from individual staff members, outside organization or members of general public?

**Response:** The Generic Issues Program encourages open communication and input from both individual staff members and members of the general public. Those sources that identify new generic issues are treated equally. The safety / risk and regulatory assessments are performed if the proposed issues meet the seven screening criteria presented in SECY-07-0022 (ML063460239). The risk analyses are based on the established methods explained in documents such as the Regulatory Guide 1.177 (ML003740176) and the RASP Handbook Vol. 1 Rev 1.01 (ML080070303), Vol. 2 Rev 1.01 (ML080300179), and Vol. 3 Rev 1 (ML080300182).

A number of candidate issues have been identified by the staff members such as GI-203 (Potential Safety Issues with Cranes that Lift Spent Fuel Casks) and GI-196 (Boral Degradation). Generic issues may also be identified by the members of general public such as GI-201 (Small-Break LOCA and Loss of Offsite Power) that was proposed by NRR following an allegation from a member of general public. More information about each of the individual generic issues can be found in NUREG-0933. (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0933/sec3/>)

**Question Number:** 6-20

**Question/Comment:** NRC reviews LERs, inspection reports etc. for potential candidates for precursor analysis. What percentage of the potentially interesting reports is not possible to model in the PRA, considering the well known limitations of PRA to incorporate other input than technical, i.e. Management, Organizational and Safety Culture (MOSC) factors? How to

assess the risk significance of such operating experience that is not easily, and with decent uncertainties, modeled in a PRA?

**Response:** Although there have been some efforts to explore the impact of Management, Organizational, and Safety Culture factors on risk, there are no consensus methods and current PRAs do not routinely address this impact. Consequently, the ASP Program does not review which candidates for precursor analysis involve Management, Organizational, and Safety Culture factors, and does not address the potential impact of these factors.

**Question Number:** 6-21

**Question/Comment:** This para. describes the analysis results of the Accident Sequence Precursor Program. What are the NRC actions in detecting essential events – precursors or an increasing trend?

**Response:** The Industry Trends Program (ITP) is based on the following general concepts:

Industry trend information is derived from quantitative, industry-wide data.

Trends are identified on the basis of long-term (i.e., four or more years) data, rather than short-term data. This minimizes the impact of short-term variations in data, which may be attributable to such factors as operating cycle phase, seasonal variations, and random fluctuations.

Trends and contributing factors are assessed for safety significance. The results of inspections, analyses of significant events and abnormal occurrences, and other analyses may be used to facilitate an evaluation of the trends. The agency's response is commensurate with the safety significance.

The NRC provides oversight of plant safety performance for individual power plants using both inspection findings and plant-level performance indicators (PIs) as part of its ROP. Individual issues that are identified as having generic safety significance are addressed using a number of NRC processes, including the generic communications process and the generic safety issue process. The NRC staff developed the ITP to complement these processes by monitoring and assessing industry-level trends in safety performance.

If a statistically significant adverse trend in industry safety performance is identified or an indicator exceeds a pre-established prediction limit that may indicate a potential short-term emergent issue, the staff will determine the appropriate response using the processes described above and the NRC's established processes for addressing and communicating generic issues.

In general, the issues will be assigned to the appropriate NRR staff for initial review. As appropriate, NRC senior management will initiate early interaction with the nuclear power industry. Depending on the issue, the

process could include requesting industry groups such as the Nuclear Energy Institute (NEI) or various owners groups to provide utility information. Industry initiatives, such as the formation of specialized working groups to address technical issues, may be used instead of, or to complement, regulatory actions. This can benefit both the NRC and the industry by identifying mutually satisfactory resolution approaches and reducing resource burdens.

Depending on the issues, the NRC may perform generic safety inspections at plants. In addition, the issues underlying the adverse trend may also be addressed as part of the generic safety issue process by the NRC RES. The NRC may consider additional regulatory actions as appropriate, such as issuing generic correspondence to disseminate or gather information, or conducting special inspections for generic issues.

**Question Number:** 6-22

**Question/Comment:** It is identified in sub-section 6.3.1.that industry has indicated that it will be submitting potentially as many as 20 applications for up to 28 reactor licenses during 2007 through 2009. At the same time in Introduction in sub-section New Reactor Licensing it is written, that the industry has expressed interest in constructing new nuclear power plants in the United States and indicated as of June 2007, that it may submit applications for up to 28 new reactor licenses over the next few years.

Question: If the number of applications indicated in item 6.3.6 is correct (not a misprint), would it mean that one application could cover the request for a number of licenses, is it the case?

**Response:** Yes, one application could cover a request for one or more reactor licenses because an applicant may be planning to construct more than more reactor on a site. Currently we are anticipating a total of 22 applications that represent a total of 34 reactor licenses.

**Question Number:** 6-23

**Question/Comment:** In sub-section 6.3.4. it is stated, that NRC considers a significant precursor as an event with a CCDP greater than or equal to  $1 \times 10^{-3}$ .

Questions:

- 1) What codes are used to generate precursors with such CCDP values?
- 2) In case the precursor is taken as "initial event", what would be the data underlying the evaluation of its probability or is it taken as equal to 1 (the event has taken place)?

**Response:** If an automatic or manual reactor trip occurred while the plant was at power, then the event is evaluated according to the likelihood that it and the ensuing plant response could lead to core damage. In this analysis, the frequency of the initiating event will be set to 1.0. The frequencies of all other initiating events are set to zero.

If the degraded condition/equipment failure had no immediate effect on plant operation (i.e., no initiating event occurred), then the analysis considers whether the plant would require the failed items for mitigation of potential core damage sequences should a postulated initiating event occur during the failure period. Nominal initiating event frequencies are used in the analysis. The component(s) that were determined to be degraded or failed during the required mission time are adjusted to reflect the degree in which the component(s) would fail during the required mission time. The probabilities of failed components are set 1.0 and nominal failure probabilities are used for all other components in the analysis. ASP analyses use a maximum unavailability period of one year.

**Question Number:** 6-24

**Question/Comment:** It is written in sub-sections 6.3.6, that NRC has a Program for Resolving Generic Issues. These Generic Issues are established in NUREG-0933 "A Prioritization of Generic Safety Issues." Further, as it follows from sub-sections 6.3.10 NRC conducts reactor safety research to support its mission. At that NRC conducts pre-application reviews for advanced non-light water reactor designs under the safety research program. Office of Nuclear Regulatory Research plans, recommends, and conducts research programs to identify, lead, and sponsor reviews that support the resolution of ongoing and future safety issues (it. 8.1.3.3, p.48).

Questions:

- 1) Is it correct to conclude that the safety related research program is based on unresolved safety issues addressed in NUREG-0933?
- 2) Would it be possible for the U.S. nuclear industry to launch its own nuclear safety research programs different from what is recommended by the Office of Nuclear Regulatory Research?
- 3) It is mandatory to have nuclear industry research program topics agreed with the Office of Nuclear Regulatory Research?
- 4) Is it correct to conclude that it is the NRC that totally defines the NPP safety research policy and from the budget money engages R&D institutions and labs to carry out research?
- 5) It is not clear how the Office of Nuclear Regulatory Research could define "...future safety issues..."?
- 6) Does the research program implemented by the NRC provide in a sufficient and adequate manner for the regulatory body functions or is it needed to make use of additional independent experts from R&D institutions and national laboratories to carry out individual reviews (pertaining to new reactors, in particular)?

**Response:** 1) A portion of the research performed by the NRC is to address issues described in NUREG-0933. A significant portion of the NRC's research is for issues that are not described in NUREG-0933.

2) The U.S. nuclear industry has many nuclear safety research programs that are independent of the research performed by the NRC. The U.S. nuclear industry is free to conduct research as it wishes. Industry research topics do not need to be submitted to the NRC for approval or concurrence.

3) The NRC does not define the nuclear power plant safety research program, either within the government or for the industry. The U.S. Department of Energy conducts nuclear power plant research that is not defined by the NRC. The Department of Energy has a separate budget from the NRC. Some money from the NRC budget is used to conduct research at universities, research institutions and laboratories. Some of the laboratories where NRC conducts research are operated by the Department of Energy.

4) Future safety issues are the issues associated with advanced reactor designs. In anticipation of license applications for advanced non-light water reactors, the NRC is beginning to identify and evaluate technical issues for those future reactors.

5) The NRC is responsible for conducting research as needed to support the regulatory functions of the agency. Frequently, national laboratories and independent experts are hired to perform the research needed by the NRC. In addition to research, independent firms and Department of Energy laboratories are often hired to support the reviews of license applications.

## ARTICLE 7. LEGISLATIVE AND REGULATORY FRAMEWORK

1. Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations.
2. The legislative and regulatory framework shall provide for:
  - (i) the establishment of applicable national safety requirements and regulations
  - (ii) a system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a license
  - (iii) a system of regulatory inspection and assessment of nuclear installations to ascertain compliance with applicable regulations and the terms of licenses
  - (iv) the enforcement of applicable regulations and of the terms of licenses, including suspension, modification, and revocation

This section explains the legislative and regulatory framework governing the U.S. nuclear industry. It discusses the provisions of that framework for establishing national safety requirements and regulations and systems for licensing, inspection, and enforcement. The framework and provisions have not changed since the previous U.S. National Report was issued. This update includes a revised discussion of 10 CFR Part 52.

**Question Number:** 7-1

**Question/Comment:** Under “New Reactor Licensing”, how would the 10 CFR Part 52 licensing process for new builds take into account changes to environmental regulations or reactor designs that could affect the conclusions from previous site approvals?

**Response:** The new reactor licensing process does account for changes to siting or design issues that could affect the conclusions from previous site approvals. Should the COL applicant select a design for which one (or more) plant parameter(s) specified in the ESP is/are not bounding for the previous analyses, then the effects of the outlying parameter(s) would be assessed to determine whether the impacts are significant [solely on those environmental issues affected by the parameter(s)]; the design information is considered new, but it must be evaluated to determine whether it is also significant before it can be reconsidered in the COL proceeding. Likewise, there are site characteristics that may have changed during the intervening period between the ESP approval and its reference in a COL application that may be unrelated to the design. For example, the socioeconomics of a region subsequent to a hurricane Katrina event may be significantly affected adversely; the bases for an earlier conclusion for a project not yet initiated would have to be reconsidered because, in the case of this example, there is evidence of new and significant information. The finality provisions in Part 52 are important elements in ensuring that the new reactor regulatory framework

is stable and predictable, but it also accounts for changes in siting and design issues that do meet the high threshold for reconsideration.

**Question Number:** 7-2

**Question/Comment:** The financial condition of the NRC during 2008 is presented in the sub-section.

What part of the budget is intended for R&D related to safety? Does it envisage the financing of external organizations?

**Response:** Of the total NRC budget, about 8% is directed to safety research. Out of this portion, numerous external organizations are paid to perform research for the NRC. No external organizations are financed in their entirety, they are only paid for the services they render.

**Question Number:** 7-3

**Question/Comment:** Under “Survey of Current Safety Issues”, please explain why the “NRC Information Notice 2007-26: Combustibility of epoxy floor coatings at commercial nuclear power plants” is not mentioned under this section.

**Response:** Under “Survey of Current Safety Issues,” we listed the safety issues that we determined to have the most significance. With regard to epoxy floor coatings, the two plants discussed in Information Notice 2007-26, both determined that the coatings did not present a challenge and would not cause fires to propagate between contiguous fire zones. In addition, the NRC did not identify any violations. Therefore, it was determined that this issue need not be mentioned in our National Report.

**Question Number:** 7-4

**Question/Comment:** Your report says that the NRC has the authority to inspect nuclear power plants in its role of security.

As for the affair, how is it positioned in Atomic Energy Act? Also, how does it have anything to do with construction permit?

**Response:** The NRC’s authority to inspect is established principally by section 161.o of the Atomic Energy Act, which says, in pertinent part, that the NRC may provide for such inspections of licensed activities “as may be necessary to effectuate the purposes of this Act ....” Under the Act, a “construction permit” is one kind of license (see sections 103.a and 185.a), and so construction is a licensed activity that the NRC has statutory authority to inspect.



**Question Number:** 7-5

**Question/Comment:** Please specify the conditions which may warrant suspension of operation of a nuclear power plant or other nuclear facilities. What type of penalties are imposed in case of an accident at a NPP power plant resulting in breach of safety barriers or damage to items important to safety due to deficiencies in the safety culture environment (e.g. inappropriate procedures, operator training and operator error) such as in case of Davis-Besse?

**Response:** The Atomic Energy Act requires the NRC to have reasonable assurance that a licensee is operating a licensed facility safely. Conditions of the licensee such as the requirements of the plant Technical Specifications provide the NRC ongoing assurance that the plant is being operated safely and provide for the licensee to take actions should safety related systems or components become inoperable. If questions about the reasonable assurance in the licensee's ability to operate the plant safely due to conditions beyond those contemplated by the license arise, the NRC has a number of tools at its disposal. If the basis for the NRC's reasonable assurance is called into question, a Demand for Information can be issued to the licensee to provide additional information that can assure the NRC that the plant is being safely operated. If such information cannot be provided or is insufficient, the NRC can upon a finding of loss of reasonable assurance, issue a suspension order or an order to take other actions the NRC deems are necessary. Because license conditions cover most of the likely scenarios in which plant shutdowns or other such actions might be necessary and the each case is highly fact dependent, there is no list of specific conditions under which the NRC would issue a suspension order.

Most significant violations at nuclear power plants result in a greater than Green (White, Yellow or Red) finding under the Reactor Oversight Process (ROP). The NRC staff, with Commission approval, can also issue a civil penalty for particularly significant ROP findings. Violations that result from willful failures, those that result in actual consequences (such as radiation over-exposures or offsite releases of radioactivity), or those that impede the regulatory process (such as the failure to make a required report to the NRC) will be assessed using the Enforcement Policy rather than under the ROP. Whether there will be a civil penalty and if so the size of the penalty depends on a number of factors including the significance of the violation, the licensee's recent enforcement history, whether the violations involved willfulness, the corrective actions taken, how the violation was identified, and the duration of the violation. In the Davis-Besse case, the NRC issued the largest civil penalty it has ever issued based on a number of factors including the significance of the violations, the fact that willfulness was involved, and the duration of the violations.

**Question Number:** 7-6

**Question/Comment:** NRC's enforcement jurisdiction is drawn from the Atomic Energy Act and the Energy Reorganization Act. Can NRC orders be appealed by any stakeholder and in that case how often does this happen?

**Response:** The NRC's orders cannot be appealed by any stakeholder, but rather only by the person against whom the order is issued, or by any other person "adversely affected" by the order. See 10 CFR 2.202. Moreover, someone who wants the agency to require more than the order requires is not "adversely affected" by the order. See *Bellotti v. NRC*, 725 F.2d 1380 (D.C. Cir. 1983). The Appeals are heard by judges drawn from the NRC's Atomic Safety and Licensing Board Panel (ASLBP), and persons against whom the orders are issued, or other adversely affected persons, may seek Commission or federal court review of an unfavorable ASLBP decision. Appeals of enforcement actions are infrequent.

**Question Number:** 7-7

**Question/Comment:** Under the title of enforcement you also describe penalties. Are there a lot of cases, in which penalties are necessary? Could you please present one or two cases?

**Response:** Since the implementation of the Reactor Oversight Process in 2000, the NRC has shifted from the use of civil penalties in most enforcement cases at nuclear power plants. Civil penalties are still applied in cases in which significant violations occur due to willful behavior, involve actual consequences (such as radiation overexposures or offsite releases of radioactivity), or the violations impede the regulatory process (failure to make a required report to the NRC). Whether there will be a civil penalty and, if so, the size of the penalty depends on a number of factors including the significance of the violation, the licensee's recent enforcement history, the corrective actions taken, and how the violation was identified. Civil penalties issued to nuclear power plants normally range from \$65,000 to \$260,000 after considering the above factors. However, in particularly significant cases, rather than assess the violation as a single occurrence, the NRC can assess violations up to \$130,000 per day per violation which in select cases has resulted in civil penalties amounting to \$1,000,000 or more.

The civil penalty assessed to Davis-Besse is discussed in the answer to question no. 41.

## ARTICLE 8. REGULATORY BODY

1. Each Contracting Party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7, and provided with adequate authority, competence, and financial and human resources to fulfill its assigned responsibilities.
2. Each Contracting Party shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy.

This section explains the establishment of the U.S. regulatory body (i.e., the NRC). It also explains how the functions of the NRC are separate from those of bodies responsible for promoting and using nuclear energy (e.g., DOE). This update was reorganized. It reports on the establishment of the NRC's Office of New Reactors and Office of Federal and State Materials and Environmental Management Programs; organizational changes; current activities; budget and workforce planning; and the Integrated Regulatory Review Service (IRRS) assessment.

**Question Number:** 8-1

**Question/Comment:** What is the policy of NRC towards review of Event Investigation Reports and root cause analysis of safety significant events performed by the licensee? Which methodology/tools are used for the purpose?

**Response:** NRC reviews LERs and related documents regarding the accuracy of the LER (e.g., based on independent NRC observations), appropriateness of corrective actions, violations of requirements, and generic issues.

A Significant Operational Event is any radiological, safeguards, or other safety related operational event at an NRC-licensed facility that poses an actual or potential hazard to public health and safety, property, or the environment. A Significant Operational Event may generate an NRC Special Inspection (SI), inspection procedure 93812, or an Augmented Inspection Team (AIT), inspection procedure 93800. Based on the significance of the SI / AIT findings determined by the Significance Determination Process (SDP) process, the NRC will verify the accuracy/completeness of the licensee's root cause analysis by performing additional inspections. These additional inspections, inspection procedures 95001, 95002, and 95003, contain the methods and tools used to evaluate the licensee's root-cause analysis.

**Question Number:** 8-2

**Question/Comment:** To what extent NRC performs audit calculations of safety analysis results presented by the Licensee in the Safety Analysis Report to support review and assessment and the licensing decision making process?

**Response:** The NRC makes a determination of safety based on information provided by the applicant and documents that determination in the Safety Evaluation Report. NRC uses confirmatory calculations to provide added assurance and as a check on the applicants' evaluation. Examples of

areas where the NRC would consider performing confirmatory analysis include: new or unique applications, first-of-a-kind engineering applications, areas where new or emerging methodologies are being applied, or areas that have historically been challenging for the agency or the applicants.

**Question Number:** 8-3

**Question/Comment:** [Contracting Party] appreciates the detail given on the human resources/knowledge management strategy to address the expected influx of reactor applications in the next few years. We are interested in the qualification programme for the office of Nuclear Reactor Regulation, in particular the oral confirmation board. Could the United States please provide some further details on the types of issues raised at typical sessions of the oral confirmation board?

**Response:** The oral confirmation board consists of three members: the board chairman, usually an Office Director or Deputy Director, and two knowledgeable staff members, usually Branch Chiefs or Team Leaders. The board develops questions and topics for the candidate to answer to ensure that the candidate possesses the regulatory knowledge, skills and abilities to perform the functions of the position. The questions include areas from the general qualification program and the position-specific program. The general qualification program provides an overview of NRC staff functions, ethics and responsibilities while the position-specific training provides more detailed technical and/or regulatory knowledge that the position requires. The questions focus on situations that require the employee to demonstrate knowledge of NRC policy and procedure as they relate to the employee expectations, ethics and the regulatory process. Oral boards are typically held for two hours but the time may vary.

**Question Number:** 8-4

**Question/Comment:** Does the regulatory staff in regional offices have opportunity (obligation) of training on simulators?

**Response:** The NRC requires completion of a simulator course for most inspectors. The only inspectors who are not required to obtain any simulator training are health physics, emergency preparedness, and vendor inspectors. All other inspectors are required to take simulator training, usually ten days, as part of initial qualification and a refresher simulator course every three years to maintain technical proficiency.

The simulator course required for initial qualification involves hands-on operation of a full scope control room simulator covering evolutions from plant startup to major accidents. It provides a working knowledge of reactor design and operation with emphasis on integrated plant operations; evaluation of normal and abnormal operating conditions; application of technical specifications to control room conditions; use of plant procedures; effects of equipment malfunction and inappropriate operator actions; and PRA insights. It provides a general understanding

of the Owners Group Emergency Procedure Guidelines (EPGs) and Emergency Operating Procedures (EOPs). Major topics include: EPG and EOP structure and usage; intent of each EPG/EOP; entry conditions and symptoms; monitoring critical plant parameters; operator and plant responses to various plant normal, abnormal, and emergency conditions.

**Question Number:** 8-5

**Question/Comment:** Do you have currently in your regulatory staff, or in a technical support organization (TSO) working for the regulatory body, an adequate number of technical experts (e.g., in the areas of reactor physics, thermo-hydraulics, and materials engineering) who can conduct an in-depth safety assessment of nuclear power plant, as would be needed for evaluation of operating events, large power upgrade, lifetime extension, or new build? Do these experts have tools and ability to conduct independent safety analysis, including both deterministic analysis and PRA? What is the number of such experts in various technical areas within the regulatory body and within the TSO? What is the outlook concerning the number of experts in a few years ahead?

**Response:** In general, the NRC has sufficient technical staff to handle review and evaluation of operating events and plant-specific licensing actions. The staff has sufficient tools and ability to conduct independent safety analysis, including both deterministic and probabilistic risk assessment.

For large reviews such as large power uprates or license renewals, the NRC generally augments its staff with technical experts from the various national laboratories or uses contractors that have staff with the needed skill sets. The NRC has been working diligently on a knowledge transfer program to ensure in-house technical expertise and historical knowledge base is maintained.

To ensure a dedicated staff of reviewers for new reactor applications, the NRC established a new office in October 2006. The office was gradually staffed throughout 2007 and currently has 439 staff and supervisors. By October 2008, the staff level is anticipated to be 479. The technical experts in the new reactor staff represent all areas needed to review new reactor design certifications, early site permits, and combined licenses including: hydrology, seismology, health physics, reactor systems, containment, PRA, fire protection, structural engineering, materials engineering, electrical engineering, and instrumentation and controls. In addition, the office has developed tools and guidance documents to help the staff perform the reviews, including updating the Standard Review Plan and developing processes for performing acceptance reviews and issuing requests for additional information.

**Question Number:** 8-6

**Question/Comment:** What kind of systematic training and development programmes you have for your new regulatory staff members? How do you ensure that they are ready to conduct their duties as regulatory staff members in the tasks assigned to them?

**Response:** The Office of Nuclear Reactor Regulation has implemented a Qualification Plan according to ADM-504 which can be viewed at ADAMS with the Accession No. ML062640556. The qualification plan consists of two parts and includes training courses, study activities and on the job training activities. The first part is the General Qualification Requirements and the second part is the Position-Specific Requirements. Each part has separate requirements and to ensure that employees are ready to conduct their duties at the end of each activity, supervisors review the assignments with the qualifying employees and signs a signature card to document completion. The qualification plan is usually completed within 18-months of assignment to the Office and culminates in an Oral Qualification Board as discussed in the answer to question 44.

The Office of New Reactors has implemented a similar formal qualification program to ensure that the staff possesses the knowledge and skills necessary to effectively perform regulatory activities in their position. The qualification process is also intended to provide staff with sufficient information to regulate in accordance with NRC regulations, policies, and procedures. Achieving qualification allows an individual to be assigned the full scope of job activities to be performed with routine oversight and supervision. The knowledge and skills required for qualification may be obtained through previous experience, formal training, study activities, or on-the-job training activities. At completion of the qualification program the staff member must pass an oral qualification board to confirm that the individual can integrate and apply Agency, Office, and position-specific (e.g., Reactor Technical Reviewer, Project Manager) competencies to actual situations.

**Question Number:** 8-7

**Question/Comment:** In the sub-paragraph devoted to the new Office of Federal and State Materials and Environmental Management Programs, it is stated that, through the Agreement State Program, States have signed agreements with the NRC to assume regulatory responsibility over certain byproduct, source, and small quantities of special nuclear material. Such agreements might lead to some discrepancy in regulations and control between States: how is this addressed?

**Response:** Under Section 274j of the Atomic Energy Act (AEA), NRC periodically reviews Agreement State Programs to determine if the individual State program is adequate to protect public health and safety and compatible with the U.S. NRC's program. The Commission Policy Statement on Adequacy and Compatibility of Agreement State Programs issued in 1997 and additional implementing guidance documents address the degree of differences that are acceptable under such State agreements. Through

the mandated periodically reviews, which includes ongoing reviews of State issued regulations, NRC ensures that a national materials program is implemented which allows individual States to address local conditions and requirements.

**Question Number:** 8-8

**Question/Comment:** In Article 8, twelve high-level recommendations from the IRRS self-assessment in fall 2006 are mentioned. Is it possible to provide details about these recommendations and the review performed might lead to some discrepancy in regulations and control between States: how is this addressed?

**Response:** Approximately 30 additional staff were involved in answering the self-assessment questions and providing input to the self-assessment team. We estimate that 2.5 staff-years of effort were expended to perform the self-assessment including analysis and documentation.

In providing the self-assessment questions to staff for response, the IRRS self-assessment team encouraged staff to go beyond a simple yes or no answer in their response. In addition, the team determined that it was essential that the self-assessment reflect both working-level and first-level management perspectives; therefore, the team encouraged organizations to ensure that responses reflected broad organizational perspectives and discouraged extensive, layered management review.

The self-assessment responses showed that the NRC's regulatory and management processes are generally consistent with international practices as described in the IAEA safety requirements documents. None of the team's recommendations represent significant issues with the NRC's regulatory structure.

The U.S. has invited an IRRS Mission to be performed in 2010 on operating power reactors. As part of its preparation for the IRRS Mission, the staff will reevaluate its corrective actions and each of the self-assessment recommendations. Management evaluations of possible corrective actions are on-going and action may not be taken for each recommendation.

The twelve recommendations are:

1. Understand International Trends Associated with Management Systems, Quality Management Systems, and Management Directives and Apply Appropriately to the NRC.

The NRC does not promptly incorporate current policy and practices into its management directive system. The NRC is working to implement adoption of an electronic directives system including performance goals and measures.

2. Continue to Consider Options to Improve Efficiency while Ensuring Public Involvement.

The NRC provides substantial opportunities for public involvement; however, questions arise as to whether the public processes are too many and too formal. The self-assessment team recommended that NRC accept appropriate litigation risk as the agency pursues improvements in efficiency and effectiveness in its public processes.

### 3. Continue to Improve the Reactor Licensing Action Review Process.

The NRC should consider establishing guidelines for rejecting license amendment applications before substantial NRC resources are expended, and the NRC should consider whether there is an appropriate appeal process for license amendment applications that are rejected. Additionally, the NRC should revisit its 2003 program to improve the quality of safety evaluations and should consider developing a training program for technical staff on the attributes of a quality safety evaluation. Finally, the NRC should consider whether improved coordination between technical review staff and inspection staff could benefit the licensing review process and the inspection program.

### 4. Capture Knowledge during Ongoing Regulatory Guidance Updating Activities and Explicitly Consider International Guidance.

The NRC is updating its review plan and guidance to support its licensing reviews of new reactor applications. The self-assessment team recommends that the philosophy behind the review plan and guidance be captured as part of this effort for knowledge transfer to new and future staff.

### 5. Consistently Apply Meaningful Management Indicators to All Levels of Management.

NRC should continue to ensure that employee position descriptions and performance plans follow agency performance objectives and show clear linkages between employee performance and awards.

### 6. Establish a Culture of Self-Assessment.

Many self-assessment team members did not have significant previous self-assessment experience and viewed the self-assessment as a learning experience. It was recommended that periodic self-assessments be conducted.

### 7. Explore Options to Meet Surges in Workload.

The NRC may need additional resources for reviews of new applications. The U.S. Food and Drug Administration has authority to collect additional fees in certain situations. The NRC should investigate whether similar authority would assist the NRC to prepare for an increase in resources needed to review new licensing applications.



8. Expand Advanced Reactor Capabilities and Facilities.

The NRC has limited expertise in technical areas related to reactor designs using advanced technologies. The self-assessment team recommended that NRC continue to support development of infrastructure for new technologies including support for research institutions.

9. Continue Knowledge Management Initiatives.

The NRC uses reemployed annuitants (retirees) to meet its resource needs. The self-assessment team recommended that NRC ensure reemployed annuitants perform mentoring and knowledge transfer to new staff as part of their duties.

10. Implement Partial Non-Fee-Based Budgeting for Research.

The NRC budget is, for the most part, derived from fees charged to licensees. This results in criticism of research that is oriented to the future and may not benefit licensees today. To address that issue, the self-assessment team recommended that part of research funding be derived from general government funds and not from fees.

11. Better Define Human Capital Management and Make the Strategic Workforce Planning Database a More Usable and Meaningful Tool for NRC Managers.

The NRC has an automated Strategic Workforce Planning (SWP) system to assist in its human capital planning. The NRC is working to make the SWP system more user-friendly and to assist managers and supervisors in using it to close gaps in skills and competencies within the NRC. The self-assessment team concurred with this approach.

12. Make the Process for Obtaining Information Technology and Information Management Resources More Responsive and User-Friendly.

NRC staff perceive that the process for obtaining information technology support for application development is difficult and slow. The self-assessment team recommended that feedback be solicited for improving the application development process.

**Question Number:** 8-9

**Question/Comment:** The NRC's hiring efforts to maintain an effective workforce is very challenging and could serve as a model for many other regulatory bodies worldwide. For the review meeting we would appreciate more information about the experience made in the recruitment and hiring process and during the training on the knowledge transfer programme.

**Response:** The NRC continuously evaluates and adjusts its human capital strategies as market conditions change. The agency maintains a vigorous and

successful recruitment program by participating in approximately 80 events each year at colleges, universities and professional conferences/meetings. We exceeded our FY 2007 hiring goal and are on our way to meeting our FY 2008 goal. However, NRC remains challenged by the high number of senior experts and managers becoming eligible to retire at a time when industry competition for skilled individuals is likely to increase.

To mitigate these challenges, NRC uses a variety of human capital strategies to maintain and bolster its technical knowledge and skills. These strategies include the use of authorities gained from the Federal Workforce Flexibility Act of 2004 and the Energy Policy Act of 2005 to waive dual compensation limitations for re-hired annuitants with critical skills, to offer retention allowances to keep highly-skilled technical staff members onboard, and to develop knowledge management tools and techniques. In addition, we use an automated strategic workforce planning tool to capture staff competencies as well as critical skill and knowledge needs. We can then determine critical skill and knowledge gaps and target recruitment efforts accordingly.

The agency continuously supports formal training and development programs in order to succession plan for leadership, technical, and other key positions. NRC maintains two high quality training facilities: the Professional Development Center in Bethesda, MD (PDC-Bethesda), and the Technical Training Center in Chattanooga, TN (TTC-Chattanooga). At the TTC-Chattanooga, employees receive the in-depth technical knowledge they need to perform inspections and other regulatory functions. These curricula include both classroom and simulator training in the existing reactor vendor designs and courses in engineering support, radiation protection, safeguards, fuel cycle technology, probabilistic risk assessment, and regulatory skills.

The NRC understands that Knowledge Management (KM) is vital to managing growth, doing “more with less,” leveraging enabling technologies for learning, and improving the effectiveness of training and development. Therefore, NRC has launched a KM program to support more effective approaches to knowledge collection, transfer, and use. The program is designed around four categories of initiatives:

- Maintaining Human Resource processes, policies, and practices to attract and retain knowledgeable staff.
- Sharing best practices in KM to build a culture of knowledge retention.
- Developing approaches for recovering knowledge that the agency has lost.
- Using IT applications to facilitate the acquisition, storage, and sharing of knowledge.

Most importantly, recruiting, developing and retaining a diverse workforce remain a top priority for NRC leadership.

**Question Number:** 8-10

**Question/Comment:** The NRC is participating in the MDEP. It is said in the part one of your report (p.14) "A longer-term multinational effort is to establish reference regulations for the review of current and future reactor design." And in Article 8 (p.51), it is said "possible convergence of the country specific regulations".

Is establishing reference regulations or converging regulations to making double safety standards with the international safety standards? How do you separate from the effort for the international safety standards?

**Response:** Under Section 274j of the AEA, NRC periodically reviews Agreement State Programs to determine if the individual State program is adequate to protect public health and safety and compatible with the U.S. NRC's program. The Commission Policy Statement on Adequacy and Compatibility of Agreement State Programs issued in 1997 and additional implementing guidance documents address the degree of differences that are acceptable under such State agreements. Through the mandated periodic reviews, which includes ongoing reviews of State issued regulations, NRC ensures that a national materials program is implemented which allows individual States to address local conditions and requirements.

**Question Number:** 8-11

**Question/Comment:** Training and knowledge management in the NRC are reported. Does the NRC give qualifications to employees who received training and passed examinations?

**Response:** Yes. The NRC has multiple qualifications programs designed to impart a body of knowledge technical staff need to know. These programs apply to many employees based on their particular position requirements. In addition, NRC licenses all individuals who either operate or supervise the operation of the controls of a commercially owned nuclear power reactor or a test/research (i.e., non-power) reactor in the United States.

**Question Number:** 8-12

**Question/Comment:** It is reported that the NRC performed the IRRS self-assessment. Do you have a plan to have an external IRRS assessment?

**Response:** See response to question 8-8.

**Question Number:** 8-13

**Question/Comment:** What is the procedure to participate in the Agency's Cooperative Severe Accident Research and Code Applications and Maintenance Programs for regulatory bodies of other countries?

**Response:** After the NRC receives an expression of interest from a foreign regulatory body in joining the Cooperative Severe Accident Research Program

(CSARP) and/or Code Application and Maintenance Program (CAMP), the NRC Office of International Program (OIP) will seek approval from the U.S. Department of State (USDOS) for NRC to enter into a bi-lateral agreement with the foreign regulatory body. If NRC receives USDOS approval, the details (e.g., cost, terms and duration of the bi-lateral agreement, etc.) will be worked out between NRC and the foreign regulatory body. Once, the bi-lateral agreement is signed by both parties (NRC and the foreign regulatory body), the participation in CSARP and/or CAMP commences.

**Question Number:** 8-14

**Question/Comment:** Please provide more information on the self-assessment performed. Apart from the team of Offices' representatives, how many other people from NRC's staff were involved?

**Response:** See response to question 8-8.

**Question Number:** 8-15

**Question/Comment:** The self-assessment team IRRS analyzed answers on questions asked and developed 12 high- level recommendations.

Have you got already results of reviewing these recommendations and is it possible to get familiarized with them?

**Response:** See response to question 8-8.

**Question Number:** 8-16

**Question/Comment:** The report states that "About 40% of staff have been with the NRC for less than 4 years." Could the US describe the types of problems experienced as the result of this relative lack of experience within the regulatory body of so many of NRC's staff? Conversely, have there been positive results from the influx of new employees?

**Response:** The number of new NRC staff has not resulted in problems due to their relative lack of NRC experience. It is a challenge to train and mentor the new staff, and the NRC has increased training tools, developed qualification programs, and assigned docents to assist new employees in adjusting to the NRC.

The new staff have been positive for the NRC in that they add their recent outside knowledge to the base of existing knowledge within the NRC. A significant number of new hires have come from the nuclear industry, both design and operating sectors, bringing with them considerable levels of experience.

**Question Number:** 8-17

**Question/Comment:** Please explain the responsibilities and powers of the Advisory Council to INPO Board of Directors.

**Response:** The Advisory Council members represent a balanced mix of professional views that is intended to provide a formal means for review and consultation on INPO's policies and programs as they relate to the attainment of INPO's goals, purposes and objectives. The Council acts solely in a consultative relationship to INPO. The principal duties and responsibilities of the Council are listed below:

1. Advise the INPO Board of Directors and staff with respect to the overall effectiveness of INPO programs and activities from an overall independent perspective.
2. Critically review INPO's key interfaces with members, associate members, participants, and government agencies (including the Nuclear Regulatory Commission and state utility regulatory organizations).
3. Challenge existing INPO practices that may no longer effectively support the Institute's mission and programs.
4. Serve as a sounding board on the desirability of potential modifications to existing INPO programs or development of new programs or activities.
5. Provide relevant concepts, examples, and experiences from other industries.
6. Suggest new activities and innovative approaches to address current issues facing the Institute.

**Question Number:** 8-18

**Question/Comment:** The report states that "INPO would have to work closely with the NRC" and "INPO ... interface with the NRC on specific regulatory issues and ...". What are the regulatory requirements and or oversight the NRC apply to INPO (for example; QA, individual or organizational safety culture, qualifications of staff, etc.)

**Response:** There are no regulatory requirements for which INPO is accountable to the NRC. The NRC may look at INPO evaluation reports, but NRC inspections are independent of INPO evaluations. The NRC/INPO Memorandum of Agreement describes the cooperative relationship between the two organizations. The NRC does not monitor INPO's programs for qualifying its own staff, nor does it monitor the quality of the programs that feed into INPO's evaluation program such as quality assurance and safety culture. The NRC inspection program looks at these issues separately.

**Question Number:** 8-19

**Question/Comment:** What would be the NRC reactive regulatory response if the INPO membership of a “member” is suspended?

**Response:** The sort of licensee performance that would lead to an INPO suspension would be unlikely to occur without significant ongoing response from the NRC. In general, the two organizations’ responses go hand in hand in that a facility experiencing degraded performance relative to the standards of one organization will normally not be meeting the standards of the other organization either.

If a utility’s performance warranted suspension from INPO, the utility would likely already be receiving increased regulatory attention from the NRC in the form of increased oversight and inspection. While these actions would not necessarily take the place of INPO’s evaluation and accreditation programs, they would ensure that the utility continued to meet the minimum requirements for safe operation.

**Question Number:** 8-20

**Question/Comment:** The list of components of the Executive Branch with which NRC has the most frequent contact and interaction omits the Department of Homeland Security (DHS). The report, under Article 16, Sections 16.6.1 to 16.6.4, makes extensive reference to the interactions with the DHS. Is there any reason for the omission of the DHS from the list in Section 8.1.6.1?

**Response:** It was an oversight to not include DHS in the list in Section 8.1.6.1. NRC has frequent contact and interaction with DHS.

## 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 NRC ensures that the prime responsibility for the safety of a nuclear installation rests with the licensee through the Atomic Energy Act. This section discussed the Enforcement Program. The NRC also ensures the safety of nuclear installations through its licensing process, which was discussed in Articles 18 and 19, and its Reactor Oversight Process, discussed in Article 6.

**Question Number:** 9-1

**Question/Comment:** One of the recommendations arising from the recent IRRS mission to Australia was that “The Australian Government should consider in any proposed future amendment to the ARPANS legislation, an explicit reference to the requirement that an operator has primary responsibility for safety to reflect Principle 1 of IAEA Fundamental Safety Principles”. Is there, anywhere in the NRC legislation or legislative instruments such as licenses, any explicit mention that the license holder retains the prime responsibility for safety?

**Response:** No. This prime responsibility is not expressed explicitly in the Atomic Energy Act itself, or in the standards issued under it. However, legal texts need not be explicit on this point. It is far more important that they give operational force to the notion, which the Act and the NRC’s standards and licenses certainly do, chiefly through requirements that licensees must comply with the Act and standards issued under it (see, for example, section 103.b of the Act), and through the authority the Act gives the NRC to take enforcement action against non-compliance (see generally Chapter 18 of the Act).

**Question Number:** 9-2

**Question/Comment:** It is reported that embedded in each license is the explicit responsibility that the license holder comply with the applicable rules and regulations and the licensee is ultimately responsible for the safety.

Does complying with the regulations mean to be ultimately responsible? Is it provided in any laws that the licensee is ultimately responsible for the safety?

The INPO states in the Part 3 of the report that the industry goes beyond compliance with regulations. Are there any laws which support this industry’s commitment?

**Response:** This prime responsibility is not directly expressed in the Atomic Energy Act itself; nor need it be, for the idea is implicit in three features of the Act: 1) its requirements that licensees must comply with the Act and standards issued under it (see, for example, section 103.b of the Act), 2) the authority the Act gives the NRC to take enforcement action against non-

compliance (see generally Chapter 18 of the Act), and 3) the absence of any authority given the NRC to design, build, or operate nuclear power plants. No law directly requires that industry go beyond compliance with the regulations, but the NRC's legal authority enables it to support the industry's pursuit of excellence. Under a formal memorandum of understanding, the NRC and INPO exchange operational data and inspection information, and the NRC's rules on training of nuclear power plant personnel give the industry scope to incorporate innovative best practices through INPO's National Academy for Nuclear Training. (See 10 CFR 50.120)

**Question Number:** 9-3

**Question/Comment:** According to the Convention responsibility for the safety of a nuclear installation rests with the holder of the relevant license. In this regard role and activities of U.S. NRC are provided in detail. U.S. NRC may kindly provide information on the activities carried out by license holders.

**Response:** License holders are legally responsible and accountable for the safe operation of their nuclear plants through a robust regulatory framework. Each U. S. nuclear utility has established and implemented programs and processes that allow them to meet the license and safety requirements through a number of means. First every plant has a design that has been approved by the regulator. Formal design changes processes are in place to ensure any deviations or changes to the plant equipment are analyzed and reviewed to make sure the plant continues to meet the requirements of the license. In addition, every plant has well-trained and qualified workers that have been trained to the high standards of the Nuclear Academy of Nuclear Training using a systematic approach to training. Plant workers use detailed procedures and approved processes to accomplish maintenance, engineering, and operational activities. To ensure that the plant is run safely, each utility has put oversight processes in place to conduct internal reviews and independent oversight of activities. These include assessments by the utility's nuclear quality assurance and oversight group, evaluations and reviews by INPO, and the station's own self-assessments. Stations are required to bring themselves back into compliance when they determine they are outside their license and to promptly notify the regulator. Through a combination of programs, processes, trained workers, and oversight activities license holder's exhibit and assert their responsibility to safe operation of the nuclear plant.

**Question Number:** 9-4

**Question/Comment:** One of NRC's law enforcement options is penalties imposition. As it is identified on page 62, Section 234 of the Atomic Energy Act provides for penalties which are currently \$130,000 per violation per day, now. In case enforcement sanctions in the form of penalties is simultaneously combined with license suspension (which itself will results in economic losses), would not it be the case when such financial burden causes the opposite effect, when a licensee cannot afford corrective measures?



**Response:** While the NRC has civil penalty authority up to \$130,000 per day per violation, the NRC normally assesses violations as a single occurrence using penalty levels that vary according to the type of licensee and their ability to pay. The intent of a civil penalty is to be remedial, ensuring the licensee takes corrective actions and prevents recurrence. The NRC views license suspension and/or revocation as the most significant actions it can take against a licensee and those actions are typically not done in conjunction with issuance of a civil penalty.

**Question Number:** 9-5

**Question/Comment:** It is stated under Article 9 that NRC ensures through the Atomic Energy Act that the prime responsibility for safety rests with the licensee. How is it this prime responsibility for safety expressed in the legal text itself?

**Response:** This prime responsibility is not expressed explicitly in the Atomic Energy Act itself, but it is indirectly expressed in three features of the Act: 1) its requirements that licensees must comply with the Act and standards issued under it (see, for example, section 103.b of the Act), 2) the authority the Act gives the NRC to take enforcement action against non-compliance (see generally Chapter 18 of the Act), and 3) the absence of any authority given the NRC to design, build, or operate nuclear power plants.

**Question Number:** 9-6

**Question/Comment:** Please explain the difference between the NRC's monitoring of licensee safety culture and INPO's evaluation of a member (licensee) safety culture. Also, please explain whether the NRC has to approve a report such as INPO SOER 02-4 on Davis-Besse event, before the recommendations of this report are implemented by the industry?

**Response:** See the response to Question 6-1 that identifies the location of information about the NRC's methods to assess licensee's safety culture. The complete description of the NRC's assessment process is described in IMC0305, "Operating Reactor Assessment Program."

The Institute of Nuclear Power Operations (INPO) performs periodic plant evaluations that include safety culture aspects. The INPO evaluation team members consider information contained in the INPO "Principles for a Strong Nuclear Safety Culture" (November 2004) as they develop observations in their function review areas. The INPO teams use proprietary information in the INPO "Performance Objectives and Criteria" to guide the conduct of the evaluation teams.

There are similarities between the NRC safety culture components (and related aspects) and the INPO safety culture principles. The NRC however uses a unique approach described in IP95003, "Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs, or One Red Input" to assess a licensee's safety culture. The NRC assessment protocol currently includes evaluating the adequacy of the licensee's assessment and

performing an independent assessment using methods such as conducting focus group and individual interviews with a spectrum of plant employees. The INPO safety culture evaluation approach is conducted in a different manner. The INPO method is proprietary and therefore the NRC is unable to provide more detailed information on INPO's process.

The NRC does not approve documents issued by the Institute of Nuclear Power Operations (INPO) such as Significant Operating Experience Report (SOER) 02-4, Rev. 1 "Reactor Pressure Vessel Head Degradation at Davis-Besse Nuclear Power Station."

INPO is an industry sponsored organization whose mission is to promote excellence in the operation of commercial nuclear electricity generating plants through activities that are complementary but independent of the NRC. NRC and INPO have entered into a Memorandum of Agreement (MOA) (available in the NRC Agencywide Documents Access and Management System ML060060035) that provides the general coordination framework for the two organizations. Periodic coordination meetings are held between the NRC and INPO where each organization discusses ongoing initiatives, such as the development of the SOER type documents. INPO is a separate industry organization that does not need NRC approval when issuing documents to nuclear power plant licensees.

IMC0305 can be found on the NRC public website:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/index.html>.

The INPO "Principles for a Strong Nuclear Safety Culture" is located on the NRC public website at:

[http://www.nrc.gov/about-nrc/regulatory/enforcement/INPO\\_PrinciplesSafetyCulture.pdf](http://www.nrc.gov/about-nrc/regulatory/enforcement/INPO_PrinciplesSafetyCulture.pdf).

IP95003 is located at <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html> on the NRC public website. The NRC and INPO Memorandum of Agreement are available in the NRC Agencywide Documents Access and Management System at ML060060035.

## 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.

**Question Number:** 10-1

**Question/Comment:** In Section 10.4.2.2, paragraph 2, the report notes that the Regulatory Oversight Process includes "organizational change management" as an element of safety culture. What criteria does the NRC use to evaluate "organizational change management" in their inspections?

**Response:** See the response to Question 6-1 that identifies the location of information about the NRC's methods to assess licensee's safety culture. The complete description of the NRC's assessment process is described in IMC0305, "Operating Reactor Assessment Program."

The Institute of Nuclear Power Operations (INPO) performs periodic plant evaluations that include safety culture aspects. The INPO evaluation team members consider information contained in the INPO "Principles for a Strong Nuclear Safety Culture" (November 2004) as they develop observations in their function review areas. The INPO teams use proprietary information in the INPO "Performance Objectives and Criteria" to guide the conduct of the evaluation teams.

There are similarities between the NRC safety culture components (and related aspects) and the INPO safety culture principles. The NRC however uses a unique approach described in IP95003, "Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs, or One Red Input" to assess a licensee's safety culture. The NRC assessment protocol currently includes evaluating the adequacy of the licensee's assessment and performing an independent assessment using methods such as conducting focus group and individual interviews with a spectrum of plant employees. The INPO safety culture evaluation approach is conducted in a different manner. The INPO method is proprietary and therefore the NRC is unable to provide more detailed information on INPO's process.

The NRC does not approve documents issued by the Institute of Nuclear Power Operations (INPO) such as Significant Operating Experience Report (SOER) 02-4, Rev. 1 “Reactor Pressure Vessel Head Degradation at Davis-Besse Nuclear Power Station.”

INPO is an industry sponsored organization whose mission is to promote excellence in the operation of commercial nuclear electricity generating plants through activities that are complementary but independent of the NRC. NRC and INPO have entered into a Memorandum of Agreement (MOA) (available in the NRC Agencywide Documents Access and Management System ML060060035) that provides the general coordination framework for the two organizations. Periodic coordination meetings are held between the NRC and INPO where each organization discusses ongoing initiatives, such as the development of the SOER type documents. INPO is a separate industry organization that does not need NRC approval when issuing documents to nuclear power plant licensees.

IMC0305 can be found on the NRC public website:  
<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/index.html>. The INPO “Principles for a Strong Nuclear Safety Culture” is located on the NRC public website at:  
[http://www.nrc.gov/about-nrc/regulatory/enforcement/INPO\\_PrinciplesSafetyCulture.pdf](http://www.nrc.gov/about-nrc/regulatory/enforcement/INPO_PrinciplesSafetyCulture.pdf). IP95003 is located at <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html> on the NRC public website. The NRC and INPO Memorandum of Agreement are available in the NRC Agencywide Documents Access and Management System at ML060060035.

**Question Number:** 10-2

**Question/Comment:** What is the frequency that licensees are performing periodic voluntary self-assessments of safety culture in accordance with industry guidelines?

**Response:** Most U.S. nuclear plants conduct a safety culture self-assessment every 1-2 years. The self-assessments are conducted in a variety of methods, but are normally based on industry developed principles and guidance.

**Question Number:** 10-3

**Question/Comment:** Several Risk-Informed applications are presented. A Risk-Informed application has of course to rely on a PSA of “sufficient” scope and quality and appropriately up-dated. Could USA give some details about the means for ensuring these necessary conditions: for example are there external reviews? Is there a recommended up-dating periodicity?

**Response:** The NRC has issued Regulatory Guide 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,” as the basis for establishing technical adequacy of a PRA used to support a risk-informed application. This regulatory guidance endorses the ASME internal events PRA

standard (ASME-RA-Sb-2005) with some clarifications. A future revision to the guide will endorse additional standards for fire PRA and external events PRA. Guidance endorsed by the NRC calls for external (peer) review of PRAs and, at this time, all licensees have completed such reviews of their internal events PRAs. Self-assessments by licensees against the applicable PRA standards, and external peer review assessments are also used by licensees to establish the degree of conformance to these standards. A licensee then assesses the technical adequacy of its PRA model(s) using Regulatory Guide 1.200 for each application. The NRC then reviews the licensee's basis for technical adequacy for the particular application.

Neither the PRA standards nor the regulatory guidance provides for a specific update periodicity. However, licensees must demonstrate that the PRA model(s) used to support an application reasonably represent the and disposition of any outstanding plant changes which are not yet incorporated in the PRA model. Therefore, PRA updates must be adequate to support application of the PRA.

**Question Number:** 10-4

**Question/Comment:** NRC does not impose regulatory requirements for licensees to perform safety culture assessments. Licensees are performing periodic voluntary self assessments of safety culture in accordance with industry guidelines. Please provide more information about these guidelines and about the experiences of NRC's graded approach in the Reactor Oversight Process framework. What role do the relevant IAEA guides play in that process?

**Response:** The nuclear power plant licensees are performing periodic safety culture assessments in accordance with the INPO SOER 02-4, Rev. 1, "Reactor Pressure Vessel Head Degradation at Davis-Besse Nuclear Power Station." The SOER recommends that licensees perform periodic safety culture assessments utilizing INPO "Principles for a Strong Nuclear Safety Culture" or equivalent as a basis for the assessment.

The NRC has gained experience from implementing the enhanced ROP for a period of 18 months. The NRC is currently performing a lessons learned evaluation to identify further aspects of the ROP that will be proposed to be enhanced. The staff has performed IP95003, "Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs, or One Red Input" for the first time at the Palo Verde Nuclear power plant. The staff is also currently assessing the lessons learned from the first IP95003 implementation.

It is possible that some licensees are also utilizing the IAEA guides, however they are not directly referenced in the INPO SOER. The NRC staff considered the IAEA guides when the ROP safety culture enhancements were developed.

INPO "Principles for a Strong Nuclear Safety Culture" is located on the NRC public website at:

[http://www.nrc.gov/about-nrc/regulatory/enforcement/INPO\\_PrinciplesSafetyCulture.pdf](http://www.nrc.gov/about-nrc/regulatory/enforcement/INPO_PrinciplesSafetyCulture.pdf).

IP95003 is located on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>.

The Palo Verde 95003 inspection report is available on the NRC public website at: <http://www.nrc.gov/reactors/plant-specific-items/palo-verde-issues.html>.

**Question Number:** 10-5

**Question/Comment:** NRC's Differing Professional Opinion Program seems to be an outstanding feature within the management of NRC. Please report about your experiences.

**Response:** The NRC's Differing Professional Opinions (DPO) Program is one method for employees to pursue differing views. It compliments the agency's longstanding Open Door Policy and the new Non-Concurrence Process (NCP). Together these processes help to support an open, collaborative working environment that encourages all individuals to promptly raise differing views without fear of retaliation. Because the DPO Program applies to issues where a prevailing staff view already exists, it is recognized as a final option in pursuing differing views. Employees are encouraged to pursue differing views as promptly as possible through informal communications before a staff view is established. When informal communications don't resolve issues, employees use the Open Door Policy and the NCP. Consequently, the DPO Program is not frequently used. The NRC reviews the DPO Program annually. The 2006 review is available in the NRC's electronic public library (ADAMS ML071160295). The NRC's position on establishing an open, collaborative working environment is showcased as part of our values on the NRC's public web site at <http://www.nrc.gov/about-nrc/values.html>.

**Question Number:** 10-6

**Question/Comment:** It is said in the report that the NRC's safety culture oversight activities remain risk informed. Please explain the risk informed safety culture oversight activities. How risk information is applied to the risk informed safety culture oversight activities?

**Response:** The ROP is risk-informed, in that it uses a "risk-informed" approach to select areas to inspect within each safety cornerstone. The inspection areas were chosen because of their importance to potential risk, past operational experience, and regulatory requirements. The safety culture enhancements have been incorporated into the ROP risk-informed framework. The ROP framework and safety culture enhancements also utilize a graded approach for oversight of nuclear power plants.

For additional information, a complete description of the enhancements to the ROP in the area of safety culture is provided in Regulatory Issue Summary 2006-13, "Information on the Changes Made to the Reactor Oversight Process to More Fully Address Safety Culture."

**Question Number:** 10-7

**Question/Comment:** The DOP and Non-Concurrence Process are explained in the report. Those seem to be effective to maintain safety culture in an organization. Please explain recent results of those programs.

**Response:** Maintaining safety culture in an organization requires a combination of elements. Success is the summation of support, skills, and structure. NRC has established a diverse structure to help employees raise and resolve differing views (Open Door Policy, the Non-Concurrence Process, and the Differing Professional Opinions Program). Establishing an open, collaborative working environment that encourages all individuals to promptly raise differing views without fear of retaliation is championed at the highest levels of the agency and is expected to be supported by all employees. (See the NRC's public web site at <http://www.nrc.gov/about-nrc/values.html>.) NRC has numerous training courses designed to provide the necessary skills to support productive communications.

The NRC reviews the DPO Program annually. The 2006 review is available in the NRC's electronic public library (ADAMS ML071160295). Because the DPO Program applies to issues where a prevailing staff view already exists, it is recognized as a final option in pursuing differing views. Consequently, the DPO Program is not frequently used. Because the Non-Concurrence Process was introduced in November 2006, it has not yet been formally reviewed. However, early feedback indicates that employees like the process better than the Differing Professional Opinions Program because it is less formal and allows issues to be raised before a prevailing view is established.

**Question Number:** 10-8

**Question/Comment:** You have made good progress in monitoring licensee safety culture. Safety culture was deemed difficult to be monitored by regulatory body for it is not directly measured and there are no objective criteria for the level of acceptance.

What components do you use in evaluation of safety culture and how do you reflect the results to ROP? In your enhanced ROP, how does the inspector make sure his/her inspection findings to have relevance with safety culture? Is there any mechanism to avoid inspectors' subjective judgment? And when the NRC asks the licensee to conduct self-assessment of safety culture, do you review the methods and results of the self-assessment? Then do you have any review procedure or guideline?

**Response:** A complete description of the enhancements to the ROP in the area of safety culture is provided in Regulatory Issue Summary 2006-13,

“Information on the Changes Made to the Reactor Oversight Process to More Fully Address Safety Culture.” The components that are used to evaluate safety culture are described in IMC0305, “Operating Reactor Assessment Program,” section 06.07.

When inspectors identify inspection findings, they determine whether it is appropriate to assign a safety culture cross-cutting aspect to the finding when the cross-cutting aspect is judged the most significant contributor to the finding. The inspectors make a judgment based upon their knowledge of the problem, including information received from the licensee such as a root or apparent cause evaluation, to select the most appropriate cross-cutting aspect.

In the current ROP methodology, it is not possible to completely remove inspector judgment from the process of identifying safety culture cross-cutting aspects. However, inspectors discuss their logic for assigning a particular cross-cutting aspect to their finding with the licensee and differences in opinion between the inspector and the licensee are aired out. Inspectors also discuss identification of cross-cutting aspects with their management. NRC headquarters staff also monitors the overall use of cross-cutting aspects by inspectors and also issue training communications to inspectors on how to identify cross-cutting aspects appropriately.

If the NRC asks that a licensee perform a safety culture assessment, the NRC will at a minimum evaluate the results of the licensee’s assessment and the licensee’s plans to address the items identified by the assessment. For example, if a licensee is asked to perform a safety culture assessment while in column 4 (Multiple / Repetitive Degraded Cornerstone Column) of the ROP action matrix, the staff will use the guidance in IP95003, “Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs, or One Red Input” to evaluate the licensee’s safety culture assessment methodology, its implementation, and the resolution of the results.

Regulatory Issue Summary 2006-13 can be found on the NRC public website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200613.pdf>.

IMC0305 can be found on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/index.html>.

IP95003 is located on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>.



**Question Number:** 10-9

**Question/Comment:** The US Report describes that NRC has conducted surveys to assess its safety culture.

What model do you adopt as regulatory body's safety culture? Do you think safety culture components, which are described in 10.4.2.2 and incorporated in enhanced ROP, could be equally applied to regulatory body? And were the survey questionnaires organized against the components?

**Response:** The 2005 NRC Safety Culture and Climate Survey was conducted by the Inspector General for the NRC with the assistance of a contractor, International Survey Research, LLC (ISR). Although the ISR model was used to conduct the survey at NRC, NRC is not aware of the specific model details and NRC has not adopted a model for its surveys.

The survey questions were grouped into the following 19 categories:

- Clarity of Responsibilities
- Management of Leadership
- Supervision
- Working Relationships
- Empowerment
- Communication
- Workload and Support
- Training and Development
- Performance Management
- Job Satisfaction
- Employee Engagement
- NRC Mission and Strategic Plan
- NRC Image
- Organizational Change
- Continuous Improvement Commitment
- Quality Focus
- Regulatory Effectiveness Process/Initiatives
- Diversity and Inclusion
- DPO

As can be seen, while there is some agreement with the 13 safety culture components listed in 10.4.2.2, Enhanced Reactor Oversight Process, the NRC Safety Culture and Climate Survey questionnaires were not organized against that list. Because ISR, an independent contractor, created the survey for the NRC and the agency was not involved in developing the survey model, the NRC has not assessed whether the list in 10.4.2.2 would be appropriate to use for its safety culture survey. Additional information on the NRC survey can be found in OIG-06-A-08, "OIG 2005 Survey of NRC's Safety Culture and Climate," February 10, 2006.

**Question Number:** 10-10

**Question/Comment:** What is the effectiveness of regulating the process of NPPs operation on the basis of risk information (risk-informed regulation)? How extensively are the risk monitoring systems used at NPPs and what is their benefit for improving operation process?

**Response:** 1) The use of risk insights in the regulation of the operation of NPPs is based on a risk-informed process, combining the traditional deterministic engineering basis of defense-in-depth and safety margins with an assessment of severe accident risk. Risk-based regulation, where risk insights are the sole basis for regulatory decision making, is not used for U.S. NPPs.

The Reactor Oversight Process assesses nuclear plant performance using a combination of objective performance indicators reported by the licensee, by NRC inspection findings, and by risk information. Risk information is used to U.S. NRC inspection and enforcement resources based on the importance to safety, as measured by core damage and large early release frequency. By choosing to inspect those plant activities that have the greatest impact on safety and overall risk, the NRC is able to use its limited resources in the most effective and efficient manner.

At the option of and application by the licensee, risk information can also be used to support amending a NPP's license in certain instances, for example, to increase Technical Specification allowed outage times or surveillance test intervals, within the context of a risk-informed decision which also considers conformance with regulations, defense-in-depth, and safety margins.

2) NPP licensees use some form of risk monitoring in assessing day-to-day operations and maintenance activities, in conformance to 10CFR50.65(a)(4) (maintenance rule). Typically, this involves assessing the risk impact of the plant configuration based on internal initiating events, and the results are used to determine acceptability of the activities. Rescheduling maintenance, or imposing compensatory measures to address the sources of increased risk, as well as increased management attention and personnel awareness of these risk sources, are the benefits which improve plant operational safety. The NRC is currently considering additional guidance for assessing the impact from external events, including fires, as part of this process.

**Question Number:** 10-11

**Question/Comment:** In July 2006 the NRC implemented revision to the ROP inspection and assessment processes related to safety culture. NRC Safety Culture. What are the main differences of the ROP new revision and how the graded approach is implemented? Could you please describe the main categories of questions about Safety Culture and Climate Survey?

**Response:** The ROP revision in July 2006 to incorporate safety culture did not change the graded approach of the ROP. In fact, a graded approach was used to incorporate the safety culture enhancements. For additional information, a complete description of the enhancements to the ROP in the area of safety culture is provided in Regulatory Issue Summary 2006-13, "Information on the Changes Made to the Reactor Oversight Process to More Fully Address Safety Culture."

**Question Number:** 10-12

**Question/Comment:** Could you explain your experience with implementation of the NRC's Differing Professional Opinion Program?

**Response:** The NRC's DPO is one method for employees to pursue differing views. It compliments the agency's longstanding Open Door Policy and the new NCP. Together these processes help to support an open, collaborative working environment that encourages all individuals to promptly raise differing views without fear of retaliation. Because the DPO Program applies to issues where a prevailing staff view already exists, it is recognized as a final option in pursuing differing views. Employees are encouraged to pursue differing views as promptly as possible through informal communications before a staff view is established. When informal communications don't resolve issues, employees use the Open Door Policy and the NCP. Consequently, the DPO Program is not frequently used. The NRC reviews the DPO Program annually. The 2006 review is available in the NRC's electronic public library (ADAMS ML071160295). The NRC's position on establishing an open, collaborative working environment is showcased as part of our values on the NRC's public web site at <http://www.nrc.gov/about-nrc/values.html>.

**Question Number:** 10-13

**Question/Comment:** It is known that several initiatives to move towards risk-informed regulations and processes have taken a long time to implement. One example is the special treatment requirements in 10 CFR 50.69. Please explain the major problems and obstacles in this process.

**Response:** Risk-informed regulations and risk-informed processes can take many years to reach the implementation phase. Typically, the areas to risk-inform must be taken from the conceptual and/or pilot phase, through a regulatory phase, to reach implementation. Often, a pilot or conceptual application is needed to fully understand the potential complexities of changing the regulatory structure. This pilot phase involves numerous interactions between the piloting licensee, industry, and regulator and

even after the pilot reaches an acceptable conclusion, the lessons learned during this phase must be fed back into the development of the regulations. The pilot phase typically takes a number of years. During the regulatory phase, which typically takes a few years to work through if they are not controversial, additional stakeholders may become more involved in the process, which can result in further issues being raised regarding the regulatory structure changes and proposed staff positions. Throughout this process, guidance that supports the risk-informed regulation implementation must be developed. After completion and issuance of the regulation and supporting guidance, the individual licensees must determine that it is in their best interest to implement these risk-informed processes, which are voluntary alternatives to existing requirements. Therefore, the entire process from piloting risk-informed concepts to widespread implementation of those concepts will take many years to complete.

**Question Number:** 10-14

**Question/Comment:** 9 out of 13 safety culture components are monitored in the ROP baseline inspections. More in-depth assessments and self-assessments of safety culture are required in cases of declining performance. How can NRC ensure that a consistent approach is used to timely detect and evaluate these non-evident conditions at all NPPs before any significant degradation occurs?

**Response:** The NRC has defined the approach in IMC0305 to identify declining licensee performance. The ROP Action Matrix uses inputs from risk significant inspection findings and the results of performance indicators to place a particular nuclear power plant site in a column of the Action Matrix. The location within the Action Matrix determines what actions the NRC will take in response to the plant performance condition. As plant performance departs from the Licensee Response column, the NRC conducts supplemental inspections (Inspection Procedures 95001, 95002, and 95003). These supplemental inspections examine the licensee problems, and the adequacy of licensee corrective actions, using the additional 4 safety culture components.

In addition, during periodic assessments (conducted every 6 months) the NRC staff looks for the existence of a Substantive Cross-Cutting Issue at the plant. This can be caused by the existence of 4 or more inspection findings during a set time frame that share the same safety culture cross-cutting aspect. The staff believes that the SCCI can be an indicator of a potential for licensee plant degradation. This condition is identified to the licensee with the expectation that it be placed in the corrective action program and that the licensee take appropriate measures to address the situation.

And finally, the NRC evaluates the adequacy of licensee actions to resolve issues identified by their own safety culture assessments as part of IP71152, "Identification and Resolution of Problems."

The staff believes that IMC0305 provides a robust means to identify declining licensee performance by defining escalating NRC actions in response to deteriorating licensee performance conditions as detected by risk significant inspection findings and results from licensee performance indicators, along with the ability to identify the existence of a Substantive Cross-Cutting issue. The staff continues to evaluate the adequacy of IMC0305 and will enhance the guidance provided in it if warranted.

IMC0305 can be found on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/index.html>.

The NRC supplemental inspections and IP71152 can be found on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>.

**Question Number:** 10-15

**Question/Comment:** Do US licensees have a Safety Policy explaining that safety is the overriding priority? Is such a policy required?

**Response:** U.S. licensees are required to meet all regulatory requirements and are expected to meet all commitments made to the NRC. Compliance to the existing regulations ensures that licensees place safety as an overriding priority. U.S. licensees are not required to have a policy stating safety as their overriding priority; however, the NRC incorporates a “safety culture” aspect into its baseline inspection program to determine when safety has descended on the list of the licensee’s top priorities.

In addition, there is an INPO document, Principles for a Strong Nuclear Safety Culture, which describes attributes of a healthy nuclear safety culture and embodies the concept that nuclear safety is an overriding priority. The Principles document establishes the expectation that safety culture applies to every employee in the nuclear organization.

**Question Number:** 10-16

**Question/Comment:** The report states that “...licensees can now implement risk-informed in-service testing programmes without following Regulatory Guide 1.175 and without prior NRC approval.” Bearing in mind the experiences at Davis-Besse (page 19), South Texas (page 19), Wolf Creek (page 15), Duane Arnold (page 16) and Quad Cities (page 16), does this mean that changes to the primary pressure circuit inspection programmes of licensees do not need prior approval by NRC?

**Response:** The full sentence on page 66 of the report reads the following, “Since Regulatory Guide 1.192 lists acceptable (and conditionally acceptable) OM Code Cases, including risk-informed categorization and component-specific code cases, licensees can now implement risk-informed in-service

testing programs without following Regulatory Guide 1.175 and without prior NRC approval.”

Regulatory Guide 1.175 deals specifically with risk-informed inservice testing (IST) of pumps and valves, and therefore, does not contain alternate approaches for inservice inspection (ISI) of piping systems. The operating experiences referenced in the question would not be germane to a discussion of Regulatory Guide 1.175. Instead, Regulatory Guide 1.175 provides an approach for developing a risk-informed IST program, which a licensee may submit to the NRC for approval as an alternative to following the ASME Code for Operation and Maintenance of Nuclear Power Plants (OM Code) incorporated by reference in the regulations (10 CFR Part 50.55a). Some ASME OM Code Cases contain risk-informed approaches for categorization and component-specific testing requirements as alternatives to the requirements contained in the body of the ASME OM Code. The NRC staff reviews all ASME OM Code Cases for acceptability and lists acceptable code cases in Regulatory Guide 1.192, along with any conditions. (ASME code cases not approved for use are listed in Regulatory Guide 1.193.) Certain code cases may be based on or implement a risk-informed approach to component testing, which if after review and acceptance by the NRC staff, may be used by licensees without prior individual NRC approval.

With regards to inservice inspection requirements NRC Regulatory Guide 1.147, “Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1,” identifies NRC reviewed and approved ASME Code Cases which licensees may implement without individual NRC approval. All ASME Code Cases which are listed in Regulatory Guide 1.147 are reviewed by NRC staff for acceptance. Certain Code Cases may be based on or implement a risk-informed process, which if after review and acceptance by NRC staff, may be used by licensees without prior individual NRC staff approval.

**Question Number:** 10-17

**Question/Comment:** The NRC is considering an approach that, in addition to the ongoing effort to revise some specific regulations to be risk-informed and performance-based, would establish a comprehensive set of risk-informed and performance-based requirements applicable for all nuclear power reactor technologies as an alternative to current requirements. At the same time in Appendix B “NRC Major Management Challenges for the Future”, Challenge 3 “Development and implementation of a risk-informed and performance –based regulatory oversight approach”. This issue is formulated as follows: “The NRC faces the challenge of integrating PRA into regulatory decision-making”.

Question:

- 1) How are you going to regulate using alternative set of requirements?
- 2) How is it supposed to resolve disputes?

3) Is not this approach in contradiction with information what is included in Appendix B?

**Response:**

On May 4, 2006, the NRC issued an Advanced Notice of Proposed Rulemaking (ANPR) noting that the “NRC is considering an approach that, in addition to the ongoing effort to revise some specific regulations to make them risk-informed and performance-based, would establish a comprehensive set of risk-informed and performance-based requirements applicable for all nuclear power reactor technologies as an alternative to current requirements.” This approach is documented in NUREG-1860. In response to stakeholder comments on the ANPR, the staff noted in SECY-07-101 (“Staff Recommendations Regarding a Risk-Informed and Performance-Based Revision to 10 CFR Part 50,” dated June 14, 2007), that the primary objective of NUREG-1860 is to demonstrate the feasibility of a possible risk-informed and performance-based approach that would serve as the technical basis for licensing a reactor employing any technology. The staff also noted that some policy and technical issues would need to be resolved.

NUREG-1860, “Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing,” establishes the feasibility of developing a risk-informed and performance-based regulatory structure for the licensing of future nuclear power plants (NPPs). As such, this NUREG proposes an approach that could be used to develop a set of requirements that could serve as an alternative to 10 CFR 50 for licensing future NPPs; however, the approach described in NUREG-1860 is not the entire process. It is an initial phase to explore the feasibility of such a concept, recognizing that for full implementation there will be outstanding programmatic, policy, and technical issues to be resolved. The second phase, which would address implementation, is comprised of several iterative steps: resolution of issues; development of draft requirements and regulations, pilots and tests; and rulemaking. Questions such as how to regulate, resolve disputes, etc. would be addressed during this implementation phase. Appendix C of NUREG-1860 provides an initial list of some of the issues. These issues would have to be resolved as part of any rulemaking.

**Question Number:** 10-18

**Question/Comment:** Nuclear Industry and NRC are continuously extending PSA application to updating (changing) of Technical Specifications.

Questions:

1) Could you give a few concrete examples of changes in licensing basis?

2) Does not this contradict to one of the main principles of safety culture- is -application of approved technologies?

3) It is mentioned in Appendix B that “... the NRC initiated an effort to address the quality of PRAs and develop standard regulatory risk-informed

activities. However, full implementation of PRA quality standards will take a number of years". In view of this, would not it be premature to revise technical specifications?

**Response:**

1) The vast majority of risk-informed applications involve changes to a plant's Technical Specifications, typically extensions of the allowed outage times associated with inoperable components, either to support unique one-time repairs, or as a permanent change to the Technical Specifications. Changes to surveillance test intervals and removal of specific requirements from Technical Specifications have also been approved using a risk-informed approach.

2) The NRC considers PRA technology to be sufficient to support risk-informed applications, and that PRA is therefore an application of an approved technology, and in fact is a technology that enhances safety decision making.

3) The current approach for revisions to Technical Specifications, established by Regulatory Guide 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," is risk-informed; that is, risk insights are used to supplement the traditional engineering evaluation of safety margins and defense-in-depth. Plant-specific PRA models have been developed by each licensee, and the industry has established peer review processes to provide a reasonably consistent level of technical adequacy. These plant-specific PRA models have been used by licensees to support compliance with regulations for the maintenance rule (10 CFR 50.65), and to support the reactor oversight process through the significance determination process evaluation of plant deficiencies. The technical adequacy of the licensees' PRA models used in support of Technical Specification changes is established by NRC reviews of the amendment request. Additionally, the NRC uses its independent plant-specific PRA models (Standardized Plant Analysis Risk (SPAR)) to provide input to the significance determination process. In order to improve the efficiency and consistency of the review process, additional regulatory guidance for demonstrating PRA technical adequacy by comparison to endorsed standards is being pursued. However, the existing processes are adequate to establish an acceptable level of PRA technical adequacy to support changes to Technical Specifications.



## 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 that are made during a plant's operation, decommissioning, as well as handling claims and damages associated with accidents. This section also explained the regulatory requirements for qualifying, training, and retraining personnel.

**Question Number:** 11-1

**Question/Comment:** Could the USA provide more details on how licensees ensure that the contractors' competencies meet the requirements?

**Response:** The NRC holds the licensees directly responsible for the quality of components used in their facilities. The NRC inspection of a contractor's products or services at a licensee's site motivates licensees to ensure that the products or services are sufficiently competent to meet or exceed regulatory expectations.

Licensees review training and qualification records, and provide training to ensure that contractor's are qualified prior to task performance. In addition, there is oversight of the contractor's work.

**Question Number:** 11-2

**Question/Comment:** What are the requirements, in U.S. regulation, aimed at ensuring that the human resources needed for guarantying the long-term safety and performance of NPPs are available?

**Response:** The NRC's explicit requirements for unit staffing are contained in Section 5.2.2 of the facilities' Technical Specifications and, in the case of licensed operators, in Section 50.54(m) of 10 CFR Part 50. However, there are no specific requirements at the present time for licensees to ensure that sufficient numbers of personnel are available to replace current operators and other staff as they leave the nuclear industry. In the future, if enough operators and other staff are not available, facility licensees may have to re-engineer their facilities and job functions to allow safe operation with fewer personnel. This could be done through automation of tasks or by providing operator aids. In any case, an exemption or other regulatory relief from the current minimum staffing requirements would have to be approved by the NRC before implementation.

See response to question 12-7 for additional information regarding industry long-term staffing initiatives.

**Question Number:** 11-3

**Question/Comment:** It is mentioned that the shift supervisor is licensed in accordance with 10 CFR Part 55. We would like to know the educational qualification specified for shift supervisors and the role of regulatory body in their licensing.

**Response:** The minimum educational qualification for licensed operators (applicable to both reactor and senior reactor operators) is a high school diploma or equivalent. Reactor operators with at least a year of operating experience may upgrade their license to the senior level by taking another NRC examination, but license applicants with a Bachelor of Science degree in engineering or the equivalent may qualify for a direct license if they have at least three years of responsible nuclear power plant experience.

The NRC licenses all individuals who either operate or supervise the operation of the controls of a commercially owned nuclear power reactor or a test/research reactor in the United States.

10 CFR Part 55, "Operators' Licenses," requires all license applicants to pass both a written examination and an operating test that are developed and administered in accordance with 10 CFR 55.41 and 55.45 (for reactor operators) or 10 CFR 55.43 and 55.45 (for senior reactor operators). The regulations allow facility licensees to develop and submit proposed examinations for review and approval by NRC staff; approximately 90 percent of licensees currently follow this process, however the NRC will prepare the examinations if requested in writing by a facility licensee. Facility licensees may administer the written examinations after they are approved by the NRC, but all of the operating tests are administered by NRC staff.

NUREG-1021, "Operator Licensing Examination Standards for Power Reactors," establishes the detailed policies, procedures, and practices for administering the required written examinations and operating tests. NUREG-1478, "Operator Licensing Examiner Standards for Research and Test Reactors," establishes similar guidelines applicable to research and test reactor facilities. These NUREGs implement the provisions of the Atomic Energy Act of 1954 and the regulations in 10 CFR Part 55 on which the operator licensing program is based. The NUREGs also ensure the equitable and consistent administration of examinations to all applicants and licensed operators at all facilities that are subject to the regulations.

**Question Number:** 11-4

**Question/Comment:** Please clarify if the INPO provides for licensee both the Guidelines for training programmes and the training programmes – are these arrangements made by INPO on behalf of licensee? Do the NRC supervisory activities in the area of implementation of training programmes mostly rely on review of INPO and NNB findings?

**Response:** 1) The NRC recognizes INPO accreditation and its associated training evaluation activities as an acceptable means of self-improvement in training. Such recognition encourages industry initiative and reduces the NRC's evaluation and inspection activities. The NRC recognizes accreditation is a means but not a requirement for meeting the requirements of 10 CFR 50.120, "Training and Qualification of Nuclear Power Plant Personnel." The National Academy for Nuclear Training, formed by INPO in 1985, focuses on and unifies industry efforts to improve training and promote professionalism among nuclear power plant personnel.

The National Academy operates under the auspices of INPO and has three components:

- Nuclear utility training activities
- The National Nuclear Accrediting Board
- INPO's training-related activities

With the support of National Academy members, INPO develops accreditation objectives and criteria; develops training guidelines; assists member utilities in developing, implementing, and maintaining performance-based training programs; and evaluates the quality and effectiveness of utility training programs. When the first training program at a facility is accredited, the facility becomes a branch of the National Academy for Nuclear Training. When all applicable training programs at all of a utility's operating nuclear plants are accredited, the utility becomes a member of the National Academy.

Neither the National Academy nor INPO provide National Academy members complete training programs. The training programs are developed by the individual National Academy members.

2) In 1979, the President's Commission on the Accident at Three Mile Island (Kemeny Commission) recommended that agency-accredited training institutions be established for operators and immediate supervisors of operators. In May 1982, INPO established an Accreditation Program for training in the nuclear industry that required all nuclear stations seek accreditation for their operator training programs by May 1984 and for maintenance and technical programs by May 1986. All nuclear stations in operation by year-end 1984 met the commitment by notifying INPO of their readiness for accreditation by the end of 1986; and by mid-1988, all had their programs accredited.

In March 1985, the NRC endorsed the INPO-managed accreditation program and, in 1993, issued a final rule establishing INPO accreditation as a means for compliance with federal regulations that training programs be established, implemented, and maintained using a systematic approach to training. Since 1993, INPO and the NRC have coordinated their activities through a Memorandum of Agreement whereby the NRC monitors, but does not participate in, implementation of the accrediting process.

The NRC generally does not review INPO and NNAB findings. The NRC assesses the effectiveness of the accreditation process and the industry's use of the systems approach to training (SAT) by observing INPO-led Accreditation Team Visits and meetings of the NNAB. These activities provide an efficient and effective assessment of industry training activities and initiatives with minimal impact on facility licensees. Although each activity provides plant-specific information, the information is used in the composite to assess the overall effectiveness of training in the nuclear industry.

The NRC also routinely reviews Licensee Event Reports (LERs), inspection reports, and operator licensing examination reports for personnel performance issues. The data obtained is analyzed to identify any training-related performance issues. The NRC occasionally obtains additional data when it conducts "for-cause" inspections of selected facility training programs (inspections of training programs whenever the causes of declining performance suggest training-related deficiencies); and during the administration, inspection, and review of licensed operator initial and re-qualification training activities.

The NRC staff annually prepares a report that documents its assessment of the effectiveness of training in the nuclear industry based on these activities.

**Question Number:** 11-5

**Question/Comment:** How many licensees have chosen to prepare their own examinations for operator licensing and how many still request the NRC to prepare the examinations? How many resources (man-days/year) are devoted by NRC to the licensing of operators?

**Response:** 1) In fiscal year (FY) 2007 (October 1, 2006 through September 30, 2007), the NRC administered a total of 52 operator licensing examinations. Forty-nine of the 52 examinations (~94 percent) were primarily facility-developed, and the NRC developed the remaining examinations. In FY 2008 (October 1, 2007 through September 30, 2008), the NRC is currently scheduled to administer a total of 46 examinations. Facility licensees have volunteered to develop 41 of the 46 (~89 percent) currently scheduled examinations.

2) In FY 2007 the NRC expended approximately 26,500 man-hours, or 3,313 man-days, in directly reviewing and/or developing, administering, grading and documenting the aforementioned 52 operator licensing

examinations. Approximately 15,400 additional man-hours, or 1,929 man-days, were expended in performing related activities such as maintaining operator docket files, developing and maintaining program guidance documents, managing the generic fundamentals examination program, conducting examiner training, overseeing regional activities to ensure consistency, and interfacing with the industry on operator licensing issues.

Note that the NRC uses the following methodology for estimating the NRC resources required to administer operator licensing examinations based on an examination for ten license applicants:

Facility-developed Examination: 406 man-hours

NRC-developed Examination: 900 man-hours

Adjustment for large examinations: 15 additional man-hours for each applicant beyond a group of 10 applicants

**Question Number:** 11-6

**Question/Comment:** With the resurgence of nuclear power worldwide, which could result in competition for experienced human resources (both locally within your country and internationally) what strategies/steps are being taken in your country by both the regulatory body and the operators to ensure that sufficient numbers of qualified staff remain available for all safety-related activities in or for each nuclear installation, throughout its life.

**Response:** The Oak Ridge Institute for Science and Education (ORISE) report on Labor Market Trends for Nuclear Engineers Through 2010 and the Labor Market Outlook for Health Physicists Updated Through 2010 both confirm that the available U.S. civilian labor supply of new nuclear engineering graduates and health physicists is substantially less than the number of job openings. For example, there will be approximately 2 to 3 job openings per each new health physicist graduate available in the labor supply through 2010 and over 2 job openings per nuclear engineering graduate available in the labor supply even though there has not yet been a rapid increase in retirements or industry growth. Competition for graduates in these fields will be even greater if the retirement rate increases and/or there is considerable growth in the nuclear-related fields.

NRC believes it is in the national interest for industry and government to anticipate these shortages and provide expanded funding to support these university programs. Early increases in funding can potentially offset the long-term impacts. In FY 2007, the NRC Nuclear Education Grant Program provided approximately \$4.7 million in grants to higher education institutions to enhance curricula and increase teaching competencies related to nuclear safety, security, and environmental protection. An additional \$4.7 million is available for similar activities in FY 2008. Also in FY 2008, the NRC Nuclear Education Scholarship and Fellowship Program provides an additional \$15 million to support

education in nuclear science, engineering, and related trades. These funds are to be used for college scholarships and graduate fellowships in nuclear science, engineering, and health physics; faculty development grants supporting faculty in these academic areas; and scholarships for trade schools in the nuclear-related trades.

Also, the U.S. nuclear power industry has initiated activities to assess and meet the continuing need for educated and experienced workers to operate the nation's nuclear power plants and to plan for the additional workforce demands of new plant construction. Industry-wide staffing surveys have been periodically conducted to assess workforce projections for degreed engineers, power plant operators, technicians, and craft workers. Collaborations and partnerships have been developed between utilities, industry organizations, government, organized labor, educational institutions, vendors, and others to target areas requiring immediate and ongoing attention. Executive oversight groups and industry task forces were formed to develop strategies and activities directed at ensuring sufficient numbers of qualified workers. Working meetings and conferences have been conducted to share information, operating experience, and to develop action plans to carry out identified strategies.

In addition, programs have been developed to target and retain key existing employees, to capture and assure knowledge transfer, and to quickly train and qualify new employees for entry into the existing workforce. Recruiting efforts have been increased to raise awareness of nuclear careers among students, career counselors, and human resource professionals and to identify other labor sources such as veterans and minorities. Governmental and industry funding continues to support U.S. nuclear engineering education (university and college infrastructures, faculty, research reactors, students) through special grants, and undergraduate scholarships and graduate fellowships. The industry has also begun a systematic engagement of the public work force and education systems to ensure that the energy and construction sectors are viewed as a priority in state-based work force development and education programs.

**Question Number:** 11-7

**Question/Comment:** The nuclear renaissance will obviously require a large number of well educated new people to enter the nuclear business. Generally, how is the supply of suitably qualified candidates today in the U.S. as compared with the demand of the nuclear sector? Does NRC have any responsibility to support the national educational system in the nuclear field and in that case what is done to that effect?

**Response:** See response to Question 11-6. The ORISE report on Labor Market Trends for Nuclear Engineers Through 2010 and the Labor Market Outlook for Health Physicists Updated Through 2010 both confirm that the available U.S. civilian labor supply of new nuclear engineering graduates and health physicists is substantially less than the number of

job openings. For example, there will be approximately 2 to 3 job openings per each new health physicist graduate available in the labor supply through 2010 and over 2 job openings per nuclear engineering graduate available in the labor supply even though there has not yet been a rapid increase in retirements or industry growth. Competition for graduates in these fields will be even greater if the retirement rate increases and/or there is considerable growth in the nuclear-related fields.

NRC believes it is in the national interest for industry and government to anticipate these shortages and provide expanded funding to support these university programs. Early increases in funding can potentially offset the long-term impacts. In FY 2007, the NRC Nuclear Education Grant Program provided approximately \$4.7 million in grants to higher education institutions to enhance curricula and increase teaching competencies related to nuclear safety, security, and environmental protection. An additional \$4.7 million is available for similar activities in FY 2008. Also in FY 2008, the NRC Nuclear Education Scholarship and Fellowship Program provides an additional \$15 million to support education in nuclear science, engineering, and related trades. These funds are to be used for college scholarships and graduate fellowships in nuclear science, engineering, and health physics; faculty development grants supporting faculty in these academic areas; and scholarships for trade schools in the nuclear-related trades.

Also, the U.S. nuclear power industry has initiated activities to assess and meet the continuing need for educated and experienced workers to operate the nation's nuclear power plants and to plan for the additional workforce demands of new plant construction. Industry-wide staffing surveys have been periodically conducted to assess workforce projections for degreed engineers, power plant operators, technicians, and craft workers. Collaborations and partnerships have been developed between utilities, industry organizations, government, organized labor, educational institutions, vendors, and others to target areas requiring immediate and ongoing attention. Executive oversight groups and industry task forces were formed to develop strategies and activities directed at ensuring sufficient numbers of qualified workers. Working meetings and conferences have been conducted to share information, operating experience, and to develop action plans to carry out identified strategies.

In addition, programs have been developed to target and retain key existing employees, to capture and assure knowledge transfer, and to quickly train and qualify new employees for entry into the existing workforce. Recruiting efforts have been increased to raise awareness of nuclear careers among students, career counselors, and human resource professionals and to identify other labor sources such as veterans and minorities. Governmental and industry funding continues to support U.S. nuclear engineering education (university and college infrastructures, faculty, research reactors, students) through special grants, and undergraduate scholarships and graduate fellowships. The industry has

also begun a systematic engagement of the public work force and education systems to ensure that the energy and construction sectors are viewed as a priority in state-based work force development and education programs.

**Question Number:** 11-8

**Question/Comment:** The National Academy for Nuclear Training holds courses and seminars for Board Members and executive staff. How many of the relevant persons are attending these courses?

**Response:** INPO, in partnership with the Goizueta Business School of Emory University, designed and conducted The Impact of Governance on the Nuclear Power Industry, a first-of-a kind nuclear education course for directors and officers of companies with nuclear electric generating assets. During the two-day program, participants hear best practices from corporate and government leaders who bring a depth of experience and expertise to the key areas of governance, oversight, and nuclear safety.

The conference focuses on strategies that board members and offices can use to work together in support of their informed governance role in commercial nuclear electric corporations. Participants concentrate on proactive ways to integrate independent oversight responsibilities. Drawing on the diverse experiences of board members and executives, this program addresses how to ensure independent oversight, while strengthening the nuclear safety culture. Two of these programs, conducted in 2006 and 2007 on the Emory campus, attracted 84 participants representing 22 U.S. utilities and 5 international utilities.

Attendance is limited to CEOs, directors, board members, director nominees, and officers who work with their company's board. The participants are drawn from companies with nuclear electric generating assets. The next conference is scheduled for September 8-10, 2008.

**Question Number:** 11-9

**Question/Comment:** It is mentioned that an e-learning system has been launched offering 90 generic and site-specific courses. In Sweden similar efforts have started at the plants but there is also a discussion on the important balance between practical teacher-led training and the use of web-based technologies. Are there any similar discussions/cautions in the US?

**Response:** Yes, there is recognition that there needs to be balance between knowledge gained through web-based or other delivery methods and hands-on learning. Therefore, the goal of the National Academy for Nuclear Training e-learning system is to efficiently provide common, generic training primarily for plant access that can be completed remotely or when first arriving on-site. This training is typically reinforced through site specific practical labs, performance demonstrations, or with supervisory coaching conducted by site training or line personnel before allowing workers into the plant. For example, supplemental personnel completing initial radiation worker training on the NANTeL system are



required to participate in radiation worker practical labs at the site to demonstrate proper work practices before performing work in a radiologically controlled area.

## 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) human factors information system, (6) support to event investigations and for-cause inspections, and (7) training. This section also discussed research activities.

**Question Number:** 12-1

**Question/Comment:** Relating to the Human Performance Programs, the report states that "Two ongoing activities include developing regulatory guidance for reviewing designs of control stations and processing requests related to deregulation." (page. 79) What is the time table for developing regulatory guidance?

**Response:** The primary documents used as regulatory guidance for reviewing designs of control rooms are Chapter 18 of the Standard Review Plan, NUREG-0800, which references NUREG-0700, "Human System Interface Design Review Guideline," Revision 2, issued May 2002, and NUREG-0711, "Human Factors Engineering Program Review Model, Revision 2" issued February 2004. These documents are revised periodically based on the availability of new information and feedback from users.

Recently industry and vendor representatives have indicated that there is a need to enhance some aspects of human machine interface guidance to cope with licensing of new reactors. This has led to the development of certain Interim Staff Guidance (ISG) documents for Computer-based Procedures and Minimum Inventory of alarms, displays, and controls which were published in September 2007 and plans to publish additional ISGs on Manual Operator Actions in 2009.

As a means to make these ISGs final, they will be incorporated into an update to NUREG-0711 and NUREG-0700. Currently the schedule calls for initiating these revisions in 2009 with an implementation period of about three years.

**Question Number:** 12-2

**Question/Comment:** As one of the ongoing activities for developing regulatory guidance, the report states that "With regard to deregulation, the NRC has been processing numerous industry requests to transfer operating licenses, which may involve changes in organizational structure affecting human performance." (page. 79) In this sentence, what's the relationship between the deregulation and changing in organizational structure affecting human performance"?

**Response:** There is no relationship between deregulation and changing organizational structure affecting human performance. Any change in organizational structure is related to the transfer of the operating license.

**Question Number:** 12-3

**Question/Comment:** In inspection at the Perry Nuclear Power Plant to assess human performance, the evaluation included observing the use of human performance error prevention tools, observing supervisors' use and reinforcement of these tools, and reviewing the licensee's performance indicators (page. 84). In this sentence, what are the human performance error prevention tools? Please give some detail information about tool including the contents, methods, etc.

**Response:** The "human performance error prevention tools" referred to in the NRC staff's inspection of the Perry Nuclear Power Plant include, but are not limited to, self-checking, peer checking, independent verification, pre-job briefings, and three-way communications. During its inspection, the NRC staff evaluated the effectiveness of these error prevention tools while plant personnel performed surveillance, maintenance and operational tasks in the field and the control room. The staff also noted that the Perry facility reinforced the use of these tools in its training program so that operators and other workers practice these techniques as much as possible in performing any task on site.

**Question Number:** 12-4

**Question/Comment:** The NRC while considering the human factors engineering issues evaluates design of the main control room and control centers outside of the main control room using Chapter 18 of NUREG-0800, NUREG-0700, "Human System Inter-face Design Review Guideline," On page 81 it is written, that no significant examples related to emergency operating and plant procedures were identified since 2004. The NRC staff with human factors expertise participated in an IP 95003 inspection at the Perry Nuclear Power Plant. The evaluation included observing the use of human performance error prevention tools during work activities in the plant, observing supervisors' use and reinforcement of these tools.

Is the re-assessment of human factors engineering design for main control room of "old NPP units" carried out? Do you have specific examples of the need to revise the main control room concept and update main control room panels? Could it be considered as the result of positive application experience or the absence of emergency situations when such instructions are needed? Could you give a few examples of such tools?

**Response:** 1) During the early 1980s, each licensee and applicant for an operating license was ordered to perform a review of their control room(s) and upgrade the human factors aspects as necessary. Part of that effort included a requirement to maintain this higher standard of human factors design over the long term. As a result, licensees of "old NPPs" (i.e.,

operating nuclear power plants) apply human factors design criteria to any modifications of the control room or remote shutdown facility involving human interfaces. Generally, these modifications have been small-scale replacements, usually due to obsolescence. A re-assessment of human factors engineering design for the main control room of "old NPP units" would not be carried out by the NRC unless new safety questions were involved, such as the ramifications of an analog-to-digital control room conversion.

2) No licensee has identified the need to revise the main control room concept and update its main control room panels. To date, licensees have made small-scale replacements, usually under the 10 CFR 50.59 review process. At most, system-level replacements have been proposed and reviewed, but thus far, no large-scale, conceptual changes to control rooms have been submitted to the NRC by any licensee of an operating plant.

**Question Number:** 12-5

**Question/Comment:** Within the Human Performance Program, are there any requirements on the licensees to use full scope simulators when testing new safety related equipment designs and technologies?

**Response:** Although some facility licensees do use their full-scope simulators to evaluate new equipment designs and procedures before they are implemented in the plant, there is no regulatory requirement to do so. Section 55.45(b) of 10 CFR Part 55, "Operators' Licenses," permits facility licensees to use a plant-referenced simulator (i.e., full scope simulator) to administer the operating tests required by Section 55.45(a), and Section 55.46 specifies a number of requirements regarding their use.

**Question Number:** 12-6

**Question/Comment:** Examples are given related to Fort Calhoun and Ginna NPPs where licensees propose to credit manual action for actuation of safety functions. How is this justified from a human factors point of view?

**Response:** The NRC reviews changes in human actions (HAs), such as those that are credited in nuclear power plant safety analyses. Changes in credited HAs may result from a variety of plant activities such as plant modifications, procedure changes, equipment failures, justifications for continued operations, and identified discrepancies in equipment performance or safety analyses. Relevant considerations for review are described in NRC information notices and generic issues. NRC Generic Letter 91-18 discusses the conditions under which manual actions may be used in lieu of automatic actions for safety-system operations. NRC Information Notice 97-78 alerts licensees to the importance of considering the effects on human performance of such changes made to plant safety systems. NRC guidance for use in determining the appropriate level of human factors engineering (HFE) review of HAs based upon their risk-importance. The guidance uses a graded, risk-informed approach that is consistent with NRC Regulatory Guide (RG) 1.174, Rev. 1. As such, this

guidance uses risk insights to determine the level of regulatory review the staff should perform. This approach can be accomplished for licensee submittals that are either risk-informed or non-risk-informed. Human actions that are considered more risk-significant receive a detailed review, while those deemed less significant receive a less detailed review. The terms "human action" and "operator action" are used synonymously because most of the types of actions addressed are performed by operations staff. In keeping with RG 1.174, the guidance does not preclude licensees from using other approaches in requesting changes to a plant's licensing basis or HAs. In fact, in the two examples cited (Fort Calhoun and Ginna), the licensees chose to use the methodology described in ANSI/ANS 58.8, "Time Response Design Criteria for Safety-Related Operator Actions". The risk-based method of reviewing HAs, described here, is intended to improve consistency in future regulatory reviews and decisions. The guidance uses a two-phased approach to reviewing HAs. Phase 1 is a risk screening and analysis of the affected HAs identified by the licensee to determine their risk-importance and the level of HFE review that is appropriate in Phase 2. The second phase is an HFE review of those HAs that are found to be risk-important.

The proposed human actions are assigned to one of three risk levels (high, medium, and low) as a result of Phase 1. The level of human factors engineering review in the second phase corresponds to these risk levels. In the second phase, human actions are reviewed using standard human factors engineering criteria to ensure the appropriate conditions are in place so that the change in human action does not significantly increase the potential for risk. Human actions in the high risk level receive a detailed human factors engineering review, while those in the medium risk level undergo a less detailed review, commensurate with their risk. For human actions in the low risk level, there is a minimal human factors engineering review or none. The final result of the human factors engineering review provides input to integrated decision-making and a safety evaluation report.

**Question Number:** 12-7

**Question/Comment:** Considering the aging of NPP staff, are any long term staffing plans required of the licensees?

**Response:** Regarding workplace aging of nuclear power plant staff, the NRC has no requirements that utilities implement any long-term staffing plans. Industry groups that represent the nuclear industry, such as the Institute of Nuclear Power Operations (INPO) and Nuclear Energy Institute (NEI), are keenly aware of the long-term staffing issue. The industry groups have several initiatives underway, but generally do not impose requirements on the utilities.

INPO considers utility attention to this issue to be an essential good business practice. During INPO accreditation visits, it reviews the utilities'

plans to maintain sufficient numbers of qualified personnel and looks at their ability to deliver the training to meet those demands.

NEI has an ongoing comprehensive program in the workforce area. This program includes systematic analysis of workforce trends and requirements, outreach efforts to attract new workers, development of educational programs to develop workers, recruitment programs and other strategies that address the policy environment affecting workforce development. These programs incorporate broad partnerships on a national, regional and local basis. In addition, the industry is engaged in efforts to improve employee retention, development, knowledge transfer, and diversity in the workforce.

One example of these programs is a state-based initiative for nuclear, energy, and construction workforce development that includes 12 state-wide consortia working to develop the future energy workforce. In addition, there is a regional consortium focused on nuclear workforce development in the Great Lakes Region. These consortia bring together industry, educational institutions, organized labor and the public sector to develop workforce solutions that meet local, state, and regional needs.

See response to question 11-2 for additional information regarding NRC staffing requirements.

**Question Number:** 12-8

**Question/Comment:** Only NRC activities concerning already existing licenses are discussed. What activities does NRC conduct concerning (plans for) new builds?

**Response:** The NRC's Office of New Reactors (NRO) is responsible for accomplishing key components of the NRC's nuclear reactor safety mission for new reactor facilities licensed in accordance with 10 CFR Part 52. The Operator Licensing and Human Performance Branch (COLP) within NRO is responsible for establishing rules, standards, plans, and policy in the areas of human performance, safety culture, training, and operator licensing for new light water reactors.

Specifically in the area of human factors engineering, the NRC evaluates the human factors engineering design of the main control room and control centers outside the main control room using, as principal review and evaluation sources, NUREG-0800, Chapter 18.0, "Human Factors Engineering," NUREG-0711, "Human Factors Engineering Program Review Model," and NUREG-0700, "Human System Interface Design Review Guidelines." In addition, COLP uses NRC Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)" and NRO-REG-100, "Acceptance Review Process for Design Certification and Combined License Applications," and Interim Staff Guidance (ISG)-105, "Minimum Inventory." Regulatory Guide 1.206 is primarily a document for the U.S. nuclear power industry which provides guidance for submitting a combined license application for a nuclear power plant under Title 10, Part 52, "Licenses, Certification, and Approvals for Nuclear Power Plants." NRO-REG-100 is guidance to the

NRC for conducting acceptance reviews for design certifications of new plants and combined license applications. Interim Staff Guidance (ISG)-105, is a document that describes the minimum inventory of human system interfaces (alarms, controls, and displays) needed to achieve and maintain the plant in a safe shutdown condition in the event of a catastrophic failure of primary plant instrumentation.

The overall purpose of the NRC's human factors engineering (HFE) review for new plant designs is to verify that:

- The applicant has integrated HFE into plant development, design, and evaluation.
- The applicant has provided HFE products (e.g., HSIs, procedures, and training) that allow safe, efficient, and reliable performance of operation, maintenance, test, inspection, and surveillance tasks.
- The HFE program and its products reflect "state-of-the-art human factors principles" and satisfy all specific regulatory requirements.

Standard Review Plan (SRP) Chapter 18 identifies 12 areas of review for successful integration of human characteristics and capabilities into nuclear power plant design. These areas of review correspond to the 12 elements of an HFE program identified in NUREG-0711.

- HFE Program Management
- Operating Experience Review
- Functional Requirements Analysis and Function Allocation
- Task Analysis
- Staffing and Qualifications
- Human Reliability Analysis
- Procedure Development
- Training Program Development
- Human-System Interface Design
- Human Factors Verification and Validation
- Human Performance Monitoring

In addition to the 12 elements of NUREG-0711, the NRC evaluates the applicant's proposed minimum inventory of alarms, controls, and displays. The concept of minimum inventory was proposed by the NRC because detailed design information is not likely to be available for NRC staff review for areas such as advanced instrumentation and controls and control room design at the time of an application for a new plant's design certification.

The same regulatory criteria are applicable to all areas of review. 10 CFR 52.47 requires that applications for design certification of new reactor designs meet the technically relevant portions of the Three Mile Island (TMI) requirements contained in 10 CFR 50.34(f). The NRC bases its HFE review on current regulatory requirements established post-TMI in 10 CFR 50.34(f), "Additional TMI-Related Requirements." The NRC reviews HFE aspects of new control rooms to verify that they reflect "state-of-the-art human factors principles" as required by 10 CFR

50.34(f)(2)(iii) and that personnel performance is appropriately supported. 10 CFR 50.34 also requires a safety parameter display system (SPDS), automatic indication of bypassed and operable status of safety systems, and monitoring capability in the control room of a variety of system parameters.

For plants licensed under 10 CFR Part 52, the requirements of 10 CFR 50.34(f) are incorporated via 10 CFR 52.47 and 10 CFR 52.79. Meeting these requirements provides evidence that plant design, staffing, and operating practices are acceptable and that plant safety will not be compromised by human error or by deficiencies in human interfaces, considering both hardware and software.

The staff may perform three different levels of review, depending on the type of information provided by an applicant: complete element level, implementation plan level, and programmatic level.

A “Complete Element” level of review is performed when the applicant has completed and submitted for staff review, the HFE activity. The review is completed when the applicant has acceptably met all of the NUREG-0711 criteria.

An “Implementation Plan” level of review is performed when the applicant has not completed an HFE activity. Page 2 of NUREG-0711 states the following: “An implementation plan gives the applicant’s proposed methodology for meeting the acceptance criteria of the element. An implementation plan review gives the applicant the opportunity to obtain staff review of and concurrence in the applicant’s approach before conducting the activities associated with the element. Such a review is desirable from the staff’s perspective because it provides the opportunity to resolve methodological issues and provide input early in the analysis or design process when staff concerns can more easily be addressed than when the effort is completed.” At a later date the staff reviews the results of the HFE activities conducted in accordance with the completed implementation plans. This may occur during the design certification (DC) review, the COL application review, or through the inspection, test, analysis, and acceptance criteria (ITAAC) closure process.

For a “Programmatic” level review, the staff uses the NUREG-0711 criteria to determine whether the applicant’s documentation provides a top-level identification of the substance of each criterion. This level of review is used when an applicant has not developed the methodology for performance of an HFE activity in sufficient detail to conduct an implementation plan review. When an HFE activity is reviewed at the programmatic level, the staff reviews the detailed implementation plan and the results of the HFE activities conducted in accordance with the implementation plan at a later date when they are completed.

To date, the NRC has applied its human factors engineering design review criteria to the certification of four new plant designs. The NRC staff is currently applying its human factors engineering review guidance and



evaluation process to the review of HFE programs for four design certification applications and several combined license applications.

**Question Number:** 12-9

**Question/Comment:** On page 81 it is written, that no significant examples related to emergency operating and plant procedures were identified since 2004.

Question:

Could it be considered as the result of positive application experience or the absence of emergency situations when such instructions are needed?

**Response:**

As stated in Article 12, Section 12.3.2, after the NRC issued Generic Letter 82-33, each licensee and applicant for an operating license submitted its proposed program for developing emergency operating procedures (EOPs). Generally, these program plans were based on consensus documents developed by the various owners' groups, e.g., Boiling Water Reactors Owners' Group, Westinghouse Owners' Group, Combustion Engineering Owners' Group. However, all of the EOPs were based on a common concept of using symptoms as entry conditions and not requiring event diagnosis to identify the correct procedure and entry point. These EOPs have been exercised frequently during simulator training and operator licensing examinations, and occasionally during actual plant events. They are very robust, and as a result, there has been no need to revise the general concept of symptom-based procedures. The revisions that have been reviewed by the NRC have been associated with changes to the facilities' Technical Specifications. No licensees or owners' groups have requested or proposed an alternative to the overall concept of symptom-based EOPs. Moreover, reactor vendors and applicants are adhering to the same symptom-based EOP approach in their new reactor designs that are currently being reviewed by the NRC for possible certification or licensing.

**Question Number:** 12-10

**Question/Comment:** The NRC staff with human factors expertise participated in an IP 95003 inspection at the Perry Nuclear Power Plant. The evaluation included observing the use of human performance error prevention tools during work activities in the plant, observing supervisors' use and reinforcement of these tools.

Question:

Could you give a few examples of such tools?

**Response:**

The "human performance error prevention tools" referred to in the NRC staff's inspection of the Perry Nuclear Power Plant include, but are not limited to, self-checking, peer checking, independent verification, pre-job briefings, and three-way communications. During its inspection, the NRC staff evaluated the effectiveness of these error prevention tools while plant personnel performed surveillance, maintenance and operational

tasks in the field and the control room. The staff also noted that the Perry facility reinforced the use of these tools in its training program so that operators and other workers practice these techniques as much as possible in performing any task on site.

## 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 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.

**Question Number:** 13-1

**Question/Comment:** Is there any practice that ISO14000 or ISO18000 is adopted by licensee in addition to ISO9001? What is the requirement and opinion of NRC for these international standards?

**Response:** NRC does not require licensees to adopt any ISO standard. NRC addressed ISO 9001 in SECY-03-0117 "Approaches for Adopting More Widely Accepted International Quality Standards." Licensees are required to Meet Appendix B to 10 CFR Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. The NRC also endorses American Society of Mechanical Engineers (ASME) standard NQA-1 guidance through Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)."

**Question Number:** 13-2

**Question/Comment:** It is said in the report that licensees perform self-assessments and the NRC reviews descriptions of their QA programmes and inspects the programme implementation. Does the NRC review or inspect licensees' self-assessments as well as their QA programmes and its implementation?

**Response:** Yes, during the conduct of IP71152, "Identification and Resolution of Problems," the staff periodically examines licensee self-assessments on a sample basis. The staff will primarily evaluate the adequacy of the licensee measures to address discrepant conditions identified during their self-assessments. The inspections assess whether licensee self-assessments and audits are effective at identifying issues, and whether those issues are evaluated and resolved by the licensee commensurate with their safety significance.

IP71152 can be located on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>.

**Question Number:** 13-3

**Question/Comment:** It is said in the report that applying QA controls to important-to-safety yet non-safety-related equipment is called augmented quality control. Please show some of this important-to-safety equipment and their safety importance. How is risk information utilized to select that equipment?

**Response:** Examples of equipment important-to-safety” can be found in NRC regulations related to Station Blackout (SBO): 10 CFR Part 50.63 and Anticipated Transients Without Scram (ATWS): 10 CFR Part 50.62. These rules were developed and back-fitted to all licensees based on risk information.

**Question Number:** 13-4

**Question/Comment:** Section 13.4 states that in specific cases, the NRC has specified that QA controls are warranted for equipment determined to be more important than commercial grade equipments. Please clarify whether augmented quality control for this important-to-safety equipment is addressed in the licensee's quality assurance programme, if so, what are the NRC review criteria for the above description?

**Response:** The NRC requires that licensees address augmented quality control for equipment that is important-to-safety in their quality assurance program. NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” Section 17.5, “Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants,” establishes the criteria that the NRC uses to evaluate whether a licensee meets the NRC's regulations for safety related, as well as, important-to-safety equipment. In addition, regulatory guidance for augmented quality can be found in other documents such as Regulatory Guide 1.155 “Station Blackout;” Appendix A “Quality Assurance Guidance for Non-Safety Systems and Equipment.”

**Question Number:** 13-5

**Question/Comment:** On page 86 it is written, that as identified in 10 CFR 21.41, NRC staff performs inspections at vendors who supply basic components to the nuclear industry.

Is it possible conclude, that NRC staff permanently carrying out inspections and control (in control points) at the vendor's sites as well equipment acceptance or use to do this periodically? Is there such a programme of inspections by NRC staff? What safety class of equipment is subjected for such inspections and control by NRC staff?

**Response:** 1) The NRC's regulations require that licensees ensure that all safety-related equipment used in nuclear power plants will perform its intended safety function. The nuclear utilities have the responsibility under 10 CFR Part 50, Appendix B, for audits and surveillances at control points at vendor's sites as well as equipment acceptance. Utility licensees are responsible for the day-to-day operation of the nuclear power plants,

which includes equipment acceptance. In addition, see the following response to your second question.

The NRC has the complete regulatory framework to inspect suppliers, require utilities to audit suppliers, and enforce the regulations to ensure the quality of parts used in nuclear power plants. The NRC has a formal inspection process and associated inspection procedures in place for inspecting nuclear suppliers. The NRC conducts periodic, independent inspections of suppliers in response to Operating Experience reports and potential concerns raised by individuals, including members of the public.

Any equipment that is supplied as a basic component, as defined in 10 CFR Part 21, is subject to inspection by the NRC. The NRC has the authority to inspect these nuclear suppliers and licensees. Control of this equipment is maintained by the nuclear suppliers and licensees. The NRC will take enforcement action against these suppliers and licensees when they are found to not comply with the regulations.

**Question Number:** 13-6

**Question/Comment:** Licensees perform a variety of self-assessments to validate the effectiveness of their QA programme implementation. To what extent does NRC review these internal audits/self-assessments?

**Response:** Yes, during the conduct of IP71152, "Identification and Resolution of Problems," the staff periodically examines licensee self-assessments on a sample basis. The staff will primarily evaluate the adequacy of the licensee measures to address discrepant conditions identified during their self-assessments. The inspections assess whether licensee self-assessments and audits are effective at identifying issues, and whether those issues are evaluated and resolved by the licensee commensurate with their safety significance.

IP71152 can be located on the NRC public website at:

<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>.

**Question Number:** 13-7

**Question/Comment:** Please explain whether the recent IAEA Safety Requirements GS-R-3 will be used in the U.S. to benchmark, modify or define supplementary requirements on Management Systems for the licensees.

**Response:** The NRC does not currently have plans to use GS-R-3 in the regulatory framework for quality assurance.

**Question Number:** 13-8

**Question/Comment:** The report describes a license applicant's QA programme as covering "...design, fabrication, construction, and testing of safety-related plant equipment." Does the use here of the word "testing" refer to the testing of

components, or is the meaning intended to be broader, covering also the commissioning of the systems into which the tested components might be fitted? Note that the word “commissioned” is not included in various phases listed in the first line of Section 13.1, nor is “commissioning” explicitly referred to elsewhere in the report under Article 13 (although it is referred to under Article 14). Is there any regulatory guidance, for example in NUREG-0800 or elsewhere, on the application of QA to commissioning activities? Could NRC provide the relevant references?

**Response:**

In this context, the term “commissioning” corresponds to “licensing” as used within the NRC regulatory framework. Accordingly, the word “testing” refers to both the testing of components as well as the commissioning of the systems into which the tested component is installed.

Each applicant for a combined license is required by 10 CFR 52.79(a)(25) [formerly 10 CFR 52.79(b)] to describe a Quality Assurance (QA) program in its final safety analysis report. The program must meet the requirements for QA programs for nuclear power plants which are set forth in Appendix B to 10 CFR Part 50. Criterion XI, “Test Control,” of Appendix B to Part 50 requires that a test program be established to assure that all testing required to demonstrate that safety-related structures, systems, and components (SSCs) will perform satisfactorily in service is identified and performed in accordance with written procedures. License applicants are required by 10 CFR 52.79(a)(28) to include plans for initial (preoperational and initial operations) testing in the application. Testing of individual components as well as integrated systems is completed under the initial test program.

Regulatory guidance to license applicants on the contents of the initial test programs is contained in Regulatory Guide 1.68, “Initial Test Programs for Water-Cooled Nuclear Power Plants,” Revision 3, March 2007. ([www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/active/01-068/01-068.pdf](http://www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/active/01-068/01-068.pdf)) Guidance for staff review of an applicants initial test program is located in NUREG-800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” Chapter 14.2, “Initial Plant Test Program - Design Certification and New License Applicants,” Revision 3, March 2007. ([www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/ch14/](http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/ch14/))

The latest guidance for the application of QA to licensing activities is provided in the following documents: NUREG-800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” Chapter 17, “Quality Assurance,” Revision 3, March 2007 (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/ch17/>); Regulatory Guide 1.28, “Quality Assurance Program Requirements (Design and Construction),” Revision 3, August 1985; and, Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation),” Revision 2, February 1978. Regulatory Guides 1.28 and 1.33 endorse consensus standards in the ANSI N45.2 series, ASME NQA-1 series, and

N18.7-1976 standard as acceptable ways of complying with the requirements of Appendix B to 10 CFR Part 50.

## 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 for the period of extended operation. It focused on assessments performed to maintain the licensing basis of a nuclear installation. Finally, this section explained verification of the physical state 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.

**Question Number:** 14-1

**Question/Comment:** Under Section 6.3.5, paragraph 2, how does the NRC evaluate the relative safety-significance of existing and emerging issues for existing NPPs (for example, does the NRC apply a risk-informed decision process or screening process)?

**Response:** The Operating Experience (OpE) Clearinghouse meets regularly to review various OpE data inputs and make decisions based on safety significance to determine if further evaluation is warranted. The Clearinghouse reviews, or “screens” new 10 CFR Part 50.72 reactor event notifications, preliminary notifications, 10 CFR Part 21 notifications of defects and non-compliance, plant status information, 10 CFR Part 50.73 licensee event reports (LERs), NRC inspection report findings, and international events. The intent of the OpE program is to determine which issues are potentially safety significant and generic, evaluate those issues, and make recommendations for any further actions the agency should take.

In making a screening decision, the Clearinghouse considers the potential safety significance using a systematic process that applies both quantitative (i.e., risk) and qualitative (i.e., potential generic implications, adverse trends, new phenomena) factors to the decision making process.

After OpE information is “screened in” as safety significant and communicated to various stakeholders, it is then evaluated to clearly



determine the extent of its impact on plant operation, safety and generic applicability. The evaluation of OpE information has two objectives. The first is to assess the significance of the issue and to glean important OpE lessons learned. The second is to make recommendations on what further actions, if any, the NRC should take to apply the lessons learned from the issue. Such actions may consist of: (1) communicating OpE lessons learned to various internal and/or external stakeholders through reports, briefings, email listservs or generic communications, (2) taking a regulatory action through a generic communication to require responses from the licensees or issuing orders for actions, and (3) influencing agency programs such as inspection, oversight, licensing, incident response, security, rulemaking, and research. Application of OpE lessons learned always involves communication of the issue to internal stakeholders. Less common outcomes of operating experience issue recommendations are rulemaking or transfer to the agency generic safety issues program.

**Question Number:** 14-2

**Question/Comment:** In Section 14.1.2.1, paragraph 3, the report states that “Research has concluded that aging phenomena are readily manageable and do not pose technical issues that would preclude life extension for nuclear power plants. Studies have also found that facilities deal adequately with many aging effects during the initial license period, and credit should be given for these existing programmes, particularly those under NRC’s Maintenance Rule (10 CFR 50.65), which helps manage plant aging.” Who carried out the research and studies that support this paragraph, and when? How were their conclusions judged to support license renewal?

**Response:** The research referred to in Section 14.1.2.1 is a generic term describing a compilation of research activities conducted by the U. S. Nuclear Regulatory Commission, the Department of Energy, the Electric Power Research Institute, the nuclear industry, contractors, etc. This effort was conducted over the time frame from issuance of the Maintenance Rule in 1991 through the second revision of the Generic Aging Lessons Learned report in 2005. The Maintenance Rule, in relation to license renewal, is used primarily in the aging management of structures.

In NUREG-1705, “Safety Evaluation Report Related to the License Renewal of Calvert Cliffs Nuclear Power Plant, Units 1 and 2,” the NRC found that the scope of the review did not allow sufficient credit for existing programs, particularly the implementation of the maintenance rule, which also manages plant aging phenomena. NUREG-1739 “Analysis of Public Comments on the Improved License Renewal Guidance Documents,” states: “The Commission has determined that the license renewal rule should credit the existing maintenance rule including the area of scoping for most SSCs when applicable. This is in accordance with the first principle of license renewal, i.e., the reliance on the current regulatory process to protect the public health and safety except for age-related degradation issues. Therefore, an applicant should exercise credit

for both the scoping of SSCs and programs developed for the maintenance rule in addressing compliance with the license renewal rule to the extent possible within the guidelines of license renewal.” NUREG-1833, “Technical Bases for Revision to the License Renewal Guidance Documents,” lists the Maintenance Rule Structures Monitoring as an aging management program, which led to the incorporation of the Maintenance Rule as an aging management program in NUREG-1801, Vol. 2, Rev. 1, “Generic Aging Lessons Learned (GALL) Report.”

**Question Number:** 14-3

**Question/Comment:** The report indicates that license renewal requirements for power reactors are based on two key principles, one of which is “When continued into the extended period of operation, the regulatory process, which assesses and verifies safety, is adequate to ensure that the licensing basis of all currently operating plants provides an acceptable level of safety. The possible exception is detrimental effects of aging on certain SSCs, and possibly a few other issues applying to safety only during the period of extended operation.” Please give examples of “detrimental effects of aging on certain SSCs” and other safety issues.

**Response:** Age-related degradation is the result of physical processes and a natural consequence of plant operation. Many plant systems, structures, and components (SSCs) have been designed for a 40 year life. The design of these SSCs has accounted for age-related factors such as fatigue, corrosion, and other effects of the environment to which the SSCs are exposed during at least this 40-year period, and are the detrimental effects of aging referred to in the question. However, since license renewal will result in operation of these SSCs beyond the 40 years assumed in their design, additional analyses and/or actions may be necessary to ensure that an acceptable level of safety is maintained during the period of extended operation.

Detrimental effects of aging are managed by the license renewal review through the use of the Generic Aging Lessons Learned (GALL) Report (NUREG-1801 Vol. 2). The GALL contains summary descriptions and tabulations of evaluations of aging management programs for a large number of SSCs. The evaluation process for the aging management programs and the application of the GALL report is described in the Summary, Volume 1, of the GALL report. Examples of detrimental effects of aging include: Changes in dimensions, Concrete cracking and spalling, corrosion of connector contact surfaces, crack growth, etc. A complete listing of the aging effects used in the GALL can be found in chapter IX section E- Aging Effects of the GALL Volume 2. Corresponding aging mechanisms can be found in chapter IX, section E- Significant Aging Mechanisms of the same document.

**Question Number:** 14-4

**Question/Comment:** In Section 14.1.3.4, last sentence, the report indicates that “license renewal applicants are required to complete an integrated plant assessment (IPA) and evaluate time-limited aging analyses.” Please explain the difference between the safety factors of an IPA and those of a periodic safety review (PSR) (e.g., under NS-G-2.10).

**Response:** The integrated plant assessment (IPA) is a licensee assessment that demonstrates that a nuclear power plant facility's structures and components requiring aging management review in accordance with Title 10 of the Code of Federal Regulations (10 CFR) Part 54.21(a) for license renewal have been identified and that the effects of aging on the functionality of such structures and components will be managed to maintain the current licensing basis (CLB) such that there is an acceptable level of safety during the period of extended operation. An IPA identifies and lists structures and components subject to an aging management review (AMR). These include "passive" structures and components that perform their intended function without moving parts or without a change in configuration or properties. These include such components as the reactor vessel, the steam generators, piping, component supports, seismic Category I structures, etc. To be in scope, the item must also be "long-lived" to be considered during the license renewal process. Long-lived means the item is not subject to replacement based on a qualified life or specified time period.

Compared to the periodic safety review (PSR), which is broadly scoped in the form of 14 identified safety factors, the IPA has a narrower scope, and is focused more on systems, structures, and components which are passive and “long-lived”. The IPA does not address active components with moving parts, nor does it address systems, structures and components which are normally covered by the reactor oversight process (ROP) or covered under other regulatory criteria. The IPA does not address these other systems, structures, and components because of the rigorous requirements of the existing ROP and the rest of the inspection program which ensure their performance on a continual basis.

**Question Number:** 14-5

**Question/Comment:** Can you clarify how the current regulations for license renewal are connected to the 20 year potential extension? Are these regulations potentially applicable to a second round of applications for renewal beyond 60 years?

**Response:** Title 10 of the Code of Federal Regulations (10CFR) part 54.31(d) states the following: “(d) A renewed license may be subsequently renewed in accordance with all applicable requirements”, thereby allowing subsequent license renewal extensions beyond the initial period of extended operation. The Atomic Energy Act of 1954 originally specified that licenses for commercial power reactors be granted for a period not exceeding 40 years. However, with the NRC regulations, this period of operation can be extended for a fixed period of time. That fixed period is

the sum of the additional amount of time the applicant requests for license renewal (not to exceed 20 years) plus the remaining number of years on the operating license currently in effect up to a maximum of 20 years. In other words, if a license renewal is granted, the plant will be licensed for the remainder of the time on its current license (20 years or less) plus the renewal time of up to 20 years. In no case, however, may the term of the license, which includes the remaining portion of the original license plus the extension, exceed 40 years.

Initiatives are already under way to more clearly identify regulations that will be affected by an additional license extension period. This will be done by utilizing past experience, regulatory and technical analyses. However, current regulations do not identify any changes in regulations between applications for renewal beyond 60 years, and initial license renewal applications. If, in the future, issues are identified in the license renewal process which has been found to require additional regulatory attention, then we will address those issues by amending the regulations.

**Question Number:** 14-6

**Question/Comment:** It is said in the report that the backfit rule requires a cost-benefit backfit analysis and economic costs will not be considered in case of ensuring compliance with NRC requirements. Please show some examples where a cost-benefit backfit analysis and economic costs are considered as well as cases where those are not considered.

**Response:** Two examples of backfits where a cost-benefit analysis was made are in rulemakings. One is an amendment to an existing rule and one is a proposed rulemaking. The amendment is to 10 CFR Part 26, "Fitness-for-Duty." The regulatory analysis for this amendment can be viewed at ADAMS Accession No. ML062780211. The regulatory analysis, which presents the results of the backfit cost-benefit analysis, concluded that the costs of the rule are justified by the substantial increase in the protection of public health and safety provided by the rule. The proposed rulemaking referred to above is for 10 CFR Part 73, "Power Reactor Security Requirements." The draft regulatory analysis and backfit analysis for this can be viewed at ADAMS Accession No. ML061920112. The regulatory analysis, which presents the results of the backfit cost-benefit analysis, concluded that the costs of the rule are justified in view of the qualitative benefits.

Two examples of cases where economic costs were not considered for backfits are discussed in NRC Generic Letters (GL) 2004-02 and GL 99-02. For GL 2004-02, "Potential Impact of Debris Blockage on Emergency Recirculation During Design Basis Accidents at Pressurized-Water Reactors," replies were required of licensees regarding the request in the GL that addressees perform an evaluation of their emergency core cooling system and containment spray system recirculation functions and, if appropriate, to take additional actions to ensure system function. This GL includes a backfit discussion which indicates that the information requested is considered to be a compliance exception to 10 CFR 50.109,

“Backfitting.” This means that the NRC need not justify the backfit on a cost-benefit basis. In GL 99-02, “Laboratory Testing of Nuclear-Grade Activated Charcoal,” the NRC asked that actions be taken and information submitted which would enable the NRC staff to make a determination that addressees are testing the nuclear-grade activated charcoal of their engineered safety features ventilation systems in accordance with a suitable testing standard to ensure that the charcoal filters are capable of performing their required safety function and that the licensing bases of their respective facilities regarding onsite and offsite dose consequences continued to be satisfied. This GL also includes a backfit discussion which indicates that the information requested is considered to be a compliance exception to 10 CFR 50.109, “Backfitting.” Again, this means that the NRC need not justify the backfit on a cost-benefit basis. These Generic Letters and others may be accessed from the NRC’s public web site at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/>.

**Question Number:** 14-7

**Question/Comment:** According to the 10 CFR 50.59, a licensee shall obtain a license amendment in case that a proposed change, test or experiment would result in more than a minimal increase in the frequency of occurrence of an accident and malfunction etc. Therefore, how does a licensee evaluate the possibility of occurrence and how do you define the "minimal increase" in section 14.1.1.1?

**Response:**

**1. MORE THAN A MINIMAL INCREASE IN THE FREQUENCY OF OCCURRENCE OF AN ACCIDENT**

Defined either quantitatively or qualitatively. It normally is more than a 10% increase, or when the frequency does not remain below 10E-6 per year.

For most licensees, accidents and transients have been divided into categories based upon a qualitative assessment of frequency. For example, American National Standards Institute (ANSI) standards define the following categories for plant conditions for most Pressurized Water Reactors (PWRs) as follows:

- Normal Operations: Expected frequently or regularly in the course of power operation, refueling, maintenance or maneuvering
- Incidents of Moderate Frequency: Any one incident expected per plant during a calendar year
- Infrequent Incidents: Any one incident expected per plant during plant lifetime
- Limiting Faults: Not expected to occur but could release significant amounts of radioactive material thus requiring protection by design

Since accident and transient frequencies were considered in a broad sense, a change from one frequency category to a more frequent

category is an example of a change that results in more than a minimal increase in the frequency of occurrence of an accident.

Changes within a frequency category could result in more than a minimal increase in the frequency of occurrence of an accident. Normally, the determination of a frequency increase is based upon a qualitative assessment using engineering evaluations consistent with the Updated Final Safety Analysis Report (UFSAR) analysis assumptions. However, a plant-specific accident frequency calculation or Probabilistic Risk Assessment (PRA) may be used to evaluate a proposed activity in a quantitative sense.

## **2. MORE THAN A MINIMAL INCREASE IN THE LIKELIHOOD OF OCCURRENCE OF A MALFUNCTION OF A SSC IMPORTANT TO SAFETY**

Defined either qualitatively or quantitatively. Normally is an increase of factor of 2 for a component or where stresses exceed code allowance.

Refers to the failure of Structures, Systems or Components (SSCs) to perform their intended design functions-including both nonsafety-related and safety-related SSCs. The cause and mode of a malfunction should also be considered in determining whether there is a change in the likelihood of a malfunction.

A determination is made as to what SSCs are affected by the proposed activity. The effects of the proposed activity on the affected SSCs should also be determined. Includes both direct and indirect effects.

Direct effects are those where the activity affects the SSCs (e.g., a motor change on a pump). Indirect effects are those where the activity affects one SSC which affects the capability of another SSC to perform its described design function. Indirect effects also include the effects of activities on the design functions of SSCs credited in the safety analyses. The safety analysis assumes certain design functions of SSCs in demonstrating the adequacy of design. Thus, certain design functions, while not specifically identified in the safety analysis, are credited in an indirect sense.

A determination is made of whether the likelihood of a malfunction of the important to safety SSCs has increased more than minimally. Qualitative engineering judgment or industry precedent is typically used to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense, if available and practical.

The effect of a proposed activity on the likelihood of malfunction must be discernable and attributable to the activity in order to exceed the more than minimal increase standard. An activity is considered to have a negligible effect on the likelihood of a malfunction when a change in likelihood is so small or the uncertainties in determining whether a change

in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed.

### **3. MORE THAN A MINIMAL INCREASE IN THE CONSEQUENCES OF AN ACCIDENT**

Consequences means radiological dose. More than minimal means more than 10% of the difference between the design-basis dose and the regulatory limit (if within Standard Review Plan (SRP) guidelines). More than 0.1 rem (if above SRP guidelines)

An increase in consequences involves an increase in radiological doses to the public or to control room operators.

Activities affecting on-site dose consequences that may require prior NRC approval are those that impede required actions inside or outside the control room to mitigate the consequences of reactor accidents. For changes affecting the dose to operators performing required actions outside the control room, an increase is considered more than minimal if the resultant "mission dose" exceeds applicable General Design Criteria (GDC) 19 criteria.

The dose consequences referred to in 50.59 are those calculated by licensees, and not the results of independent, confirmatory dose analyses by the NRC that may be documented in safety evaluation reports.

Example: If the regulatory limit is 300 rem and the licensing base dose is 25 rem, what is the maximum increase in dose that would not be more than minimal?

The maximum increase in dose would be 27.5 rem if you assume that there is no SRP limit. This is derived by taking the difference of the regulatory limit and the licensing basis value and multiplying the result by 0.10 (10%).  $(300 \text{ rem} - 25 \text{ rem}) \times 0.10 = 27.5 \text{ rem}$ . If it is assumed that the SRP limit is the typical 30 rem, then the maximum would be capped at that limit. Using this assumption the maximum increase allowed would be 5 rem.

Example: If the regulatory limit is 300 rem, the SRP guideline is 30 rem and the licensing basis dose is 33 rem, what is the maximum dose increase that is not more than minimal?

The maximum dose increase is 0.1 rem. Since the licensing basis dose (33 rem) is already above the SRP limit (30 rem), an increase of only 0.1 rem is permitted.

### **4. MORE THAN A MINIMAL INCREASE IN THE CONSEQUENCES OF A MALFUNCTION OF A SSC IMPORTANT TO SAFETY**

Consequences means radiological dose. More than minimal means more than 10% of the difference between the design-basis dose and the

regulatory limit (if within Standard Review Plan (SRP) guidelines). More than 0.1 rem (if above SRP guidelines)

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions previously evaluated have their radiological consequences affected as a result of the proposed activity. The next step is to determine if the proposed activity does, in fact, increase the radiological consequences and, if so, are they more than minimally increased. The guidance for determining whether a proposed activity results in more than a minimal increase in the consequences of a malfunction is the same as that for accidents. (See number 3)

#### **5. CREATE A POSSIBILITY FOR AN ACCIDENT OF A DIFFERENT TYPE**

The set of accidents a facility must postulate for purposes of safety analyses, including LOCA, other pipe ruptures, rod ejection, etc., are often referred to as "design basis accidents." The terms accidents and transients are often used in regulatory documents (e.g., in Chapter 15 of the SRP), where transients are viewed as the more likely, low consequence events and accidents as less likely but more serious. In the context of PRA, transients are typically viewed as initiating events, and accidents as the sequences that result from various combinations of plant and safety system response. This criterion deals with creating the possibility for accidents of similar frequency and significance to those already included in the licensing basis for the facility.

The basic principle applied in relating design requirements to each of the conditions is that the most frequent occurrences must yield little or no radiological risk to the public, and those extreme situations having the potential for the greatest risk to the public shall be those least likely to occur.

The possible accidents of a different type are limited to those that are as likely to happen as those previously evaluated. A new initiator of an accident previously evaluated is not a different type of accident.

An activity which increases the frequency of an accident previously thought to be incredible to the point where it becomes as likely as the accidents previously described could create the possibility of an accident of a different type.

Accidents of a different type are credible accidents that the proposed activity could create that are not bounded by previously evaluated accidents.

#### **6. MALFUNCTION OF AN SSC IMPORTANT TO SAFETY WITH A DIFFERENT RESULT**

A malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result



if the result or effect is the same as, or is bounded by, that previously evaluated.

An example of a change that would create the possibility for a malfunction with a different result is a substantial modification or upgrade to control station alarms, controls, or displays that are associated with SSCs important to safety that creates a new or common cause failure that is not bounded by previous analyses or evaluations.

The possible malfunctions with a different result are limited to those that are as likely to happen as those previously described.

## **7. DESIGN BASIS LIMIT FOR A FISSION PRODUCT BARRIER**

50.59 evaluation under criterion (c)(2)(vii) focuses on the fission product barriers-fuel cladding, reactor coolant system boundary and containment-and on the critical design information that supports their continued integrity. Guidance for applying this criterion is structured around a two-step approach: 1. Identification of affected design basis limits for a fission product barrier. 2. Determination of when those limits are exceeded or altered.

The first step is to identify the fission product barrier design basis limits, if any, that are affected by a proposed activity. Design basis limits for a fission product barrier are the controlling numerical values established during the licensing review as presented in the UFSAR for any parameter(s) used to determine the integrity of the fission product barrier. These limits have three key attributes: 1. The parameter is fundamental to the barrier's integrity 2. The limit is expressed numerically 3. The limit is identified in the UFSAR.

## **8. DEPARTURE FROM A METHOD OF EVALUATION**

Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and why the facility's response to accidents and events is acceptable. As such, in cases where the analytical methodology was considered to be an important part of the conclusion that the facility met the required design bases, these analytical methods were described in the UFSAR and receive varying levels of NRC review and approval during licensing.

In general, licensees can make changes to elements of a methodology without first obtaining a license amendment if the results are essentially the same as, or more conservative than, previous results. Similarly, licensees can also use different methods without first obtaining a license amendment if those methods have been approved by the NRC for the intended application.

The first step in applying this criterion is to identify the methods of evaluation that are affected by the change.

Next, determine whether the change constitutes a departure from a method of evaluation that would require prior NRC approval. The following changes are considered a departure from a method of evaluation described in the UFSAR: Changes to any element of analysis methodology that yield results that are non conservative or not essentially the same as the results from the analyses of record; Use of new or different methods of evaluation that are not approved by NRC for the intended application.

**Question Number:** 14-8

**Question/Comment:** Could you please recall what is included in the licensing basis for a particular plant?

**Response:** The licensing basis for a commercial nuclear power plant is comprised of selected information exchanged between a licensee and the NRC. The information is related to design features, equipment descriptions, operating practices, site characteristics, programs and procedures, and other factors that describe a plant's design, construction, maintenance, and operation. The information is contained in a variety of document types. Although it is widely used, the term "licensing basis" is not defined in 10 CFR Part 50 or the major regulatory guidance related to Part 50.

A definition is contained in 10 CFR Part 54, Requirements for renewal of operating licenses for nuclear power plants. This definition states that the current licensing basis (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

**Question Number:** 14-9

**Question/Comment:** It is stated that "The NRC must determine through a backfit analysis that the proposed backfit will substantially increase the overall protection of the public health and safety (or common defense and security) and that the direct and indirect costs for the facility are justified in view of the increased protection". Please clarify if it is the NRC that has to perform the cost-benefit analysis. If this is the case, why is this approach preferred to that of requiring the licensee to perform a cost-benefit analysis for justifying an exemption from the Backfit Rule?

**Response:** It is not within the purview of the licensee to justify an “exemption from the Backfit Rule” as is stated in this question. Rather, the NRC may claim an exception to the requirement in the Backfit Rule to justify the imposition of a backfit on a licensee on a cost-benefit basis based on the NRC’s determination that; 1) a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, 2) regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public, or 3) the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

**Question Number:** 14-10

**Question/Comment:** This section explains the governing documents and process used to maintain the licensing basis.

Why is there no reference in this sub-section to Section 19.2 of NUREG-0800, 2007 revision where general guidance on assessment of risk information used to support permanent plant-specific changes to the licensing basis is provided? May be the necessity of this phenomenon investigation was the regulatory issue caused units operation suspension? Have the problem of strong pressure oscillations effecting pool walls and condenser device elimination been resolved for restarting Units 2 and 3 in the 1990s?

**Response:** NUREG-0800 provides NRC staff review guidance for initial license applications, and for proposed amendments to existing licenses. Section 19.2 is specifically applicable only to proposed changes which use risk insights as part of the justification for the change. Other sections of NUREG-0800 may also apply to the staff review of any specific license amendment request. Other regulatory documents, such as regulatory guides or regulatory information summaries, may also be used in preparation and review of license changes. Section 14.1.1.1 was intended to identify the specific applicable regulations which govern the licensing basis, and not be an all-inclusive listing of applicable regulatory documents.

**Question Number:** 14-11

**Question/Comment:** As background, it is reported that all 4 Units of NPP Browns Ferry with BWR type reactors, which were shut down in 1985, are equipped with Mark-1 containment. This containment has bubble-condenser for pressure-suppression. After resolving management and regulatory issues, TVA successfully restarted Units 2 and 3 in the 1990s. It is known, that during bubble condenser operation the condensation of steam bubbles may occur in under heated water. In case, if adequate design measures will not been undertaken the strong pressure oscillations during steam bubbles condensation will emerge effecting pool walls and condenser device.

**Response:** 1) No, this was not the reason the plants were shutdown. All three Browns Ferry Nuclear Plant (BFN) units were voluntarily shut down by the TVA to address performance and management issues. After the shutdowns, TVA specified corrective actions that were completed before restarting and they committed not to restart any unit without NRC's concurrence. All three units retained their operating licenses during their respective long-term shutdown. On May 22, 2007, the licensee restarted Unit 1 after 22 years.

2) Yes, the problems with containment oscillations were resolved in 1985 as discussed in Safety Evaluation of Browns Ferry Nuclear Plant, Units 1, 2 and 3, Mark I Containment Long-Term program, Pool Dynamic Loads review, May 6, 1985 which can be requested from the NRC Legacy Library. However, this is not the reason the plants were shutdown. The Units 1, 2 and 3 were shutdown voluntarily by the TVA to address performance and management issues.

**Question Number:** 14-12

**Question/Comment:** In this paragraph it is explained that the NRC proceeded to the authorization for the restart of Browns Ferry Unit 1, which reached 100% power during June 2007. It is also mentioned that there will be carried out some tests after the restart, at least 2 of them would be executed within the following months. It would be desirable to count on more detailed information, taking into account that the reason as well as the scope/range of this test has not been explained. Are these tests related with the RG- 1.68 "Initial Test Programs for Water-Cooled Nuclear Power Plants" or are they a consequence of the authorized power increase of the Unit 1?

**Response:** After the restart of Browns Ferry Unit 1 two tests were scheduled on the plant and they are related with RG 1.68 "Initial Test Programs for Water-Cooled Nuclear Power Plants". The Main Steam Isolation Valve Closure Large Transient Test (MSIV) was performed on June 23, 2007 and its main purpose was to isolate the four main steam lines from the main condenser. The plant responded to the scram as expected, all the established test criteria for the transient test were met and Unit 1 returned to power operation on June 26, 2007. The second test, the Generator Load Reject and MSIV Closure LTTs test, was not performed based on the good integrated systems response to the June 9 unplanned turbine trip and scram and because of the good plant response from the June 23, 2007 MSIV test.

**Question Number:** 14-13

**Question/Comment:** In the first paragraph it is mentioned the NRC's reactor oversight process has been applied for every cornerstone in the case of Browns Ferry. However, it is also mentioned that, due to the absence of historical data for this specific plant for three of the cornerstones, it would be necessary to carry out additional inspections included in the Basis inspection programme for this plant. Which are those aforementioned cornerstones? To which inspections is the redaction of the article referring to?

**Response:** Of the seven ROP cornerstones (initiating events, mitigating systems, barrier integrity, emergency preparedness, occupational radiation safety, public radiation safety, and security), there are two which necessitate additional temporary baseline inspections for a new start such as Browns Ferry Unit 1 – initiating events (IE) and mitigating systems (MS). In the IE cornerstone, the two performance indicators (PIs), Unplanned Scrams per 7000 Critical Hours and Unplanned Power Changes per 7000 Critical Hours are rate-type PIs and use critical hours in the calculation, therefore some period of time is needed before the results can be used in the assessment program. With respect to the Mitigating Systems Performance Indicator (MSPI), these indicators are based on 12 quarters of component and system data, and therefore require additional time before they can be implemented. During this time, additional baseline inspections are conducted in these cornerstones, specifically to look at the systems and components monitored by the PIs, as well as following up on plant trips and significant unplanned power changes.

**Question Number:** 14-14

**Question/Comment:** NRC makes the argument that the objectives of the Periodic Safety Review concept are accomplished in the U.S. by other means on an ongoing basis. How does the U.S. system ensure a continuous improvement of safety of the existing reactors by requiring the licensees to assess current safety standards and practices and on that basis implement reasonably practicable improvement measures? The U.S. Backfit Rule puts the burden of proof on NRC to justify any additions to the licensing bases of the plants.

**Response:** As noted in the NRC's Strategic Plan for Fiscal Years 2008-2013 (NUREG-1614, Vol. 4, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v4/index.html#mission>), the mission of the NRC is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. NRC does not regulate for continuous improvement in safety of the existing reactors, but instead regulates to ensure adequate protection of public health and safety.

We regulate the safety and performance of operating reactors, in part, through the NRC's Reactor Oversight Process (<http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html>). The NRC also maintains an ongoing Memorandum of Agreement with the Institute of Nuclear Power Operations (INPO). INPO is an organization sponsored by the nuclear utility industry whose mission is to promote the highest levels of safety and reliability - to promote excellence – in the operation of nuclear electric generating plants. As such, NRC and INPO undertake complementary but independent activities as defined in the Agreement.

**Question Number:** 14-15

**Question/Comment:** What requirements apply on safety review and approval of NPP organizational changes such as reduction of staff, outsourcing of safety related activities, merging of production units etc?

**Response:** The requirements that apply to safety review and approval of NPP organizational changes such as reduction of staff, outsourcing of safety related activities, merging of production units, etc., are similar to changes made to structures, systems or components. Proposed changes that satisfy the definitions and one or more criteria in 10 CFR 50.59 must be reviewed and approved by the NRC before implementation. 10 CFR 50.59 although provides a threshold for regulatory review, and not a final determination of safety for a proposed change.

**Question Number:** 14-16

**Question/Comment:** The report describes developments since the mid 1970ies. In 1977 the NRC had, following extensive review, identified the 27 "SEP lessons learned" In 1991, 22 of the 27 issues had not been resolved, and the staff determined that none of those 22 issues required immediate action, and they were placed into another regulatory process. What is the status of these 22 issues today? When are they expected to be fully resolved? Are these issues of such a kind that they can be modeled in a PRA?

**Response:** The 27 SEP issues were evaluated under Generic Issue 156. In SECY-90-343 the staff concluded that 22 SEP issues remained unresolved for purposes of justifying the adequacy of the current licensing bases. Of the 22 SEP issues, NRC concluded that 19 of the issues were not a new or separate issue from existing considerations, and closed the 19 issues. The remaining 3 issues were either covered by existing requirements or addressed as part of resolution of other issues.

In the process of screening the SEP issues, PRA studies were applied to some of these issues. In an RES evaluation, consideration of a 20-year license renewal period did not change these conclusions or priorities of the issues. The last SEP issue (GI-156.6.1) was closed with no changes to existing regulations or guidance in December 21, 2007 (ML073130570). The status of each of the 22 SEP issues are presented in NUREG-0933:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0933/sec3/156r7.html>.

**Question Number:** 14-17

**Question/Comment:** In the INPO report it is mentioned regarding plant evaluations that the number of plants in the 1 and 2 categories has remained relatively constant, even as standards of excellence has improved. Does this mean that there is a constant number of plants not improving but the individual plants may be different from year to year? How could this be explained?

**Response:** There is no limit on the number of plants that can be in the INPO 1 (excellent) category. Although all U.S. plants strive for the excellence category, not all succeed during their respective 24-month INPO evaluation and assessment cycle. Every year there is migration into and out of the INPO 1 category as some plants achieve excellent performance levels and others are unable to sustain excellent performance. The fact that the overall absolute number of plants in the top two categories has been relatively steady, while the standards needed to attain those assessment categories has steadily increased, highlights the continuous improvement being made by the industry, not just any particular plant. One value of an assessment process is that the plant, utility, and INPO can appropriately focus their efforts on the most important concerns while still promoting continuous improvement.

**Question Number:** 14-18

**Question/Comment:** Would you give detailed information about the NRC's position and NRC activities concerning "Multinational Design Approval Program"?

**Response:** The NRC has been an active supporter of the Multinational Design Evaluation Program since its inception. The NRC is participating in MDEP Stage 1, which involves sharing information on the EPR design review with Finland and France. Representatives of the NRC have held several meetings with representatives of the French and Finnish regulatory agencies to discuss technical details of the EPR review and exchange documents. The NRC is also one of the 10 participating countries in MDEP Stage 2. One of the more significant outcomes of Stage 2 is the development of a multinational vendor inspection program. The NRC views this program as an effective and efficient way to obtain information on component manufacturers that are located throughout the world, by sharing information and inspection results with other regulatory authorities. The Chairman of the NRC is a member of the MDEP Policy Group, and an NRC senior manager acts as the Chair of the MDEP Stage 2 Steering Technical Committee. The NRC Commission has endorsed continued support for MDEP activities by the NRC staff.

**Question Number:** 14-19

**Question/Comment:** The report says “The NRC must determine through a backfit analysis that .....” Why, if the prime responsibility for safety rests with the licensee (Article 9), should it be the responsibility of NRC to identify, and then justify by means of a backfit analysis, any improvements that might be beneficial to the safety of the plant?

**Response:** The NRC does not have sole responsibility for identifying and justifying improvements, nor in fact have improvements been solely the work of the NRC. For example, the improvements in the plant designs that have been certified under 10 CFR Part 52 of the agency’s regulations are largely the work of the industry, and the NRC does not have to perform a backfit analysis before it accepts such improvements. Nonetheless, a regulator should be, and the NRC is, authorized to identify and impose improvements. The backfit rule simply helps to ensure that the government’s action to impose such changes has been well-thought out.

**Question Number:** 14-20

**Question/Comment:** A large section of the report is devoted to explaining the NRC stance on periodic safety reviews (PSR) and is very elucidatory and helpful. Nevertheless, could the NRC expand on why stand-back, backward and forward looking reviews, at intervals of approximately ten years, would not be complementary to the continuum of assessment and review as described in the report?

**Response:** The NRC believes that its assessment program and annual self-assessments are comprehensive and that this added review would be somewhat redundant and not a cost-effective use of resources. One of the tenets of the ROP is to focus resources on those areas and specific issues most important to safety. We continuously adjust resources to ensure that the plants and/or generic safety issues with the greatest impact on public health and safety are receiving the attention warranted by their significance. There have also been, and likely will continue to be, numerous independent audits/evaluations of the ROP as summarized on the NRC’s public website at:

<http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/program-evaluations.html>.

**Question Number:** 14-21

**Question/Comment:** What kinds of systematic aging review programmes are ongoing (by power companies or regulators)?

**Response:** Passive, long-lived components (for example, concrete or polymers) have aging management plans. The plans involve inspection (visually or with advanced condition monitoring) to detect degradation and perform repairs or periodic replacement. The aging of active components (for example, pumps, valves, or motors) is managed by the station’s preventive maintenance program. U.S. utilities use a common flowchart based



process to categorize plant equipment by importance and develop preventive maintenance. The process is a living process based on component performance. Specific programs exist to address aging and other degradation mechanism concerns with reactor coolant system materials in both PWR and BWR reactor types. These programs focus in particular on BWR vessel and internals, and on PWR alloy 600 materials and welds including steam generator tubing.

**Question Number:** 14-22

**Question/Comment:** This section explains the governing documents and process used to maintain the licensing basis.

Question:

Why is there no reference in this sub-section to Section 19.2 of NUREG-0800, 2007 revision where general guidance on assessment of risk information used to support permanent plant specific changes to the licensing basis is provided?

**Response:**

NUREG-0800 provides NRC staff review guidance for initial license applications, and for proposed amendments to existing licenses. Section 19.2 is specifically applicable only to proposed changes which use risk insights as part of the justification for the change. Other sections of NUREG-0800 may also apply to the staff review of any specific license amendment request. Other regulatory documents, such as regulatory guides or regulatory information summaries, may also be used in preparation and review of license changes. Section 14.1.1.1 was intended to identify the specific applicable regulations which govern the licensing basis, and not be an all-inclusive listing of applicable regulatory documents.

## 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 that apply to licensing and to facility changes.

**Question Number:** 15-1

**Question/Comment:** Many modifications have been implemented for the new regulatory requirements of NRC, at meantime, how do the licensees reduce the collective dose exposure of staff?

**Response:** NRC regulations in 10 CFR 20.1101 require that , to the extent practical, NRC licensees use procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses that are as low as is reasonably achievable (ALARA). As described in Chapter 15.4.1, ALARA programs developed and matured in the post TMI accident time frame. The success of these programs is demonstrated in the dramatic decline in average annual collective dose. Common elements of ALARA programs at operating reactors include:

Training. Ensuring that all operating staff understands that it is their job to work in a manner that minimizes their dose.

ALARA Committees. Committee of plant Senior Vice Presidents and plant managers that establish departmental dose goals and thereby assign ALARA responsibilities and accountability to individual Departmental Managers and Supervisors.

Dose Assessment and Work Planning. ALARA planning is integrated into overall plant outage and maintenance planning. Identifies whether additional protective measures or engineering controls (i.e., temporary shielding or confinement, job mock-up training, etc.) are needed to ensure that resulting doses meet ALARA goals.

Dose Tracking and Work Controls. Real time monitoring of collective dose, by work activity, throughout the year.

Performance Assessment and Feedback. Post job meetings to identify methods to improve ALARA performance.

Source Term Control and Plant Modifications. Use of proper chemistry controls and shutdown clean up procedures to minimize the radioactivity is systems and components.

**Question Number:** 15-2

**Question/Comment:** Could USA recall the dose limits for occupational workers and for the public?

**Response:** Annual Occupational Dose Limits:

- 5 rem (0.05 Sv) total effective dose equivalent (sum of the deep-dose equivalent and the committed effective dose equivalent for each organ or tissue, except the skin and the lens of the eye).
- 15 rem (0.15 Sv) dose equivalent to lens of the eye
- 50 rem (0.5Sv) Sum of the deep-dose equivalent and the committed dose equivalent for each organ or tissue (except lens of the eye)
- 10% of the above limits for an occupationally exposed minor
- 0.5 rem (5 mSv) to the embryo/fetus of a declared pregnant worker (during entire pregnancy)

Annual Public Dose Limit:

- 0.1 rem (1mSv) total effective dose equivalent

**Question Number:** 15-3

**Question/Comment:** In the third paragraph: "Using the average collective dose ... at TMI Unit 2". Could USA specify why the doses were randomly variable before the accident at TMI Unit 2? Has the Licensee implemented some actions in order to reduce the collective dose? In the affirmative, could USA give some examples of corrective actions which resulted in dose reductions?

**Response:** Collective dose is strongly dependent on the amount of work performed in radiologically significant areas of the plant. Major maintenance and repair activities were somewhat randomly distributed among the plants operating in the early years of the nuclear industry. Due to the significant plant modifications required across the industry following the accident at Three Mile Island (TMI), the increased number of operating staff, and, in part, the growth of the radiological source term in the aging plants, average collective dose increased dramatically following the TMI accident, putting more emphasis on dose reduction and ALARA measures. In the last 30 years the industry has implemented a wide range of measures to reduce the collective dose resulting from plant operations. These include measures to minimize radioactive material generated during operation, such as improved water chemistry controls, and minimization of cobalt bearing materials in the reactor systems and components; extensive work planning, and plant modifications to increase the efficiency of workers in radiological areas (such as installing permanent work platforms and shielding in lieu of erecting temporary scaffolding and shielding during each refueling/maintenance outage).

**Question Number:** 15-4

**Question/Comment:** Could USA specify the values of the authorized limits for each nuclide or group of nuclides as well as the gaseous and liquid releases? Could USA

specify the ratio between the limits and the releases for each nuclide or group of nuclides?

**Response:** The authorized concentration limits of radionuclides in liquid and gaseous effluents released to the environment are specified in table 2 of Appendix B to 10 CFR Part 20. The concentration values are equivalent to the radionuclide concentrations which if inhaled or ingested continuously over the course of a year would produce a total effective dose equivalent of 0.05 rem (0.5 mSv).

In addition, 10 CFR 50.34a requires operating power plants to have equipment that maintains the radioactive material in plant effluents and the resulting dose to members of the public as low as is reasonably achievable (ALARA.) In Appendix I to 10 CFR Part 50, numerical design objectives are identified which are considered ALARA. Specifically, release of radioactive material in liquid effluents must not result in a radiation dose of greater than 3 millirem to any individual in an unrestricted area.

Routine releases of radioactive material in liquid and gaseous materials are significantly below the design objectives specified in Appendix I to 10 CFR Part 50. The dose impact to members of the public from spills and leaks to ground water has been determined to be insignificant. A full evaluation of the impact to the public can be found in the Liquid Radioactive Release Lessons Learned Task Force Final Report which has been posted on the NRC website.

**Question Number:** 15-5

**Question/Comment:** It is said in the report that the 2004 average collective dose value of 1.0 person-Sv was the lowest average recorded since 1969. How has the regulatory body committed or concerned to reduce collective dose value?

**Response:** The NRC requires licensee to implement procedures and engineering controls to ensure that radiation doses are ALARA (see Question 15-1 above). The effectiveness of these ALARA programs is reviewed by NRC inspectors biennially as part of the routine Reactor Oversight Process.

**Question Number:** 15-6

**Question/Comment:** According to Section 15.3, an annual occupational dose limit on the effective dose equivalent in 10 CFR Part 20 is 0.05 Sv/yr. The current 10 CFR Part 20 provides a level of radiation protection that in almost all situations is comparable to that provided by international standards. ICRP 60 and IAEA RS-G-1.1 recommend that the management should take the necessary corrective steps when doses to an individual worker exceed 0.02 Sv/y. What corrective steps does the NRC take in the case of exceeding 0.02 Sv/y?

**Response:** The statement that the current NRC requirements in 10 CFR 20 provide a level of radiation protection that in almost all situations is comparable to

that provided by the ICRP 60 recommendations refers to the fact that only a very small percentage of occupationally exposed workers in the US exceed a dose of 2 rem (0.02 Sv) in a year. For example, of the 116,354 workers in the US nuclear power industry monitored for radiation exposure in 2006, only 0.07% exceeded a dose of 2 rem (0.02 Sv). NRC does not require corrective actions for personnel exposure in excess of 2 rem.

**Question Number:** 15-7

**Question/Comment:** Please explain the plan to reflect the results of investigation on the contamination of underground water into license renewal?

**Response:** This issue is being addressed in the revision to NUREG -1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants." The staff added a discussion of the recent events concerning the inadvertent leak of radioactive water that have occurred at nuclear power plants and the resultant small impacts to the public and the environment. In addition to the issue being addressed on a generic basis, the NRC staff conducts an onsite environmental audit of every plant seeking renewal of its operating license. As part of this audit, the NRC staff reviews the plant's groundwater protection program and documents the information in the Supplemental Environmental Impact Statement for that plant.

**Question Number:** 15-8

**Question/Comment:** Please provide more information about those cases of occupational doses exceeding 0.2 Sv/year. What were the causes? What was the NRC reaction? What measures have been taken to reduce these doses?

**Response:** The "0.2 Sv per year" referred to on page 108 of the report was a typographical error. It should be corrected to read "exceed 0.02 Sv per year." No worker in the US nuclear power industry has exceeded 0.2 Sv in a year. As noted in Answer 128 above, only a very small percentage of workers exceed 0.02 Sv in a year.

**Question Number:** 15-9

**Question/Comment:** What is the dose limit for the population? Can you formulate a general conclusion regarding the radiological impact of the NPP's operation on the environment and population? What are the doses received by the population due to the NPP's operation? How are the results of the radioactive releases monitoring programmes (performed by the operators) verified?

**Response:** The USA establishes dose limits for individual members of the public, but not for collective population dose. The individual dose limits to the public can be found in 10 CFR Part 20, Subpart D – Radiation Dose Limits for Individual Members of the Public. Some of the dose limits for members of the public that licensed facilities must meet include the total effective dose equivalent to an individual member of the public shall not exceed 0.1 rem (1 mSv) in a year and the dose in any unrestricted area from external

sources shall not exceed 0.002 rem (0.02 mSv) in any one hour. Licensees are also required to comply with the environmental radiation standards in 40 CFR Part 190 (25 mrem per year whole body, 75 mrem to the thyroid and 25 mrem to any other organ).

NRC requires operating power plants to maintain their liquid and gaseous effluents ALARA. Appendix I to 10 CFR Part 50 specifies that ALARA criteria are achieved if the annual dose to a member of the public from liquid effluents is not in excess of 3 mrem to the total body or 10 mrem to any organ. The ALARA criteria is met if the annual dose to a member of the public from gaseous effluents is not in excess of 5 mrem to the total body or 15 mrem to the skin. Operating power plants are required to have effluent and environmental monitoring programs in place which will confirm that the design objectives specified in Appendix I to 10 CFR Part 50 are met. The plants must submit an annual report on the effluent and environmental monitoring programs documenting the results of the monitoring programs. The effluent and environmental monitoring programs are routinely inspected by NRC regional inspectors to ensure compliance with the regulations. Doses to members of the public from liquid and gaseous effluents have consistently been far below the design objectives in Appendix I to 10 CFR Part 50.

**Question Number:** 15-10

**Question/Comment:** What were the H-3 values detected in groundwater, on site and off site? What corrective actions have been taken?

**Response:** Values of H-3 that have been detected in ground water on a licensee's site vary widely. The highest level of activity identified in an onsite ground water sample was approximately 1.4E6 pCi /l. The values of H-3 that have been detected in ground water off a licensee's site are between 1,400 pCi/l and 1,600 pCi/l. Corrective actions that have been taken vary from site to site but include replacement of corroded or broken pipes and remediation of ground where liquid spills have occurred.

The Nuclear Energy Institute (NEI) has developed a voluntary ground water protection initiative (GPI). This voluntary initiative is to be implemented by all currently operating and decommissioning power plants by August 2008. All new plants that may be built will also adopt the GPI. One of the objectives of the GPI is for all plants to perform a site risk assessment which will identify site risks based on plant design and work practices. It is expected that the site risk assessment will evaluate all systems, structures, or components that contain or could contain radioactive material and identify existing leak detection methods in order to prevent future leaks or spills.

**Question Number:** 15-11

**Question/Comment:** In the past three years, there have been several discoveries of radioactive ground water contamination at nuclear power facilities located throughout the United States. Investigation has determined that most of the contamination resulted from undetected leakage from facility SSCs that contained radioactive liquids. The NRC resolution was required each participating nuclear plant to have a plan in place by July 2006 that established several short-term actions, such as developing an enhanced communication protocol to ensure notification of State and local officials of less significant unmonitored release events. The industry initiative also required several long-term actions to improve leak detection monitoring capability and improve understanding of site hydrology and geology.

What method of NPP's releases monitoring provided discover radioactive ground water contamination? Is the system of permanent NPP's releases monitoring exist at each site? What problems of water migration in ground layers had not been resolved on the stage of NPP's siting (site permit)? Degradation of what physical barriers occur? Is it possible to conclude, that permanent control of state and maintenance of barriers integrity had not been organized in place?

**Response:**

1) There were a number of different reasons why the plants discovered ground water contamination on their sites. Some of the plants discovered the contaminated ground water as a result of implementing the NEI GPI and installing ground water monitoring wells onsite. Some contamination was discovered when broken or corroded underground pipes were identified. Some ground water contamination was the result of large liquid effluent spills.

NRC requires operating power plants to maintain their liquid and gaseous effluents ALARA. Appendix I to 10 CFR Part 50 specifies that the ALARA criteria are met if the annual dose to a member of the public from liquid effluents is not in excess of 3 mrem to the total body or 10 mrem to any organ. The ALARA criteria are met if the annual dose to a member of the public from gaseous effluents is not in excess of 5 mrem to the total body or 15 mrem to the skin. Operating power plants are required to have effluent and environmental monitoring programs in place which will confirm that the design objectives specified in Appendix I to 10 CFR Part 50 are met. The plants must submit an annual report on the effluent and environmental monitoring programs documenting the results of the monitoring programs. The effluent and environmental monitoring programs are routinely inspected by NRC regional inspectors to ensure compliance with the regulations.

2) From the lessons learned from operating power plants, NRC has developed guidance for staff who will be reviewing the license applications for new reactors. The guidance for the new reactors includes information on liquid, gaseous and solid waste management systems and also on process and effluent monitoring instrumentation. Additionally, NRC is revising regulations in 10 CFR Part 20 for materials licensees and

for new reactors to minimize the introduction of residual radioactivity into the site, including the subsurface.

3) Some of the H-3 contamination of ground water occurred because underground pipes had eroded, cracked or broken. Some of the ground water contamination was identified as a result of the NEI GPI. Current NRC regulations do not require licensees to have onsite ground water monitoring wells. The NEI GPI which has been adopted by this voluntary initiative is expected to be implemented by all currently operating and decommissioning power plants and by any new plant. One of the objectives of the GPI is for all plants to perform a site risk assessment which will identify site risks based on plant design and work practices. It is expected that the site risk assessment will evaluate all systems, structures, or components that contain or could contain radioactive material and identify existing leak detection methods in order to prevent future leaks or spills. The GPI also expects that long term programs to perform preventative maintenance or surveillance will also be developed.

**Question Number:** 15-12

**Question/Comment:** Taking into account the big amount of dosimetric information gathered by the NRC, would not be convenient to present in the National Report the collective dose values received in both BWR and PWR reactors separately as well as demonstrative graphics about the evolution of such parameters? Why is not included information about the internal dose assessments results, for both BWR and PWR?

**Response:** The CNS Report provides a high level summary of US nuclear power operating experience. Annually, the NRC publishes a detailed analysis of the occupational radiation exposure received at commercial nuclear power plants in its NUREG-0713 series. Volumes 22 through 27 of NUREG-0713, covering the years 2000 to 2005, can be found on the Electronic Reading Room/Documents Collections page of the NRC public web site (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/>). Volume 28 (2006), published November 2007, should also be available at this web site soon.

**Question Number:** 15-13

**Question/Comment:** In the dosimetric data base of the USNRC there were 78127 workers' data, receiving 115 Svp and average individual value of 1.5 mSv. Has any of these workers of the nuclear power plants received a dose higher than the value established by the US Laws? How many 'overcomings' of the Registration Level happened in the internal dose measurements in LWRs? What is the value for the Registration Level for internal contamination?

**Response:** There were no individuals who have received doses in excess of the NRC limits for occupational exposures (see Question 15-2 above). The NRC does not have a "Registration Level" for internal contamination. Both the 0.05 Sv limit on total effective dose equivalent, and the 0.5 Sv limit on individual organ dose equivalent, include a committed dose equivalent



component (integrated over 50 years) from internal contamination. Licensees are required to monitor the intake of radioactive materials, and record the resulting dose from those intakes, if the individual is likely to receive in one year an intake in excess of 10 % of the applicable ALIs (Annual Limits on Intake) listed in appendix B to 10 CFR Part 20. The ALIs are the annual intake for each nuclide that, based on standard-man model assumptions, result in a committed effective dose equivalent of 5 rem (.05 Sv) or a committed dose equivalent of 50 rem (.5 Sv) to any organ or tissue, whichever is most limiting.

**Question Number:** 15-14

**Question/Comment:** It is reported that many licensees and agencies have administrative dose limits that are similar to or lower than, those in the Basic Safety Standards and most other licensees operate at occupational doses far below these limits and standards, and therefore, are considered ALARA. Does this mean that the doses need not to be reduced further even if this would be possible at small costs and with simple actions? Not really ALARA in our understanding!

**Response:** NRC reactor licensees establish administrative dose limits as an added measure to ensure that the NRC dose limits are not exceeded. The administrative dose limits are not a threshold for ALARA. Licensees are still required to reduce doses as far below their administrative limits as is reasonably achievable.

**Question Number:** 15-15

**Question/Comment:** The U.S. should be complemented for the reduction of radiation doses during 1995-2005.

**Response:** Thank you for your comment.

**Question Number:** 15-16

**Question/Comment:** Please expand on the reasons for the U.S. not being prepared to adopt the recommendations in ICRP Publication 60, and IAEA's Basic Safety Standards, in line with the majority of the IAEA Member States?

**Response:** RC decided to await the completion of the ICRP recommendations before considering whether revisions to the radiation protection standards would be appropriate. ICRP has now completed its recommendations (ICRP Publication 103) and the NRC staff has initiated efforts to examine and catalog issues for consideration. The NRC staff plans to complete its evaluation and provide options for Commission consideration in December 2008, regarding possible revision of the NRC radiation protection standards.

## 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) 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.

**Question Number:** 16-1

**Question/Comment:** Issuing the GS-R-2 Preparedness and Response for a Nuclear or Radiological Emergency, the EPR-Method (2003) Method for Developing Arrangements for Response to a Nuclear or Radiological Emergency and other relevant publications the IAEA has revised the international safety standards in the area of Emergency Preparedness. Did the U.S. NRC implement the follow up revision of its own regulating documents describing the Emergency Preparedness and Response related requirements for the nuclear industry? What were the major changes?

**Response:** After Sept 11, 2001, the staff conducted a review of EP regulations. As part of the EP review, the staff met with internal and external stakeholders including Department of Homeland Security, regional NRC inspectors, State, local and Tribal government representatives, non-governmental organizations, industry representatives, regional public meetings with State and local representatives and industry working groups. From these meetings five broad topical areas were identified for EP rulemaking: (1) security-based emergency action levels (EAL); (2) security-based drills and exercise scenarios; (3) offsite protective action recommendations (PARs); (4) abbreviated notification to the NRC and off-site response organizations (ORO); and (5) public alert and notification systems (ANS). This rulemaking is in progress.

**Question Number:** 16-2

**Question/Comment:** It is said in the report that the U.S. regulation requires emergency response exercises to be conducted every 2 years at operating nuclear power plant sites. Is an emergency response exercise required to be conducted prior to nuclear power operation? Is conducting an emergency response exercise prior to power operation is a condition for issuing the operating license?

**Response:** 1) Yes, an emergency response exercise is required to be conducted prior to nuclear power operation and it is required prior to power operation as a condition for issuing the operating license. NRC emergency preparedness regulations provide that no initial operating license for a nuclear power reactor will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.” A successful emergency response exercise involving State and local governments is fundamental to making this finding.

A full participation emergency exercise, including the participation of each State or local government within the plume exposure pathway emergency planning zone (EPZ) and each State within the ingestion pathway EPZ, must be conducted within two years prior to issuance of the first license authorizing operation above 5 percent of rated power (i.e., full power). If this full participation exercise is conducted more than a year prior to issuance of the full power operating license, a partial participation exercise of the applicant’s onsite emergency plans must be conducted within one year prior to the issuance of a full power license. For sites with a reactor already operating, a full or partial participation exercise shall be conducted for each subsequent reactor constructed on the site.

NRC regulations as found in 10CFR50 Appendix E, VI, F state: “(i) For an operating license issued under this part, this exercise must be conducted within two years before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated power) of the first reactor and shall include participation by each State and local government within the plume exposure pathway EPZ and each state within the ingestion exposure pathway EPZ. If the full participation exercise is conducted more than 1 year prior to issuance of an operating licensee for full power, an exercise which tests the licensee's onsite emergency plans must be conducted within one year before issuance of an operating license for full power. This exercise need not have State or local government participation.

2) For a combined license issued under part 52 of this chapter, this exercise must be conducted within two years of the scheduled date for initial loading of fuel. If the first full participation exercise is conducted more than one year before the scheduled date for initial loading of fuel, an exercise which tests the licensee's onsite emergency plans must be conducted within one year before the scheduled date for initial loading of fuel.

3) For a combined licensee issued under part 52 of this chapter, if the applicant currently has an operating reactor at the site, an exercise, either full or partial participation, shall be conducted for each subsequent reactor constructed on the site.“

**Question Number:** 16-3

**Question/Comment:** What main changes have been introduced in the field of emergency preparedness as a result of the terrorist events of September 11, 2001, and Hurricane Katrina, August 2005?

**Response:** In response to the attacks of 9/11, the NRC consolidated its nuclear security and emergency planning and response programs in the newly created Office of Nuclear Security and Incident Response to better integrate these programs.

The NRC has worked with nuclear power plant (NPP) licensees to implement various emergency preparedness enhancements based on the unique changes posed by hostile action (security)-based events on existing EP programs. These enhancements, as outlined in NRC Bulletin 2005-02, "Emergency Preparedness and Response Actions for Security-Based Events,' dated July 18, 2005, include:

- Changes to emergency classification level definitions and associated action levels to clarify conditions when the physical security of the NPP site may be challenged or breached in respect to existing four emergency classifications.
- Prompt notification of the NRC to support subsequent communications to other licensees regarding a potential security threat and to inform other Federal agencies in accordance with the National Response Framework.
- Address a regime of onsite protective measures appropriate for a terrorist attack, particularly an imminent airborne threat, to maximize the safety of site personnel.
- Address the augmentation of licensee emergency response organization based on the challenges posed to emergency facility staffing due to a potential or on-going terrorist threat. This would include the use of designated alternate facilities offsite to support emergency response functions.

Incorporation of hostile action (security)-based event scenarios as part of the routine EP drill and exercise program to test the ability of licensee and offsite emergency organizations to response to a terrorist threat against a NPP.

These enhancements were implemented by order or by voluntary initiatives by the regulated industry. The NRC is currently pursuing rulemaking to formally codify its expectations in this regard. The demonstration of key on-shift operations and EP assessment and mitigative actions in response to potential or on-going terrorist events was

also included in periodic force-on-force exercises conducted by NPP security forces.

In addition, the NRC has supported Department of Homeland Security efforts on the Comprehensive Review (CR) Program as it applied to the Nuclear Sector. The CR program was initiated post-9/11 to evaluate the status of the nation's preparedness to contend with terrorist attacks against critical infrastructure (power generation and distribution, chemical plants, transportation assets, etc) and to identify security enhancements and protective measures. The NRC worked closely with Federal, state, and local homeland security authorities, as well as the private-sector owners and operators in performing these reviews at each licensed nuclear facility. The CR Program has contributed, and will continue to contribute, to our homeland security by:

- Fostering candid, open dialogue among all stakeholders to reach decisions about what additional protective and response measures are most appropriate for the given facility, the community, and the nuclear sector; identifying and resolving gaps in protection, planning, security, and response for the community around the facility, the facility itself, and federal/state/local emergency responders, and by identifying equipment shortfalls for protective and emergency response operations; and
- Supporting investment and budgeting decisions for the most efficient allocation of resources through various grant programs.

Additionally, the NRC made changes to its own incident response organization. The Operations Branch of Incident Response instituted the HERO (Headquarters Emergency Response Officer) position and developed the Security Information Database (SID). The HERO position was established to address the additional communication and coordination involving security issues for our licensees. The SID was developed to give the licensees a vehicle to report security issues that may not reach codified reporting criteria, but should be reported to the regulator for information sharing and trending purposes.

Following the 2005 Hurricane season, the NRC updated its hurricane response procedure which includes better integration of Federal, State, and local planning and response activities for radiological materials licensees. Emphasis has also been added to the tracking of radiological sources, including the development of an electronic mapping system for certain quantities of sources and material. Additionally, several new electronic weather and hurricane tracking systems have been added to the tools currently utilized in the Headquarters Operations Center. The NRC, in conjunction with the Federal Emergency Management Agency (FEMA), has developed a procedure addressing timely assessment of onsite and offsite emergency response capabilities in the wake of significant storm damage to emergency response infrastructure (e.g., emergency facilities, evacuation routes, alert and notification systems, and communication capabilities).

**Question Number:** 16-4

**Question/Comment:** Could you please briefly describe the Top Officials exercises?

**Response:** The Top Officials (TOPOFF) Exercise is the nation's premier exercise of terrorism preparedness involving top officials at every level of government. It's a full-scale assessment of the nation's capacity to prevent, prepare for, respond to, and recover from terrorist attacks involving weapons of mass destruction. TOPOFF 4 was conducted October 15 – 20, 2007. The States of Arizona and Oregon, the Territory of Guam, and three international partners: Australia, Canada, and the United Kingdom joined the Department of Homeland Security and other Federal agencies in this important effort.

Since this exercise did not involve NRC-licensed facilities or materials, the NRC participated in this exercise in a limited capacity.

The Executive Team (ET) was fully staffed for the beginning of the exercise and then scaled down to a small cell. The ET received briefings from the Safeguards Team (ST) and the Protective Measures Team (PMT), and they participated in Classified Video Conferences as part of the Domestic Readiness Group, a part of the White House Homeland Security Council.

The ST participated fully and met its objectives to obtain intelligence information, brief the ET on developments, and to issue Safeguards Advisories to NRC licensees.

The PMT had a few responders participate over 2 days during the exercise. They interacted with other Federal responders such as the Federal Radiological Monitoring and Assessment Center (FRMAC), Department of Energy, National Atmospheric Release Advisory Center/Interagency Modeling and Atmospheric Assessment Center, etc., and they compiled radiological information and provided daily briefings to the ET.

Four staff from the NRC (1 Headquarters and 3 Regional) participated as responding members of the FRMAC on location in the Joint Field Office in Portland, Oregon.

The Headquarters Operations Officers demonstrated their ability to effectively communicate with the National Operations Center.

**Question Number:** 16-5

**Question/Comment:** Information to the public is most important in a nuclear emergency situation. To what extent is the media taking part in the drills and exercises performed in the US?

**Response:** Media are offered an opportunity to participate but few accept the invitation. Media representatives are more likely to participate in exercises at the high profile sites; for example, media interest is high at the Indian

Point Energy Center located outside of New York City. Licensees do provide periodic familiarization sessions on current information and communication processes and protocols for media who cover the site. “Mock” media are often used to exercise licensee public affairs staff and spokespersons during drills and exercises. Mock media can be composed of journalism students from nearby colleges/universities, volunteers from the community.

**Question Number:** 16-6

**Question/Comment:** With what purpose U.S. NRC requires from the licensee the submission of emergency response plans of local governments and the State, if those plans are not reviewed and the assessment is based on DHS/FEMA conclusions?

**Response:** DHS/FEMA reviews the offsite emergency preparedness programs for the Nuclear Regulatory Commission. The regulations state: “(2) The NRC will base its finding on a review of the Federal Emergency Management Agency (FEMA) findings and determinations as to whether State and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented, and on the NRC assessment as to whether the applicant’s onsite emergency plans are adequate and whether there is reasonable assurance that they can be implemented. A FEMA finding will primarily be based on a review of the plans. Any other information already available to FEMA may be considered in assessing whether there is reasonable assurance that the plans can be implemented. In any NRC licensing proceeding, a FEMA finding will constitute a rebuttable presumption on questions of adequacy and implementation capability.” 10 CFR 50.47(a)(2). The NRC is responsible for the final determination on the overall state of emergency preparedness.

**Question Number:** 16-7

**Question/Comment:** Is there an explanation for the apparent inconsistency between the statement in 16.2: “Participation by State and local governments in emergency planning for nuclear power plants in the United States was, and still remains, largely voluntary.” and the statement in Section 16.3 of the report which says that “Under NRC regulations, the licensee and State and local government must discuss and agree upon [emergency action] levels, and the NRC must approve them”? Is there a possible gap between the areas of responsibility of DHS, NRC, the States and local government?

**Response:** The quoted requirement applies to the initial emergency action level (EAL) scheme submitted by the applicant. Once the applicant’s plan is approved and the facility license issued, the licensee is no longer required to obtain State and local agreement and can implement changes to the EALs without prior NRC approval if the changes do not decrease the effectiveness of the emergency plans. Although the technical details of the EALs are the purview of the applicant’s plans with NRC oversight, the developers of State and local plans need to be aware of the overall

framework of the EAL scheme if their plans are to adequately interface with the applicant's plans. This requirement for soliciting State and local concurrence does not supplant the NRC's authority and responsibility for approval and oversight of the licensee's plans, nor does it extend responsibility and authority for EAL approval to the State or local governments. As such, the organization relationships between DHS, NRC, and State and local governments are unaffected by the cited requirement.

The NRC has the final authority over its applicants and licensees. The Federal government, including NRC and DHS, cannot require State and local governments to participate in emergency preparedness activities. Amendment 10 to the Constitution of the United States clearly establishes the authority of the State vis-a-vis the Federal Government "Amendment 10 - Powers of the States and People. The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." However, since regulation of nuclear power plants was reserved by law to the NRC, the applicant or licensee can be required by the NRC to obtain agreement from States and local governments on specific issues, for example, EALs.



**Question Number:** 16-8

**Question/Comment:** The NRC regulations establish four classes of emergencies in order of increasing severity. Typically, licensees have established specific procedures for carrying out emergency plans for each class of emergency. The event classification initiates all appropriate actions for that class, including notification of offsite authorities, activation of onsite and offsite emergency response organizations, and, where appropriate, protective action recommendations for the public.

The start of protective action for the public in some cases makes evident, that personnel actions during emergency operating procedures implementation were not successful. Are there special criteria in emergency operating procedures or instructions, which exactly identifies necessity to start with protective action for the public (Emergency planning) implementation?

**Response:** Protective actions for the public are required when a general emergency (GE) is declared. General emergency conditions are tied to emergency action levels (EAL). When plant conditions meet the EAL criteria for a general emergency, plant officials are required to declare a GE and make the appropriate protective action recommendation to offsite officials. Some facilities annotate their emergency operating procedures with notes to alert operators of the requirements of the various emergency classifications; however, this is not required by NRC regulations.

**Question Number:** 16-9

**Question/Comment:** It is stated, that emergency preparedness is the final barrier between reactor operations and protection of public health and safety. However, in this case all physical barriers are already damaged. May be the 5-th level of Defense in Depth is meant?

**Response:** In the United States, there are 4 levels to "defense in depth". Emergency planning is the fourth level of the NRC's "defense-in-depth" safety philosophy. Briefly stated, this philosophy:

- Requires high quality in the design, construction and operation of nuclear facilities and equipment to reduce the likelihood of malfunctions in the first instance;
- Recognizes that equipment can fail and operators can make errors, therefore requiring safety systems to reduce the chances that malfunctions will lead to accidents that release fission products or other radioactive and hazardous materials; and
- Recognizes that, in spite of these precautions, accidents can happen, therefore requiring systems in place to prevent the release of fission products or other radioactive and hazardous materials offsite.

The added feature of emergency planning to the defense-in-depth philosophy provides that, even in the unlikely event of a release of radioactive and hazardous materials to the environment, there is

reasonable assurance that actions can be taken to protect the population around nuclear facilities.

## ARTICLE 17. SITING

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

- (i) evaluating all relevant site-related factors that are likely to affect the safety of a nuclear installation for its projected lifetime
- (ii) evaluating the likely safety impact of a proposed nuclear installation on individuals, society, and the environment
- (iii) re-evaluating, as necessary, all relevant factors referred to in subparagraphs (i) and (ii) so as to ensure the continued safety acceptability of the nuclear installation
- (iv) consulting Contracting Parties in the vicinity of a proposed nuclear installation, insofar as they are likely to be affected by that installation and, upon request, providing the necessary information to such Contracting Parties, in order to enable them to evaluate and make their own assessment of the likely safety impact on their own territory of the nuclear installation

This section 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.

**Question Number:** 17-1

**Question/Comment:** What are the regulatory requirements towards the assessments and justifications to be carried out by the licensees in order to prove that a selected certified NPP design is compatible with the specific conditions and characteristics of a site applying for construction? Please give reference to a document if existing.

**Response:** The site safety regulations which consider physical characteristics of the site (such as seismic and meteorological factors) that could affect the design of the plant are found in 10 CFR Part 100, "Reactor Site Criteria"; Appendix A, "Seismic and Geologic Siting Criteria for Nuclear Power Plants," to 10 CFR Part 100; Subpart B, "Evaluation Factors for Stationary Power Reactor Site Applications on or after January 10, 1997," of 10 CFR Part 100; and 10 CFR 100.23, "Geologic and Seismic Siting Criteria."

The requirements in 10 CFR 100.23 apply to applicants for an early site permit, a combined license, a construction permit, or an operating license on or after January 10, 1997. Regulatory Guides 1.165, "Identification and Characterization of Seismic Sources and Determination of Safe Shutdown Earthquake Ground Motion," issued March 1997, and 1.208, "A Performance-Based Approach to Define the Site-Specific Earthquake

Ground Motion,” issued March 2007, describe methods acceptable to NRC staff for implementing those requirements, and NUREG-0800, Section 2.5.2, Revision 3, guides the staff in its reviews.

**Question Number:** 17-2

**Question/Comment:** The report states, “In summary, new seismic demand for design of new reactors ensures that the frequency at which nuclear structure, systems and components will reach the threshold of elastic limits under seismic loads combined with dead, live, and postulated accident loads is  $10^{-5}$  per reactor year.” Please clarify if the above mentioned frequency limit is applied equally to both safety related and non-safety related SSCs.

**Response:** Section 17.2.2, Assessments of Seismic and Geological Aspects of Siting, last paragraph, provides the following: In summary, new seismic demand for design of new reactors ensures that the frequency at which nuclear structures, systems and components will reach the threshold of elastic limits under seismic loads combined with dead, live and postulated accident loads is  $10^{-5}$  per reactor year. Hence the margin of a plant to failure under a design basis seismic event is greater than 1.67.

Safety related SSCs are those that are relied upon to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure. Regulatory Guide 1.29, Seismic Design Classification provides a method of identifying seismic Category I SSCs. The list of seismic Category I SSCs serves as an overall list of safety related SSCs. Those non-safety related SSCs, the failure of which, can prevent or interfere with the safe function of safety related SSCs should be capable of withstanding the effects of the design basis seismic loads in combination with dead, live and any simultaneous effects of accidents.

It should be noted that the performance requirement of  $10^{-5}$  per year frequency of inelastic deformation for design of safety related SSCs leads to a seismic design response spectrum derived from  $10^{-4}$  per year seismic hazard curves (see American Society of Civil Engineers Standard 43-05). In addition, new reactor designs are expected to demonstrate that an as-built plant has a plant level seismic margin of 1.67 times the design-basis seismic event at a high confidence in low probability of failure level.

**Question Number:** 17-3

**Question/Comment:** Four early site permits have been recently submitted. Does the USA make a public inquiry before giving authorization, despite the proximity of existing installations?

**Response:** The NRC performs the same review of an early site permit application for a site where there already exists one or more operating nuclear power plants as it does for a “greenfield” site where there are no existing facilities. That review provides for early public notification of the intended application for an early site permit, public access to the application and NRC safety review information, public involvement in the environmental review, and an adjudicatory hearing prior to the NRC’s final decision on the early site permit where the public has the opportunity to participate. Early site permit applicants may use information previously approved by the NRC when it granted a construction permit or operating license for facilities at or near the proposed site.

**Question Number:** 17-4

**Question/Comment:** In accordance to the 4th paragraph of Section 17.1 and 1st paragraph of Section 17.2.1, recent ESP application sites in Virginia, Illinois, Mississippi and Georgia, are located adjacent to existing operating NPP sites, and the new site criteria (10 CFR 100.23, R.G. 1.165, R.G. 1.208) were applied to these sites. Do you have procedure to reflect the new results to existing NPPs in operation, when new ESP results are different from the old ESP results used in existing NPPs in operation?

**Response:** In support of early site permits (ESPs) for new reactors, the NRC staff reviewed updates to seismic source and ground motion models provided by applicants. The seismic update information included new models to estimate earthquake ground motion and updated models for earthquake sources in seismic regions such as eastern Tennessee, and around both Charleston, South Carolina, and New Madrid, Missouri. This new data and models resulted in increased estimates of the seismic hazards for plants in the Central and Eastern United States (CEUS), but these estimates remain small in an absolute sense. The staff reviewed and evaluated this new information along with recent U.S. Geological Survey (USGS) seismic hazard estimates for the CEUS, used for building code applications (as opposed to nuclear power plant licensing). From this review, the staff identified that the estimated seismic hazard levels at some current CEUS operating sites might be higher than seismic hazard values used in design and previous evaluations.

The NRC staff compared the new seismic hazard data with the earlier evaluations conducted as part of the Individual Plant Examination of External Events Program. From this comparison, the staff determined that seismic designs of operating plants in the CEUS still provide adequate safety margins.

**Question Number:** 17-5

**Question/Comment:** How does NRC identify the seismic sources at sea near NPP for NPP siting?

**Response:** The NRC does not identify the seismic sources for NPP siting. The applicants are required by regulation to identify and assess all the potential seismic sources (on land and at sea) to support the application for a new NPP.

**Question Number:** 17-6

**Question/Comment:** Last paragraph in the part of Section 17.2.1 describes that the licensee is expected to monitor the environs around the NPPs and 'report changes' in the environs in its safety analysis report. Is the 'reporting changes' compulsory or optional? If that is compulsory, what are the items to report and how often the report to be submitted?

**Response:** The regulations do not specify the items to be reported. Changes in the environs have the potential to affect the design function of structures, systems or components described in the Final Safety Analysis Report through indirect or secondary effects. Licensees are expected to evaluate changes in the environs to determine if the change affects operation of the facility and whether implementation of compensatory measures is necessary. These changes would be reported in the licensee's periodic updates to the Final Safety Analysis Report, required by 10 CFR 50.71(e).

For example, installation of an airport nearby could impact a licensee's aircraft collision probability; or installation of a chemical storage facility nearby could affect a licensee's toxic gas response.

**Question Number:** 17-7

**Question/Comment:** Section 17.2.1 (Background) refers to 10CFR100 regarding the demographic factors. According to 10CFR100.12 as related to the population center, the boundary of the population center shall be determined upon consideration of population distribution. Do you have any standard or guideline on how to determine the boundary of the population center considering population distribution?

**Response:** The reference in the question should be 10 CFR 100.11, "Determination of exclusion area, low population zone, and population center distance."

10 CFR 100.3, "Definitions," defines the population center distance as the distance from the reactor to the nearest boundary of a densely populated center containing more than about 25,000 residents.

In addition, 10 CFR 100.11(a)(3) states that an applicant should determine a population center distance of at least one and one-third times the distance from the reactor to the outer boundary of the low population zone. In applying this guide, the boundary of the population center shall

be determined upon consideration of the population distribution. Political boundaries are not controlling in the application of this guide. Where very large cities are involved, a greater distance may be necessary because of total integrated population dose consideration.

**Question Number:** 17-8

**Question/Comment:** All new and advanced reactor designs are required to demonstrate that they have a plant level seismic margin of 1.67 times the design basis safe shutdown earthquake with high confidence (95%) in low (5%) probability of failure.

Has this calculation been carried out for plant site specific conditions? If not, is the standard value of the design basis safe shutdown earthquake adopted as the parameter common for all sites (for example, design basis safe shutdown earth-quake exceeding 7 points per MSK-64)?

**Response:** This calculation has been done generically for four (4) certified designs, not on a site-specific basis. The value is applicable to all standard designs and is consistent with the prescribed ground motion response spectrum curve.

**Question Number:** 17-9

**Question/Comment:** How is the implementation of art.17 (iii) of the CNS demonstrated, with regard to the re-evaluation of all relevant site-related factors so as to ensure the continued safety acceptability of the nuclear installation?

**Response:** Siting criteria and acceptable methodologies for implementing these criteria are delineated in the NRC regulations and regulatory guides. Prospective applicants for new reactor licensing provide details and analyses consistent with the regulations which are evaluated by the staff. The staff evaluates the information consistent with its review guidance to ensure quality and uniformity, to provide assurance that a given design will comply with NRC regulations, and to provide adequate protection of the public health and safety.

**Question Number:** 17-10

**Question/Comment:** It is said in the report that the licensee is expected to monitor the environs around the NPP. How has the ambient radioactivity assessed before power operation so as to be able to assess the effects of the NPP operation?

**Response:** Ambient radioactivity may be assessed before power operation via two methods: an estimate of background radiation for the proposed site based on historical data or at least a year's radiation data from a meteorological tower at the proposed site.

## 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, under “Verification by Analysis, Surveillance, Testing and Inspection,” also addressed this obligation. 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.”

**Question Number:** 18-1

**Question/Comment:** The report states that “the NRC has certified four standard plant designs under the design certification process in 10 CFR Part 52 – General Electric’s advanced BWR (1997), and Westinghouses’s System 80+ (designed and license by Combustion Engineering), AP600 and AP1000 (1997, 2000, and 2006, respectively).” Since these designs were certified, a number of changes in regulatory requirements have taken place and potential changes are being considered, such as those related to, “Digital Instrumentation and Controls”, large LOCA, lessons learned for operating experience, PRA, etc. Please explain how the “new” requirements are applied to designs that had previously been certified.

**Response:** The NRC’s regulations cannot impose new requirements on a previously-certified design except under certain circumstances, including but not limited to, design changes necessary to assure adequate protection to public health and safety or common defense and security, correction of material errors in the original design, or changes which substantially increase overall safety, reliability or security of the design. Please refer to 10 CFR 52.63.



**Question Number:** 18-2

**Question/Comment:** Could USA explain how they take benefit from the experience gained by the foreign countries operating U.S. designed NPPs?

**Response:** The NRC receives information regarding international OpE from the International Nuclear Event Scale (INES), the Web-based Incident Reporting System (WBIRS), bilateral agreements, and international conferences. This information is collected, screened, evaluated, and applied using the same processes which are used for domestic OpE. The screening of international events is performed only to determine if the information has applicability to the current fleet of operating reactors. Several international events have been shared internally with cognizant technical staff through the web-based OpE Community forum. In addition, multiple international events have been “screened in” for further evaluation due to their risk significance and potential generic applicability to current U.S. operating reactors. Several generic communications have been developed from OpE received from reactors in foreign countries.

**Question Number:** 18-3

**Question/Comment:** Section 18.1.1 (Governing Documents and Process) discusses the new inspection programme under 10CFR52. It is described in Page 129 that the new inspection programme revises the 10 CFR Part 50 construction inspection programme. In the other hand, Section C.II.1 (ITAAC) of RG 1.206 explains details about ITAAC and ITP to be described in Section 14.2 of the FSAR which are needed as part of COL application. Regarding ITAAC and the ITP (especially the Preoperational Tests), please address the following:

RG 1.206 specifies that both the Preoperational Tests (Section 14.2 of FSAR) and the ITAAC should be submitted for COL application. In Page C.II.1-3 of RG 1.206, it is described that “The Preoperational tests described in Section 14.2 of the FSAR portion of a COL application is not a substitute for ITAAC.” However, it is considered that most of Preoperational Tests are similar to those of ITAAC. Why does the COL-ITAAC require duplicate information?

If additional test requirements are imposed by ITAAC as compared to the Preoperational Tests in Section 14.2 of the FSAR, does that mean that the new plants licensed under 10CFR52 must go through more stringent tests than the existing plants licensed under 10CFR50?

**Response:** As stated in 10 CFR 52.80(a), the purpose of ITAAC is to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria are met, the facility has been constructed and will operate in conformity with the COL, the provisions of the Atomic Energy Act, and the NRC regulations. ITAAC should be based on information provided in the detailed design criteria for SSCs contained in the FSAR. These design criteria establish the necessary design, fabrication, construction, testing, and performance requirements.

Preoperational testing consists of those tests conducted following completion of construction and construction-related inspections and tests, but prior to fuel loading, to demonstrate, to the extent practical, the capability of structures, systems, and components to meet performance requirements to satisfy the design criteria, consistent with Appendix A, "General Design Criteria," and Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50.

In order to satisfy both ITAAC and preoperational testing, COL applications would need to include information on both requirements. However, as stated in Section C.II.1 of RG 1.206, the results of preoperational tests can be used, to the extent practical, to satisfy ITAAC test requirements. This approach would prevent duplication of effort with regard to testing required to satisfy ITAAC.

Part 52 requires that licensees provide adequate testing to satisfy both design and performance requirements consistent with the design criteria contained in the FSAR. Both preoperational tests and tests necessary to meet ITAAC requirements are derived from these design criteria. Since licensees may rely on preoperational testing to meet ITAAC, no additional test requirements are expected to be imposed by ITAAC.

**Question Number:** 18-4

**Question/Comment:** Could you please provide more information/references to regulatory requirements/guidance specific for the licensing of deferred plants?

**Response:** On October 14, 1987, the NRC published a statement of its policy with regard to the procedures that apply to nuclear power plants while in a deferred status and when they are being reactivated. The statement addresses regulations and guidance applicable to deferred and terminated plants; maintenance, preservation, and documentation requirements, and the applicability of new regulatory requirements and other general administrative considerations. The policy was published in the Federal Register at 52 FR 38077. It was also distributed via Generic Letter 87-015, "Policy Statement on Deferred Plants".

The Commission provided specific direction to the staff regarding licensing activities for Watts Bar Nuclear Plant (WBN) Unit 2 in a July 25, 2007 Staff Requirements Memorandum associated with SECY-07-0096. The Commission instructed the staff to implement the policy on deferred plants. Further, the Commission directed the staff to implement a licensing review approach that employs the current licensing basis for WBN Unit 1 as the reference basis for the review and licensing of Unit 2. The Commission instructed the staff to review any exemptions, reliefs and other actions granted for WBN Unit 1 to determine the appropriateness for WBN Unit 2; to encourage TVA to adopt updated standards for WBN Unit 2 where it would not significantly detract from design and operational consistency between Units 1 and 2; and to look for opportunities to resolve issues such as generic safety issues where the unirradiated state of WBN Unit 2 makes the issue easier to resolve than at WBN Unit 1.

**Question Number:** 18-5

**Question/Comment:** This section explains the defense-in-depth philosophy followed in regulatory practice. At the same time, Regulatory Guide 1.174 provides guidance on using a PRA in risk-informed decisions on plant-specific changes. The general design criteria establish the minimum requirements for the principal design criteria, which in turn establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs that are important to safety.

Does the application of risk assessment results influence the defense-in-depth philosophy which in its essence is of deterministic nature? Does not it make the defense-in-depth weaker?

**Response:** Risk assessment results cannot be used to allow nonconformance to any regulations, including the general design criteria. One of the key principles of risk-informed decision making is to maintain compliance with regulations. Once compliance is established, however, the risk assessment results may be used to identify specific aspects of the plant design and licensing basis which have significant safety margins or defense-in-depth, which could allow changes to the license (i.e., changes to Technical Specifications or license conditions) without having a significant safety impact. In such cases, it may be appropriate to accept a reduction in defense-in-depth which does not cause any substantial risk increase, while still maintaining adequate safety margins.

**Question Number:** 18-6

**Question/Comment:** The Defense-in-depth is basically a deterministic concept to prevent and mitigate nuclear accidents. To what extent could the risk-informed approach contribute to this concept? (This is a very fundamental question to be further discussed at the review meeting).

**Response:** For the current reactor licenses, changes to the licensing basis (including defense-in-depth) are addressed by Regulatory Guide 1.174, which requires separate consideration of deterministic safety (defense-in-depth, safety margins, compliance with regulations, and performance monitoring). Although risk insights can inform the decision on the acceptable level of defense-in-depth, risk cannot be used to justify elimination of deterministic safety features. For future advanced reactor designs, NRC is considering changes to more directly integrate risk insights into the plant design and licensing process.

**Question Number:** 18-7

**Question/Comment:** Have you met specific problems to find spare parts or replacement components properly qualified to a high safety class, as needed for plant lifetime management? If yes, how have you addressed the problem?

**Response:** Almost all, if not all, utilities are faced with the problem of obsolete components and equipment and have an organization tasked with trending system performance and long-term system reliability planning.

Assessing the problem of finding adequate replacement parts is typically part of their function.

Some stations perform commercial dedication of non-safety related parts in order to bring them up to the required quality standards. In other cases, some stations are reverse engineering components and equipment, ranging from pumps to circuit cards. Also, a few third party vendors are building and selling equivalent replacement parts for some critical components that the original vendor is no longer manufacturing.

In addition, Utility Obsolescence Procedures and Program Guidelines have been written by several utilities and other utilities have dedicated programs to assess the end-of-life of active components to prioritize future upgrades, refurbishment, or inspections. An industry working group (the Nuclear Utilities Obsolescence Group) has been formed to share operating experience concerning these challenges.

**Question Number:** 18-8

**Question/Comment:** It is mentioned that licensees have voluntarily replaced analog instrumentation with digital systems. Furthermore, safety issues not relevant to analog systems and the need for regulatory activities in this area are described on Page 131. Since this is a common generic issue, please report about the digital I&C key areas of concern and the efforts for resolution.

**Response:** In 2007, the NRC formed the Digital I&C Steering Committee to develop and implement a project plan to address the need for additional guidance in certain digital instrumentation and control (I&C) areas. Six task working groups were established to address specific issues. The issues are:

- Cyber Security,
- Diversity and Defense-in-Depth,
- Risk-Informed Digital I&C,
- Highly-Integrated Control Room – Communications,
- Highly-Integrated Control Room - Human Factors
- Licensing Process Issues

The Project Plan has been developed and is publicly available in ADAMS (Accession No. ML071900253). The principal purpose of the Steering Committee and the Project Plan is to ensure the quality and uniformity of NRC staff reviews and to present well-defined bases for the evaluation of license applications of digital I&C technology. This is accomplished by the development of interim staff guidance documents (ISGs). The Project Plan includes long-term actions which when completed will replace the ISGs. There are currently 17 long-term actions described in the Project Plan that involve Rulemaking, Standard Review Plan Revisions, NUREG development, and Regulatory Guide revisions.

To date the NRC staff has issued the following four ISGs:

- Diversity and Defense-In-Depth,
- Highly Integrated Control Room (HICR) Communications,
- HICR – Human Factors
- Cyber Security.

These ISGs are publicly available on the NRC public web site (<http://www.nrc.gov/reading-rm/doc-collections/isg/digital-instrumentation-ctrl.html>).

The task working groups are working to complete five additional ISGs:

- Risk Informing Digital I&C Guidance for Reviewing New Reactors, scheduled to be issued in March 2008,
- Licensing Process excluding Cyber Security, scheduled to be issued in July 2008,
- Manual Operator Action, scheduled to be issued in July 2008,
- Fuel Cycle, scheduled to be issued in October 2008, and
- Licensing Process including Cyber Security, scheduled to be issued in February 2009.

**Question Number:** 18-9

**Question/Comment:** Most recently, W used separate effects tests programmes, integral systems tests and analyses to demonstrate that its passive safety systems will perform as predicted in its SAR for the AP600 and AP1000 standard plant design. Is the NRC staff involved in the process of such testing? If yes, how the NRC staff is involved?

**Response:** The NRC primarily conducts separate effects or integral systems tests independently from applicants to support regulatory decisions. On occasion, the NRC has participated in joint testing with the industry focused on data development. The data were then used independently by the industry and the NRC in support of analytical activities. The independent test programs may be conducted in facilities which performed testing for the industry, or in facilities solely funded by the NRC. Such facilities have included universities, national laboratories, and international agency/partnership facilities.

**Question Number:** 18-10

**Question/Comment:** It is reported that the NRC and the NEI developed guidance concerned with cyber security. How are the results of licensees applying cyber security guidance? How are licensee's cyber security improved?

**Response:** Following the September 11, 2001, terrorist attacks on the United States, the NRC issued several orders to power reactor licensees to enhance their site security posture. Two of these orders explicitly mandated new digital system security (i.e., cyber security) measures, the details of which are not publically available. In addition, in 2007, the NRC completed a rulemaking that added an external cyber attack to the list of adversary

characteristics in the design basis threat for radiological sabotage (see 10 CFR 73.1). Finally, the staff proposed a series of new requirements in October 2006 that would mandate implementation of a comprehensive cyber security program for digital systems at power reactor sites associated with safety, security and emergency preparedness (see proposed rule 10 CFR section 73.55(m)).

In 2005, the power reactor industry, as represented by the Nuclear Energy Institute (NEI), completed development of a comprehensive cyber security implementation guidance document, known as NEI 04-04. The NRC staff reviewed and endorsed Revision 1 of this document in December 2005. NEI 04-04 is also not available to the public. In anticipation of the forthcoming new NRC regulations, the industry committed to implement the guidance in NEI 04-04 Revision 1 at all power reactor sites by May 2008.

Finally, the staff is developing a new regulatory guidance document (i.e., a Regulatory Guide) for cyber security that will provide implementation details associated with the NRC's new regulations described above. Once the rulemaking and associated guidance is complete, the NRC plans to modify the security inspection program to include evaluations of power reactor compliance with the new cyber security requirements.

**Question Number:** 18-11

**Question/Comment:** What changes have been made or are planned to be introduced to the Appendix A to 10 CFR Part 50 as a result of NRC's experience in the certification of new designs?

**Response:** The NRC's experience with the new designs will be reflected in new or modified regulatory documents, but it may be that the experience will be reflected mainly in a new risk-informed, technology-neutral framework, rather than in changes to Appendix A, some of which may nonetheless be incorporated into the new framework. See the advance notice of rulemaking for a new Part 53, 71 Federal Register 26267 (May 4, 2006). For the likely elements of such a framework, see NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," December 2007. The staff notes that Appendix A has been understood from the beginning not to encompass all relevant standards even for water-cooled reactors (see the last paragraph of the introduction to Appendix A).

## 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 programmed 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) programmes 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 associated programs in granting the initial authorization to operate a nuclear installation and in monitoring its 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.

**Question Number:** 19-1

**Question/Comment:** For the lessons learned from Kashiwasaki Kariwa nuclear power plant earthquake event, whether NRC has the requirement to assess the anti-seismic ability of the operating nuclear power plants in United States?

**Response:** In the assessment of the Kashiwasaki Kariwa earthquake performed to date, no critical issues have arisen which would necessitate additional actions in nuclear power plants in the United States. The NRC requires that the design of nuclear facilities account for seismic loading. Newly updated NRC guidelines indicate that seismic loading levels used in design must meet or exceed 10,000 year earthquake ground motion for new nuclear power plant facilities. Information on NRC seismic guidelines is available in the Regulatory Guide 1.208, "A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion," and in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants." Seismic design requirements are detailed in the Code of Federal (CFR) regulations in part 50 and part 100 of 10 CFR. In addition to the updated guidelines that apply to new facilities, the NRC also periodically reassesses the nuclear power plants for seismic safety when new information becomes available.

The existing operating nuclear power reactors in the U.S. are designed to withstand conservative site-specific design basis earthquake ground motions developed based on appropriate consideration of the most severe earthquakes historically reported for the site and the surrounding area, with sufficient margin for the limited accuracy, quantity and time period of available historical data. In the 1990s, the NRC conducted an Individual Plant Examination of External Events (IPEEE) assessment of severe accident vulnerabilities of plant components beyond design basis earthquake for each U.S. operating reactor. The conclusion was that additional seismic design capacity exists for safety-related components beyond the postulated seismic design demand. The IPEEE program considered seismic events; internal fires including seismic-induced; and high winds, floods and others (HFO) as accident initiating events. Component failures such as those seen at the Kashiwasaki-Kariwa (KK) Nuclear Plant (e.g. fire protection piping, transformer fire, etc.) were addressed in the IPEEE assessment. Thus, operating nuclear power plants in the U.S. are conservatively designed for earthquake events with additional safety margins and are expected to perform safely as designed during credible seismic events. Therefore, the NRC does not intend to impose any new requirements on U.S. operating reactors to reassess their seismic design based on the impact of the July 2007 Japanese earthquake experienced at the KK Nuclear Plant.

It is noted that in the case of the July 2007 Japanese earthquake, the ground motions recorded at the KK Nuclear Plant exceeded the design basis earthquake ground motions of the plant. If an operating reactor in the U.S. experienced an earthquake that exceeded its design basis SSE and the IPEEE evaluation limits, then the NRC would issue an



appropriate generic communication requesting licensees to reassess their seismic design in relation to the facts of that seismic event.

**Question Number:** 19-2

**Question/Comment:** How about the progress of nuclear power plants to modify the technical specification by usage of risk-informed technology or PRA results? What are the criteria when NRC assesses these modifications?

**Response:** The use of risk information and technology has long been a fundamental ingredient in improving technical specifications. In the 1983 publication "Technical Specifications - Enhancing the Safety Impact" (NUREG-1024), the NRC Task Group on Technical Specifications commented on the technical specifications of the era:

"The Task Group recognizes that the times associated with surveillance frequencies, allowable outage times, etc., have been established on a deterministic basis using engineering judgment. The Task group also believes that engineering judgment must be the primary basis for any changes to the Technical Specifications. However, the Task Group believes that the use of insights from probabilistic risk assessments could be a significant aid in arriving at these judgments."

Technical Specifications have taken advantage of risk technology as experience and capability have increased. Guidance documents have been prepared to assist in requesting risk-informed completion time (also called allowed outage time) and surveillance test interval extensions (Regulatory Guide 1.177 and Standard Review Plan Chapter 16.1 [NUREG-0800]). Use of this guidance (categorized as "Option 1" in the framework of the Risk-Informed Regulatory Improvement Program) has resulted in risk-informed amendments at numerous plants and in owners groups continuing to submit topical reports to support additional applications for Standard Technical Specification (STS) changes.

Before issuance of the maintenance rule, 10 CFR 50.65, in July 1991, technical specifications primarily governed plant operations. They dictated what equipment must normally be in service, how long equipment can be out of service, compensatory actions, and surveillance testing to demonstrate equipment readiness. The maintenance rule marked the advent of a regulation with significant implications for the evolution for technical specifications. The goal of these technical specifications is to provide adequate assurance of the availability and reliability of equipment needed to prevent and, if necessary, mitigate accidents and transients. The maintenance rule shares this same goal but operates at a more fundamental level with a dynamic and more comprehensive process.

In addition to specifying a process for monitoring the effectiveness of maintenance, including performance and condition monitoring, and for balancing maintenance unavailability and equipment reliability, the maintenance rule requires licensees to assess and manage plant configuration risk that results from maintenance. The maintenance rule has put in place many of the mechanisms, measures, and processes

envisioned by staff as needed to enhance the safety impact of technical specifications. Thus, achieving synergy between the static technical specifications and the dynamic maintenance rule is a major aim of the effort to create risk management technical specifications.

Eight initiatives for fundamental improvements to the STS are being developed by the industry and discussed with the NRC staff in public meetings:

- Initiative 1, TS Actions End States Modifications: This initiative would permit, for some systems, entry into hot shutdown rather than cold shutdown to repair equipment;
- Initiative 2, Missed Surveillances, Surveillance Requirement (SR) 3.0.3: This initiative permits the extension of up to one surveillance interval of an inadvertently missed surveillance, after assessing and managing the risk (approved September 2001);
- Initiative 3, Modification of Mode Restraint Requirements of Limiting Condition for Operation (LCO) 3.0.4 and SR 3.0.4: This initiative permits, for most systems, transitioning up in mode with inoperable equipment, relying on compliance with the technical specification actions of the higher mode, after assessing and managing the risk (approved April 2003);
- Initiative 4b, Flexible Completion Times: This initiative would permit, contingent upon the results of a plant configuration risk assessment, temporary extension of the existing completion time within an LCO using a quantitative implementation of 50.65(a)(4);
- Initiative 5b, Relocation of all SR Frequency Requirements out of TS: This initiative would permit SR frequencies to be determined in and relocated to a licensee-controlled TS program;
- Initiative 6, Modification of LCO 3.0.3 Actions and Completion Times: This initiative would convert default or explicit entry into the LCO 3.0.3 shutdown track into a completion time for corrective action before beginning shutdown.
- Initiative 7, Non-TS Support System Impact on TS Operability Determinations: This initiative would permit a risk-informed delay time before entering LCO actions for inoperability due to loss of support function provided by equipment outside of technical specifications;
- Initiative 8a and 8b, Remove/Relocate Non-safety and Non-risk Significant Systems from TS that do not meet the four criteria of 10 CFR 50.36: Initiative 8a would review technical specifications to remove systems that were included solely because they were judged risk significant at one time and have now been shown by analysis not to be. Initiative 8b would make the scope of technical specifications depend only on risk significance.

**Question Number:** 19-3

**Question/Comment:** The report states “To date, over half of the operating commercial nuclear plants have converted their technical specifications to the improved standard technical specifications.” What are the implications for those plants that have not converted their technical specifications?

**Response:** There are no safety implications for those plants that have not converted their Technical Specifications to the improved STS. However, for these plants, there is the added burden associated with ensuring compliance with a substantially larger number of Technical Specifications requirements which could result in plant transients or shutdowns with no resulting safety benefit.

In 1992, the NRC issued the improved STS to more clearly define the content and form of requirements necessary to ensure safe operation of nuclear power plants in accordance with Title 10, Code of Federal Regulations (10 CFR) Section 50.36, “Technical Specifications.”

In its Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors, issued on July 22, 1993 (58 FR 39132), the Commission placed the highest priority on license amendment applications to convert the technical specifications to the improved STS.

The policy statement reasoned that since 1969 there had been a trend towards including in Technical Specifications for not only those requirements derived from safety analyses and evaluation included in the safety analysis report, but also essentially all other Commission requirements governing the operation of nuclear power reactors. This extensive use of Technical Specifications is due in part to a lack of well-defined criteria for what should be included in Technical Specifications. This has contributed to the volume of Technical Specifications and to the several-fold increased, since 1969, in the number of license amendment applications to effect changes to the Technical Specifications. Technical Specifications cannot be changed by licensees without prior approval by NRC. It has diverted both staff and licensee attention from the more important requirements in these documents to the extent that it has resulted in an adverse but unquantifiable impact on safety. The NRC continues to believe that total adoption of the improved STS will focus licensee and plant operator attention on those plant conditions most important to safety. This should substantially improve the efficiency of the regulatory process, and ensure that licensee and NRC resources are applied to significant safety matters.

**Question Number:** 19-4

**Question/Comment:** With respect to approved procedures for operations and maintenance, are there any requirements on the licensees to involve the concerned staff in development of these procedures?

**Response:** Criterion V “Instructions, Procedures, and Drawings” of Appendix B to 10 CFR Part 50, “Quality Assurance Criteria for Nuclear Power Plants and

Fuel Reprocessing Plants” contains requirements for procedures. However, there is no specific requirement to involve the working staff in development of the procedures.

**Question Number:** 19-5

**Question/Comment:** It is mentioned that the ROP includes techniques to ensure that adequate engineering and technical support is available throughout the lifetime of the nuclear installation. Please explain the acceptance criteria for this. Are there any requirements related to engineering and technical support competencies to be available on-site as opposed to at the corporate level?

**Response:** The Reactor Oversight Process has several inspection procedures that inspect various areas of the plant to ensure that continuous and adequate engineering and technical support is available. For example, the NRC inspects the effectiveness of the licensee’s implementation of changes to the facility systems, structures, and components (SSCs), risk-significant normal and emergency operating procedures, test programs, and updated final safety analysis report (UFSAR) in accordance with the requirements of the Code of Federal Regulations Part 50.59. We review the licensee’s evaluation of equipment operability and degraded and non-conforming conditions affecting plant SSCs. The NRC inspects the licensee’s implementation of plant modifications to verify that the design basis, licensing basis, and performance capability has not degraded.

There is no requirement for the licensee to maintain an engineering department on site. However, it is typical that most licensees have an engineering staff at the site to deal with emergent activities and other short term projects. An engineering staff may also be maintained at the corporate level to support a fleet of nuclear plants and have oversight of long-term projects. It is the licensee’s responsibility to provide long-term engineering and technical support for life-cycle of the plant.

**Question Number:** 19-6

**Question/Comment:** In 1992 and 2000 the NRC modified the licensee event reporting requirements of 10 CFR 50.72, “Immediate Notification Requirements for Operating Nuclear Power Reactors,” and 10 CFR 50.73, “Licensee Event Report System,” delete reporting requirements for some events that were determined to be of little or no safety significance. Has this cancellation of the requirement affected the content and detection of precursors?

**Response:** No, please refer to NUREG-1022, Revisions 1 and 2 for further details on the changes in reporting requirements. The current reporting requirements, along with the inspection program, are more than adequate to detect all potential risk-significant events.

**Question Number:** 19-7

**Question/Comment:** Please explain the principles or criteria applied by the regulator and operator for screening other experience than incidents (e.g., management issues, unexpected degradation, design weaknesses, external hazards not considered earlier), for the purpose of ensuring adequate sharing of important experience with international interested parties (regulatory bodies, operators, designers, international bodies). Identify the relevant guide documents, if any, used for the screening.

**Response:** The NRC Operating Experience (OpE) Program has four phases for collecting, screening, evaluating and applying lessons learned, as described in the associated office instruction. The OpE Clearinghouse meets regularly to review various OpE data inputs and make screening decisions to determine if further evaluation is warranted. The Clearinghouse screens many data sources including new reactor event notifications, licensee event reports (LERs), preliminary notifications, Part 21 notifications, NRC inspection report findings, international events, and plant status information. Often these reports describe issues other than incidents, such as design weaknesses, system vulnerabilities, and external hazards. These issues are screened similar to incidents.

The NRC shares domestic OpE with the international community through multiple channels. Each reported domestic event is rated daily using the International Nuclear Event Scale (INES). Events that are rated Level 2 or above (on a scale of 0-7 with 7 being the most severe) are reported internationally through the Nuclear Events Web-based System (NEWS). In addition, the NRC submits about 20 reports (reactor-related generic communications) each year to the Web-based Incident Reporting System (WBIRS), which is available to regulators and other nuclear organizations in foreign countries. The NRC also participates in various international conferences sponsored by the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA) where various plant issues are shared. These reports and presentations are not only incident-based but may also describe other issues such as unexpected degradation, design weaknesses, and external hazards.

For U.S. stations, INPO has guideline documents that describe the industry Operating Experience Program and actions for stations to meet program requirements. Among the requirements is for stations to voluntarily report on events occurring at their stations with lessons that other stations can learn from. About 30 event reports per station are typically submitted to INPO each year, which cover a variety of issues including equipment failures or degradation events that had operational consequences, events involving human error, conditions that do not meet design, and near-miss events that had potential for personal injury, operational impact or equipment damage.

**Question Number:** 19-8

**Question/Comment:** Please explain how the regulatory body ensures or verifies that the operators are informed and properly analyze the operating experiences reported through the well established international channels (e.g., WANO, IRS), and that they address the lessons learned by taking proper actions.

**Response:** The NRC maintains a group of engineers who collect, screen, evaluate, propose corrective actions, and perform follow-up activities, regarding US and international operating experience. This group interacts routinely with INPO and regularly obtains international experiences through many information collection channels.

For operating experience items that are safety significant, the NRC may take regulatory action through a generic communication to require responses from the licensees or issuing orders for actions, or they may influence agency programs such as inspection, oversight, licensing, incident response, security, rulemaking, and research. Less common outcomes of operating experience issue recommendations are rulemaking or transfer to the agency generic safety issues program. The specific actions of the NRC are determined by the safety significance of the experience, and the applicability to the operators.

The NRC inspection program also includes a biennial Problem Identification and Resolution (PI&R) inspection at each utility. One of the objectives of a PI&R inspection is to determine whether utilities are complying with NRC regulations regarding corrective action program implementation. In a PI&R inspection, NRC inspectors look at the utility's response to Operating Experience from all sources including NRC, INPO, and industry. The NRC evaluates the effectiveness of the licensee's corrective action program in identifying, evaluating, and correcting problems, including those identified through operating experience.

**Question Number:** 19-9

**Question/Comment:** Please explain your national policy and practice of sending feedback reports to the international interested parties on actions that have been taken in your country as response to significant events reported through international channels (e.g., WANO, IRS).

**Response:** The NRC receives information regarding international operating experience (OpE) from the International Nuclear Event Scale (INES), the Web-based Incident Reporting System (WBIRS), and from bilateral agreements and international conferences. This information is collected, screened, evaluated, and applied using the same processes which are used for domestic OpE. The screening of international events is performed only to determine if the information has applicability to the current fleet of operating reactors. Several international events have been shared internally with cognizant technical staff through NRC's web-based OpE Community forum. In addition, a few international events have been screened in for further evaluation due to their risk significance and potential generic applicability to the current operating reactors. Several

generic communications have been developed due to experience at reactors in foreign countries. The NRC does not often provide direct feedback to foreign countries regarding actions take domestically in regard to foreign events. This type of OpE feedback information would be shared with foreign countries if asked, and it is often discussed at conferences. However, there is no formal feedback mechanism in place for communicating what actions were taken in response to foreign events.

INPO freely shares event information with its members and with WANO. WANO broadly distributes event information to its members so that they are aware of the issues and can implement actions that may preclude similar events at their stations.

**Question Number:** 19-10

**Question/Comment:** Under §19.6, the report states that “Over the years, decreasing trends in the number of reactor transients and significant events and improvements in reactor safety system performance have been evident.” But, under § 19.7, it states that “the NRC revised its Operating Experience Program in 2005...

Could the USA explain the reasons which motivated the decision to revise this programme, since the situation was deemed satisfactory before this decision?

**Response:**

In 2003, the NRC created the Reactor Operating Experience Task Force (ROETF) to evaluate the agency’s reactor operating experience (OpE) program and to recommend specific program improvements.

The task force conducted a broad assessment of the NRC’s OpE program, evaluating both the functional elements and the programmatic and process elements required for an effective program. The functional elements of an OpE program involve both short-term and long-term efforts directed at identifying safety issues, assessing their significance, and taking actions to address the issues. The actions could involve informing licensees, taking regulatory action, and revising agency programs. To be effective, the functional elements need to support and work in concert with agency licensing, inspection, and research programs. The ROETF was also aware that during the period of this task force evaluation, the agency was taking actions related to the OpE program to address lessons learned from the Davis-Besse event. These actions included an OpE function realignment, revision of an inspection procedure to enhance the use of OpE and a review of past generic communications to identify areas for additional follow-up.

Overall, the task force determined that the agency’s previous reactor OpE activities included each of these necessary functions. The task force found that the most significant overall program weakness was the absence of a clear agency vision of how all of the agency’s OpE program activities should function together and be integrated with the licensing, inspection, and research program activities. As a result the agency had not fully leveraged lessons learned from OpE to further program goals.

Agency-level procedures that provide this vision had not been updated for many years, and no individual was designated as having responsibility for program coordination activities. As a result, although the primary OpE program functions of collecting, screening, trending and evaluating OpE were generally understood, the responsibilities and processes for utilizing the lessons learned from the evaluations to improve the agency's regulatory process were not well defined.

The collection, storage, and retrieval of OpE information and data are vital to an effective OpE program. The task force determined that although there was a large amount of OpE data available, much of the data was not readily accessible, the interface was often not user friendly, and some OpE information was not routinely sent to a central OpE organization for screening and further dissemination. While it is important for NRC staff to have access to the appropriate OpE information to perform their jobs, they must also be aware that they are an important source of OpE information. There was no convenient and clearly understood process for NRC staff to forward OpE information that may have generic applicability to an OpE organization for follow-up and assessment.

**Question Number:** 19-11

**Question/Comment:** The NRC operating experience programme was revised in 2005. Is the effectiveness of this Operating Experience Feedback (OEF) programme assessed on a regular basis? What criteria are used for this purpose? What are the experiences with the Clearinghouse approach?

**Response:**

1) An Effectiveness Review of NRC's Operating Experience (OpE) Program was completed in June 2006. The Effectiveness Review assessed the program's performance during its first year of existence. A follow-up effort is underway to determine how well the OpE staff has responded to the Effectiveness Review.

2) The criteria used to evaluate the program during the effectiveness review were the same as the program's main goals: "NRC's ability to collect, communicate, evaluate, and apply the lessons learned from OpE." The staff solicited feedback from internal NRC stakeholders (users of OpE data) in order to determine how well the program was satisfying its high-level goals as stated in Management Directive 8.7: "It is the policy of the NRC to have an effective coordinated program to systematically review OpE of the nuclear power industry and non-power reactors, assess its significance, provide effective communication to stakeholders, and apply the lessons-learned to regulatory decisions and programs affecting nuclear reactors."

3) The Clearinghouse approach has provided excellent day-to-day continuity for tracking OpE information and screening the information for safety significance. The daily meeting provides the opportunity to put all collected OpE through the same screening process and results in consistent decisions to determine which information requires further communication and more detailed evaluation by the NRC technical staff.



The Clearinghouse continues to be one of the hallmarks of the NRC's OpE program.

**Question Number:** 19-12

**Question/Comment:** In 2005 the NRC put in force the revised Operating Experience Program, which incorporates a number of recommendations concerning better defined roles and responsibilities, a central clearinghouse, and improved collection, storage, and retrieval of information on operating events and experience. On another hand Institute of Nuclear Power Operations (INPO) activity is also dealing mainly with implementation of the following programmes: periodical assessments conducting on NPP's sites and other auxiliary enterprises of branch, operating experience analysis, exchange of information and provision of assistance.

What is the difference between the activities of the NRC and INPO established in 1979 year? What was the reason for developing additional operating experience programme?

**Response:**

1) The NRC established requirements for utilities to adopt industry operating experience into training and other programs in the 1980 NUREG 0737 following the accident at Three Mile Island. The INPO Significant Event Evaluation-Industry Notification (SEE-IN) program was concurrently being developed to provide an industry wide method to collect, screen and share lessons from significant events. This serves to relieve individual stations from analyzing and prioritizing large amounts of information, and was endorsed by the NRC in 1982.

The NRC and INPO work together in accordance with the NRC/INPO Memorandum of Agreement to share their ongoing Operating Experience (OpE) activities. Both organizations' OpE programs strive to collect, communicate, and evaluate data that meets a certain safety criteria and has generic applicability across all or part of the industry. Since the INPO reporting threshold is lower, INPO can develop products and recommendations focused on standards of excellence.

Much of the information collected and evaluated by INPO is given voluntarily by utilities when they report it into the INPO Nuclear Network. This database is available to any INPO member utility, and reports are loaded into INPO's Plant Events Database (PED) for further evaluation of their significance. Another tool that INPO has for gathering statistics on equipment reliability is the Equipment Performance and Information Exchange (EPIX) database. Many of INPO's OpE documents refer to data and trends that are part of EPIX. All data in EPIX comes from the utilities. INPO also develops OpE data from findings, or areas for improvement, identified in their plant evaluations. Of course, INPO reviews all public reports that are issued by the NRC, such as event notifications, licensee event reports, generic communications, inspection reports, and morning reports.

The NRC receives OpE information from several sources as well. INPO Significant Event Reports, Significant Operational Event Reports,

Significant Event Notifications, and Topical Reports are all distributed to NRC as part of the Significant Event Evaluation and Information Network (SEE-IN) database. In addition, the NRC has access to EPIX and can evaluate equipment performance data when necessary. NRC's resident inspectors provide daily feedback from the site to OpE evaluators both on reportable events and on other issues that do not rise to the reportability threshold. NRC's OpE evaluators also screen licensee event reports, event notifications, NRC inspection reports, 10 CFR Part 21 reports, and various other sources for notable OpE.

2) In 2003, the NRC created the Reactor Operating Experience Task Force (ROETF) to evaluate the agency's reactor operating experience (OpE) program and to recommend specific program improvements.

The task force conducted a broad assessment of the NRC's OpE program, evaluating both the functional elements and the programmatic and process elements required for an effective program. The functional elements of an OpE program involve both short-term and long-term efforts directed at identifying safety issues, assessing their significance, and taking actions to address the issues. The actions could involve informing licensees, taking regulatory action, and revising agency programs. To be effective, the functional elements need to support and work in concert with agency licensing, inspection, and research programs. The ROETF was also aware that during the period of this task force evaluation, the agency was taking actions related to the OpE program to address lessons learned from the Davis-Besse event. These actions included an OpE function realignment, revision of an inspection procedure to enhance the use of OpE and a review of past generic communications to identify areas for additional follow-up.

Overall, the task force determined that the agency's previous reactor OpE activities included each of these necessary functions. The task force found that the most significant overall program weakness was the absence of a clear agency vision of how all of the agency's OpE program activities should function together and be integrated with the licensing, inspection, and research program activities. As a result the agency had not fully leveraged lessons learned from OpE to further program goals. Agency-level procedures that provide this vision had not been updated for many years, and no individual was designated as having responsibility for program coordination activities. As a result, although the primary OpE program functions of collecting, screening, trending and evaluating OpE were generally understood, the responsibilities and processes for utilizing the lessons learned from the evaluations to improve the agency's regulatory process were not well defined.

The collection, storage, and retrieval of OpE information and data are vital to an effective OpE program. The task force determined that although there was a large amount of OpE data available, much of the data was not readily accessible, the interface was often not user friendly, and some OpE information was not routinely sent to a central OpE organization for screening and further dissemination. While it is important for NRC staff to

have access to the appropriate OpE information to perform their jobs, they must also be aware that they are an important source of OpE information. There was no convenient and clearly understood process for NRC staff to forward OpE information that may have generic applicability to an OpE organization for follow-up and assessment.

**Question Number:** 19-13

**Question/Comment:** INPO has a strong and very useful OEF programme. If there a risk that individual utilities rely fully on INPO for this work and do not perform the necessary local assessments? How is such a risk counteracted?

**Response:** In Generic Letter 82-04, the NRC approved industry use of INPO's Significant Event Evaluation and Information Network (SEE-IN) program to relieve individual nuclear plant operators and constructors of the necessity of setting up large staffs to obtain and screen the large volume of raw data pertaining to operational experience (OpE) throughout the industry. The existence of the SEE-IN program does not relieve utilities of their responsibility to have an internal procedure for handling and addressing OpE. Each utility has its own OpE program. Much of the information that makes INPO's program strong and useful comes directly from inputs by individual utilities into INPO's Nuclear Network. This, along with utility event notification reports, provides much of the source material used by INPO to develop SEE-IN documents, along with other OpE reports and recommendations. Part of INPO's Evaluation program looks at the utilities' processes for collecting, screening, and disseminating OpE.

The NRC inspection program also includes a biennial Problem Identification and Resolution (PI&R) inspection at each utility. One of the objectives of a PI&R inspection is to determine whether utilities are complying with NRC regulations regarding corrective action program implementation. In a PI&R inspection, NRC inspectors look at the utility's response to OpE from all sources including NRC, INPO, and industry. The NRC evaluates the effectiveness of the licensee's corrective action program in identifying, evaluating, and correcting problems. In addition, the NRC assesses the licensee's use of OpE information.

**Question Number:** 19-14

**Question/Comment:** Does a methodical comparative evaluation of stored event data (of one or more licensees) exist to detect systematic causes particularly in the field of human and organizational factors? How is foreign NPP operation experience taken into account?

**Response:** The NRC does not perform a methodical comparative evaluation of stored event data that detects systematic causes in the field of human and organizational factors for domestic or foreign nuclear power plants. However, the NRC does maintain databases that compile information on human performance issues and plant events for review and analysis by the staff.

The NRC uses the Human Factors Information System (HFIS) to store data on human performance issues documented in NRC Inspection Reports (IRs) and Licensee Event Reports (LERs) at each plant. The HFIS database is not all-inclusive but does provide a general overview of the types and approximate numbers of performance issues at the plants for reference by the staff in its programmatic oversight of training, procedures, organizational processes, human-system interface, communication, and inspections.

The NRC uses the following databases to capture and store operating event details for future reference and analysis:

Event reports made by our facility licensees under 10 CFR 50.72 are publicly available on the NRC's website. The event reports are also entered in a searchable internal database that the staff can use to identify events related to certain human or organizational factors.

LERs that are reported under 10 CFR 73 are entered in a database that the NRC staff can search for topics of interest.

INPO provides the NRC with copies of Significant Event Reports (SERs) and related documents as part of the Significant Event Evaluation and Information Network (SEE-IN) program. These reports are loaded into an internal NRC database that can be used by the staff for title or key-word searches. Some SEE-IN documents are redacted versions of World Association of Nuclear Operators (WANO) events and may contain information related to international facilities.

The NRC also has access to the International Atomic Energy Agency (IAEA) Incident Reporting System (IRS). Again, IRS has a search function that can be used to find events related to specific topics.

INPO identifies and analyzes trends across the industry on an ongoing basis using methods from database word searches to statistical analyses. Both short term and long term trends are looked at. Data sources reviewed include operating experience event reports and equipment failure database information, which have cause-codes assigned to each entry. Other sources could include performance indicators and results of team evaluations or peer reviews. The industry identified trends are published in one of several different type documents depending upon the importance of the issue, such as a Topical Reports, Significant Event Reports, or Significant Operating Experience Reports. International operating experience is also reviewed during these efforts to determine trends and applicable lessons.

**Question Number:** 19-15

**Question/Comment:** For the issue of the storage of spent fuel removed from reactors, the report makes reference to the report prepared to satisfy the reporting requirements of the Joint Convention. A synthetic presentation of this report would have been appreciated.

Could USA summarize the main lines of the current situation of spent fuel issues?

**Response:**

All commercial operating nuclear power reactors are storing spent fuel in U.S. Nuclear Regulatory Commission (NRC) licensed on-site spent fuel pools (SFPs) or independent spent fuel storage installations (ISFSIs). Nuclear power plants being decommissioned may have spent fuel stored on site. Spent fuel is typically stored on site pending disposal when a nuclear power plant is decommissioned. NRC amended its regulations in 1990 allowing licensees to store spent fuel in NRC-certified dry storage casks, at approved reactor sites.

Spent fuel from both domestic and foreign research reactors, in addition to limited quantities of commercial spent fuel, is stored at U.S. Department of Energy (DOE) and other research reactor facilities throughout the country. DOE also stores spent fuel from former defense production reactors. Storage of radioactive waste at DOE sites is managed consistent with regulatory guidelines used at commercial nuclear facilities.

The need for alternative storage began to grow in the late 1970s and early 1980s when pools at many commercial nuclear reactors began to fill with stored spent fuel. Dry cask storage allows spent fuel already cooled in the spent fuel pool for at least one year to be surrounded by inert gas inside a container called a canister. The canisters are typically steel cylinders either welded or bolted closed. The steel cylinder provides a leak-tight containment of the spent fuel. Additional steel, concrete, or other material surrounds each cylinder to provide radiation shielding to workers and the public. Some cask designs can be used for both storage and transportation. Various dry cask storage systems are in use. In some designs, canisters containing the fuel are placed vertically or horizontally in a concrete vault to provide radiation shielding. In other designs the canister is placed vertically on a concrete pad and both metal and concrete outer cylinders are used for radiation shielding.

The U.S. commercial nuclear power industry had generated about 47,000 metric tons heavy metal (MTHM) of spent fuel as of the end of 2002. About 4,200 MTHM of this spent fuel were in dry cask storage at 30 commercial nuclear power plants. About 2,450 MTHM of spent fuel is stored at government facilities.

Additional information on the status of spent fuel management safety is provided in the U.S. National Report prepared per the Joint Convention addresses and is quite lengthy in that regard. The report can be viewed at [http://www.em.doe.gov/pdfs/Second\\_National\\_Report--Final\\_Rev\\_30.pdf](http://www.em.doe.gov/pdfs/Second_National_Report--Final_Rev_30.pdf).

## APPENDIX A: ACKNOWLEDGEMENTS

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## APPENDIX B: LIST OF ACRONYMS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
AIT	Augmented Inspection Team
ALARA	as low as reasonably achievable
AMR	aging management review
ANS	alert and notification systems
ANSI	American National Standards Institute
ARPANS	Australian Radiation Protection and Nuclear Safety
ASME	American Society of Mechanical Engineers
ASP	Accident Sequence Precursors
ATWS	Anticipated Transients Without Scram
BFN	Browns Ferry Nuclear Plant
BRIIE	Baseline Risk Index for Initiating Events
BWR	boiling-water reactor
ΔCDP	core damage probability
CAL	Confirmatory Action Letters
CAMP	Code Application and Maintenance Program
CAROLFIRE	Cable Response to Live Fire
CCDP	Conditional Core Damage Probability
CEUS	Central and Eastern United States
CFR	Code of Federal Regulations
CLB	current licensing basis
CNS	Convention on Nuclear Safety
COL	combined operating license
COLP	Operator Licensing and Human Performance Branch
CR	Comprehensive Review Program
CRE	Collective Radiation Exposure
CSARP	Cooperative Severe Accident Research Program
DC	design certification
DHS	Department of Homeland Security
DOE	U.S. Department of Energy
DPO	NRC's Differing Professional Opinions Program
DRA	NRC'S Division of Risk Analysis
EAL	emergency action levels
ECCS	emergency core cooling system
EFO	Equipment Forced Outages
EGC	Exelon Generation Company
EOPs	Emergency Operating Procedures
EP	Emergency Preparedness
EPA	U.S. Environmental Protection Agency
EPGs	Emergency Procedure Guidelines
EPR	European Pressurized Reactor
EPRI	Electric Power Research Institute
EPZ	emergency planning zone
ERO	Emergency Response Organization
ESP	Early Site Permit
ET	Executive Team
FEA	Finite Element Analysis

FEMA	Federal Emergency Management Agency
FOR	Forced Outage Rate
FRB	Fire Research Branch
FRMAC	Federal Radiological Monitoring and Assessment Center
FSAR	final safety analysis report
FY	fiscal year
GDC	General Design Criteria
GE	general emergency
GIP	Generic Issue Program
GL	NRC's Generic Letters
GPI	ground water protection initiative
HAs	human actions
HERO	NRC's Headquarters Emergency Response Officer
HFE	human factors engineering
HFO	high winds, floods and others
HRA	Human Reliability Analysis
I&C	instrumentation and control
IAEA	International Atomic Energy Agency
ICCDP	incremental conditional core damage probability
IE	initiating events
INES	International Nuclear Event Scale
INPO	Institute of Nuclear Power Operations
IPA	integrated plant assessment
IPEEE	Individual Plant Examination of External Events Program
IRRS	Integrated Regulatory Review Service
ISFSIs	independent spent fuel storage installations
ISG	Interim Staff Guidance
ISI	inservice inspection
ISR	International Survey Research, LLC
IST	inservice testing
ITAAC	inspection, test, analysis, and acceptance criterion/criteria
ITP	Industry Trends Program
KK	Kashiwazaki-Kariwa
KM	Knowledge Management
LB	large-break loss-of-coolant accident
LBB	Leak Before Break
LCO	Limiting Condition for Operation
LER	Licensee Event Report
LOCA	loss-of-coolant accident
LOOP	loss of offsite power
LP	low pressure
LWR	light-water reactor
MDEP	Maine Department of Environmental Protection
MOSC	Management, Organizational and Safety Culture
MOU	memorandum of understanding
MSIV	Main Steam Isolation Valve Closure Large Transient Test
MSK	Medvedev-Sponheuer-Karnik
MTHM	metric tons heavy metal
NANTeL	National Academy for Nuclear Training e-Learning
NCP	Non-Concurrence Process
NEI	Nuclear Energy Institute



NGNP	Next Generation Nuclear Plant
NIST	National Institute of Standards and Technology
NNAB	National Nuclear Accrediting Board
NPP	nuclear power plants
NRC	U.S. Nuclear Regulatory Commission
NRO	NRC's Office of New Reactors
NRR	NRC's Office of Nuclear Reactor Regulation
OEF	Operating Experience Feedback
OIP	NRC's Office of International Program
OpE	Operating Experience
ORISE	Oak Ridge Institute for Science and Education
ORO	off-site response organizations
PARs	protective action recommendations
PBMR	Pebble Bed Modular Reactor
PDC-Bethesda	NRC's Professional Development Center in Bethesda
PDR	Public Document Room
PIs	plant-level performance indicators
PMT	Protective Measures Team
PRA	Probabilistic Risk Assessment
PSA	probabilistic safety analysis
PSR	periodic safety review
PTS	pressurized thermal shock
PWR	pressurized water reactor
PWSCC	primary water stress corrosion cracking
QA	quality assurance
R&D	research and development
RCS	Reactor Coolant System
RES	NRC's Office of Nuclear Regulatory Research
ROETF	Reactor Operating Experience Task Force
ROP	Reactor Oversight Process
SAT	systems approach to training
SBO	Station Blackout
SCC	stress corrosion cracking
SDP	Significance Determination Process
SEE-IN	INPO's Significant Event Evaluation-Industry Notification
SEP	Systematic Evaluation Program
SERI	System Energy Resources, Inc.
SFPs	spent fuel pools
SI	Special Inspection
SID	Security Information Database
SNL	Sandia National Laboratories
SOER	Significant Operating Experience Report
SPAR	Standardized Plant Analysis Risk
SRP	Standard Review Plan
SSA	Safety System Actuations
SSC	Structures, Systems or Components
SSF	Safety System Failures
ST	Safeguards Team
STS	Standard Technical Specification
SWP	Strategic Workforce Planning
TI	Temporary Instruction

TMI	Three Mile Island
TOPOFF	Top Officials
TSO	technical support organization
TTC-Chattanooga	Technical Training Center in Chattanooga, TN
U.S.	United States of America
UFSAR	Updated Final Safety Analysis Report
USA	United States of America
USDOS	U.S. Department of State
USGS	U.S. Geological Survey
UT	ultrasonic testing
WANO	World Association of Nuclear Operators
WBIRS	Web-based Incident Reporting System