NUREG-1650
Addendum 1

The United States of America National Report for the Convention on Nuclear Safety

Answers to Questions From the Peer Review By Contracting Parties

April 2002

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

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ABSTRACT

This report documents the U.S. Nuclear Regulatory Commission's answers to questions raised by contracting parties during their peer reviews of the U.S. National Report for the Convention on Nuclear Safety (NUREG-1650). 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 2001 to the second 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 2002. 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

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). 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 2001 to the second 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 2002. (The U.S. National Report is also posted on the NRC's website at www.nrc.gov. and is linked to the IAEA's website at http://www.iaea.org/ns/nusafe/scv_nrpt.htm.)

Seventeen countries submitted questions on the U.S. National Report. Upon receiving questions from contracting parties, the NRC staff categorized them according to the article of the U.S. National Report that addressed the relevant material. 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. 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 three appendices. Appendix A identifies contributors, Appendix B identifies and defines the acronyms used, and Appendix C provides figures and tables associated with the NRC's Reactor Oversight Process and reactor licensing process that may be illustrative to the reader.

INTRODUCTION TO U.S. NATIONAL REPORT

This section of the 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 initiatives. It then highlighted major regulatory accomplishments since the original U.S. National Report was written in 1998. Finally, it referenced the list of nuclear installations in the U.S.

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

Question Number: 01.01

Question: The U.S. National Report for the Convention on Nuclear Safety gives comprehensive answers regarding the articles of the convention. The additional questions are mostly related to specific details

Answer: No answer required.

Question Number: 01.02

Question: Are foreign reactor types like the EPR also licensable in the USA?

Answer: Yes, the NRC can license foreign reactor types in the United States.

To license a reactor type, the NRC staff reviews the application in accordance with the licensing process in 10 Code of Federal Regulations (CFR) Part 50 or Part 52. The NRC staff uses the review guidance in the Standard Review Plan (NUREG-0800) to determine if the design meets the applicable regulations, regulatory guidance, and industry codes and standards. In addition, the NRC requires the applicant to demonstrate by tests, analyses, or a combination thereof that the new design features will perform as predicted in the safety analysis.

The Commission's Policy Statement on Advanced Reactors states that advanced reactors must provide at least the same degree of protection of the public and the environment that is required for the current generation light-water reactors. The policy further states that the Commission expects future reactor designs to achieve a higher level of safety for select technical and severe-accident issues than designs of currently operating nuclear power plants.

The NRC conducts pre-application reviews of new designs such as the pebble-bed modular reactor to identify safety issues that need to be addressed in the license application. In some cases, NRC conducts confirmatory research to reach independent conclusions on safety issues. The NRC does a detailed and comprehensive review of new designs to ensure that appropriate safety margins are established and maintained.

Question Number: 01.03

Question: Introduction to the Report and Article 9 say that NRC has taken actions to reduce the regulatory burden. Could you give some details and elaborate on the actions taken by NRC in the rulemaking area and how can one measure or identify the reduction of regulatory pressure on the licensees?

Answer: The NRC strategic plan explains unnecessary regulatory burden and how the agency measures it. An unnecessary regulatory burden is a requirement that goes beyond what is necessary and sufficient for providing reasonable assurance that the public health and safety, the environment, and the common defense and security will be protected. Over the past several years, using the ever-increasing body of domestic and international technical knowledge and operating experience, the NRC has risk-informed its regulations to reduce excessive conservatism. For example, recent risk-informed revisions to inservice inspection and testing requirements have allowed NRC licensees to focus resources on the high-risk-significant systems, structures, and components (SSCs) and pay less attention to low-risk-significant SSCs. The NRC has also risk-informed containment integrity testing (Appendix J to 10 CFR Part 50), the content of technical specifications (10 CFR 50.36), and the process for controlling changes to facilities and procedures (10 CFR 50.59). The NRC is currently working on a risk-informed revision to its regulation on post-accident hydrogen control (10 CFR 50.44). The revision would eliminate the requirement for hydrogen recombiners. NRC is also working on a rule to reduce the scope of SSCs that are subject to so-called special treatment requirements such as quality assurance and environmental qualification. Under this rulemaking, SSCs of low-safety significance (on the basis of a risk-informed assessment) would receive normal industrial (or "commercial") treatment. They would be expected to perform their design function but without additional margin, assurance, or documentation requested for high-safety-significant SSCs.

NRC receives feedback from the industry on its attempts to reduce unnecessary burden. NRC does cost-benefit analyses of proposed rulemakings. NRC's annual performance plan includes measures of the agency's progress in reducing unnecessary regulatory burden. The performance plan measures include the number and timeliness of the completion of licensing actions, license transfers, license renewals, and power uprates. NRC has no direct measure of costs averted by NRC activities.

Question Number: 01.04

Question: Although a few examples are given, no description is provided in the US report about typical programmes and practices in the nuclear industry, related to the obligations of the convention. What is the reason for only presenting the regulatory perspective?

Answer: The U.S. Government is the signator to the Convention and as such is responsible for producing the U.S. Report. However, in the future, the industry may participate.

Question Number: 01.05

Question: The report states that electricity prices are being increased so that the NPP will be self financing. Clarification is sought as to when NEC plc will be in a position to finance safety improvements on all 6 units?

Answer: No response required. Question does not refer to a U.S. facility.

ARTICLE 6. EXISTING NUCLEAR INSTALLATIONS

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

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

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

Question Number: 06.01

Question: Further to the ROP as described in Article 6.2.2, is it possible to provide an idea of the NRC effort required to run the scheme. For example, how many NRC inspector-days are required - on average and the extremes- per power station?

Answer: Most inspection time for the Reactor Oversight Process (ROP) is spent on the baseline inspection program. The baseline inspection program requires approximately 5000 inspector hours per year for a two-unit site. Licensees are also subject to inspections for non-green inspection findings. These inspections take from 30 hours to as much as 2000 hours for serious safety issues. NRC also sends special inspection teams to sites in response to events (approximately 400 hours per inspection), and performs inspections to resolve generic safety issues (approximately 30 hours per year). If all inspection areas and performance indicators remain in the licensee response region of the action matrix, the licensee is subject only to the baseline inspection program. The inspection time for a two-unit site can be considerably more than 5000 inspector-hours if declining performance is identified through performance indicators, inspection findings, or significant operational events.

Question Number: 06.02

Question: Article 6, Paragraph 5, describes the colour coding applied to performance ranges in cornerstone areas. Red is clearly the colour coding that indicates a significant reduction in the safety margin in the area measured. Please describe the basis for determining whether the reduction in safety margin is significant.

Answer: When a plant performance indicator or inspection finding indicates that there has been a significant reduction in the safety margin, the NRC generally performs a diagnostic supplemental inspection to help determine if continued operation of the facility is warranted. The following conditions may result in a determination of unacceptable performance and a shutdown order from the NRC:

(a) multiple significant violations of the facility license, technical specifications, regulations, or orders.

(b) loss of confidence in the licensee's ability to maintain and operate the facility in accordance with the design basis (e.g., multiple safety-significant instances in which the facility was determined to be outside of its design basis because of inappropriate modifications, the unavailability of design basis information, inadequate configuration management, or the demonstrated lack of an effective problem identification and resolution program).

(c) a pattern of failure of licensee management controls to effectively address previous significant concerns to prevent the recurrence.

Question Number: 06.03

Question: Section 6.2.4 of the U.S. report describes the program for resolving generic safety issues. It can be expected that many of the generic safety issues require research efforts, and it is also important that the number and importance of such issues is decreasing over time (risk-informedly). What is the USNRC process for keeping the number and importance of generic safety issues under control?

Answer: The NRC generic issues program is described in NUREG-0933, "A Prioritization of Generic Safety Issues." The program prioritizes generic issues and estimates dollar and manpower costs of resolving the issues. Senior management oversees the program. Resources for generic safety issue resolution are allocated by the annual NRC budget process.

The purpose of prioritization to is allocate resources to safety issues that have a high potential for reducing risk. There are four priority rankings: high, medium, low, and drop. For a reduction in core damage frequency (CDF) greater than 10^{-4} per reactor-year, a HIGH priority is assigned on the basis of safety importance alone, regardless of other considerations, such as a high cost estimate that might result in a low priority score. Below a minimal safety significance threshold, the priority is always drop because if the potential risk reduction is trivial, there is no basis for regulatory action on safety grounds. In between are issues less important or less trivial for which a high, medium, low, or drop priority may be appropriate on the basis of the cost-benefit analysis and safety significance. The NRC has resolved many generic safety issues and believes that few generic safety issues will be identified in the future. The trend for identification of new generic safety issues has been steadily decreasing to the point where fewer than three generic safety issues are being identified per year. The NRC is currently revising the generic issue program to expedite the screening of newly identified generic safety issues.

Question Number: 06.04

Question: Risk-informed regulatory decision making: In this approach NRC is using a subsidiary objective of a core damage frequency of 10^{-4} per reactor-year. It is clear that meeting this objective is not sufficient to ensure that a core melt event will not take place in one of the 400 existing reactors in the world in the next 20 years (estimated average remaining lifetime). Could the United States of America explain the rationale for choosing this objective?

Answer: This CDF subsidiary objective is for U.S. plants only, not for all plants worldwide. The intent of establishing the subsidiary objective was to make it unlikely that a core damage accident would occur at U.S. plants over the life of the plants. By establishing the CDF subsidiary objective, the NRC made it clear that any core damage accident at a U.S. nuclear power plant was unacceptable, regardless of whether a radiological release would occur or whether the number of persons exposed would be relatively small. The subsidiary objectives are consistent with the agency's policy of defense in depth in that both the frequency of core damage accidents and the probability of radiological release must be very low.

Question Number: 06.05

Question: Periodic safety review: Most countries have decided to perform periodic safety reviews in accordance with the IAEA recommendations. The objectives of these reviews are the reassessment of the safety demonstration including PSA results and the verification that the plant's equipment and procedures are in accordance with the requirements defined by the safety studies. Could the United States of America explain how the objectives of the periodic safety reviews are fulfilled in the US nuclear power plants?

Answer: NRC relies on its regulatory process rather than periodic safety reviews to oversee nuclear power plants and upgrade requirements as they are determined necessary. When issuing the original operating license, the NRC made a comprehensive determination that the design, construction, and proposed operation of the nuclear power plant satisfied NRC's requirements and provided reasonable assurance of adequate protection to the public health and safety. However, the licensing basis does not remain fixed but evolves throughout the term of the operating license in response to NRC regulatory activities of the licensee activities.

Considered together, NRC regulatory activities provide ongoing assurance that the licensing basis of nuclear power plants ensure an acceptable level of safety. NRC's activities include research, inspections (periodic regional inspections and daily oversight by the resident inspector), audits, investigations, evaluations of operating experience, and regulatory actions to resolve identified issues. NRC's activities may result in changes to the licensing basis for nuclear power plants through the promulgation of new or revised regulations, acceptance of licensee commitments to modify nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. NRC also issues documents such as bulletins, generic letters, regulatory information summaries, and information notices. Licensee commitments in response to these documents also change a plant's licensing basis. In this way, NRC's consideration of new information provides ongoing assurance that the licensing basis for the design and operation of all nuclear power plants provides an acceptable level of safety. This process continues for plants that receive renewed licenses.

A licensee may also request changes to the current licensing basis for a plant. Such changes are subject to NRC's regulatory controls on changes (e.g., 10 CFR 50.54, 50.59, 50.90, and 50.92). These regulatory controls ensure that there is a documented basis for licensee-initiated changes to the plant licensing basis and that NRC review and approval is obtained before implementation if a change to the licensing basis raises safety questions. The plant Final Safety Analysis Report (FSAR) is periodically updated to reflect changes to the licensing basis.

NRC meets the objectives of periodic safety reviews through strict regulatory controls on proposed design changes after issuance of the initial operating license and the ongoing NRC regulatory activities that impose new requirements needed to maintain safety.

Question Number: 06.06

Question: Did the United States of America evaluate the interest of periodic safety reviews compared to the US regulatory process?

Answer: NRC is aware of the recommendations of the IAEA safety guide on performing periodic safety reviews for operational nuclear power plants. However, as discussed in the response to Question 06.05, NRC believes that the objectives of periodic safety reviews are met on an ongoing basis.

Question Number: 06.07

Question: Program for Resolving Generic Issues: International studies have shown that the risks associated with the low power and shutdown states could be important for LWR plants, inducing some countries to implement design changes in their LWRs. Could the United States of America indicate if this safety issue is considered as a generic one and if its resolution has led to design changes at the US nuclear power plants?

Answer: The issue of shutdown risk and the need to develop a new shutdown rule was presented to the Commission in SECY-97-168. The proposed rule would have required licensees to maintain a shutdown-mitigation capability beyond the capability required in technical specifications. The Commission decided that the proposed rule was unnecessary, considering licensees' implementation of voluntary measures. In the staff requirements memorandum for SECY-97-168, the Commission directed the staff to monitor and inspect licensees' shutdown mitgation capabilities to ensure that the current level of safety is being maintained.

Question Number: 06.08

Question: Considerably large extended power uprates (up to 20%) were, are, and will be under review.

1) What was the scope of new analyses performed for safety demonstration and was it reviewed?

2) Which were the most essential results of evaluations of consequences with regard to core design, system design, control of accidents, radiological releases?

Answer: 1) Power uprates require a license amendment and are therefore all reviewed by the NRC. The analyses required for power uprates are complex and involve almost every technical discipline in the NRC Office of Nuclear Reactor Regulation. Following is a list of some of the areas evaluated and reviewed for power uprates:

Reactor Core/Fuel Performance
Reactor Coolant System
Containment Performance
Emergency Core Cooling System/Loss-of-Coolant Accident (LOCA)
Special Events/Limiting Operational Transients
Radiological Consequences
System/Component Capabilities
Instrumentation and Controls
Electrical Power and Environmental Qualification
Human Performance/Operator Response
Risk Assessment

2) The NRC staff conducts a thorough review of power uprate applications to ensure that a proposed power uprate meets all applicable regulatory requirements.

For power uprates greater than 5 percent, the staff also conducts a review of risk information submitted by licensees. The risk information provides confirmatory insights and allows the staff to assess the impact of the power uprate on plant risk. Risk reviews to date confirmed that power uprates would create no new vulnerabilities.

With regard to evaluations of incident control, radiological releases etc., for power uprates, the importance of the results depends on the plant design and existing margins, which are plant-specific.

Question Number: 06.09

Question: Performance Color Coding: How does the NRC ensure that different NPPs are interpreting the color codes for performance monitoring and reporting in the same way?

Answer: The accuracy of the performance indicators depends on the accuracy of the data submitted by licensees. The industry has developed, and the NRC has endorsed NEI 99-02, "Regulatory Assessment Performance Indicator Guideline," a guidance document for licensee use to assure consistency in the collection and reporting of performance indicator data to the NRC. The NRC also performs inspections to verify performance indicator data submitted by licensees.

During the initial implementation of the ROP, the NRC established the frequently-asked-questions process to (1) address questions and feedback from internal and external stakeholders, (2) make changes to existing performance indicators and thresholds based on lessons learned, and (3) develop new performance indicators and thresholds. The frequently asked questions process gives NRC and industry personnel an opportunity to raise questions about the interpretation of the reporting criteria. The NRC/Industry ROP Working Group reviews frequently asked questions to resolve questions and to develop approved responses. Revisions to NEI 99-02 incorporate resolved frequently asked questions, giving power reactor licensees clear guidance on the accurate and consistent reporting of performance indicator information.

Question Number: 06.10

Question: As to the change of plant ownership:

1) What is the feature of the licensing condition in securing safety to compare with new reactor licensing?

2) What about the dealing with decommissioning fund?

Answer: 1) Under the NRC's regulations in 10 CFR 50.80, a license transfer applicant must demonstrate the same technical and financial qualifications as required for an initial license.

2) The decommissioning funding assurance requirements in 10 CFR 50.75 and 50.82 are described in Article 11 of the U.S. National Report. An applicant to transfer ownership or operation of a nuclear plant must continue to provide the decommissioning funding assurance required by these sections.

Question Number: 06.11

Question: It is reported that the Revised Reactor Oversight Process (ROP) started its operation in 2000.4(13.4.2). In the NRC RIC Meeting held in 2000, the further development on the following items has been proposed: emergency preparedness. What is the future programs on the revise of current PI concerning above topics?

Answer: The emergency preparedness performance indicators are drill exercise performance, emergency response organization drill participation, and alert and notification system reliability. A revised Regulatory Assessment Performance Indicator Guideline (NEI 99-02 Revision 2) was issued in November 2001. No further revisions are planned at this time.

Question Number: 06.12

Question: The framework of ROP (Figure-1) consists of the performance indicator (PI) and the base-line inspection. And as a supplementary, you proposed "cross-cut" items such as: Human performance Safety-conscious work environment Problem identification and resolution. It might be more difficult to evaluate these " cross-cut " items in comparison to the PIs and BLIs. [i.e., baseline inspections] What kind of plan do you have for development?

Answer: NRC has no plan for changing our evaluation of the crosscutting elements. To ensure adequate performance in each cornerstone area, the crosscutting elements are considered and where possible, linked to performance indicators or inspection areas.

Risk-informed, performance-based regulation shifts NRC's role from improving human reliability to monitoring human reliability. In the past NRC was pro-active because the accident at Three Mile Island Unit 2 revealed serious deficiencies in programs to ensure effective and safe human performance. The success of the human performance improvement programs has allowed NRC to now take a more performance-based approach to oversight of human performance. If plant performance is acceptable, NRC assumes that the performance of plant personnel is also acceptable. If risk-informed inspections (e.g., Maintenance Rule verification inspections, configuration control inspections) and plant performance indicators for each cornerstone together indicate that plant performance is meeting the cornerstone objectives, then those findings also provide an indication of the acceptability of the associated human activities. Supplemental verification inspections of problem identification and resolution programs are conducted to ensure that human performance is specifically and appropriately investigated through licensees' root cause analysis and corrective action programs, including the investigation of potential common-cause failures caused by human actions.

Question Number: 06.13

Question: 1) What is the process inside USNRC in implementing the ROP?

2) Have you invented additional organization or committee for the ROP? If so, please describe them briefly.

3) When the risk assessment for an inspection finding is needed, who is responsible for that? Is that USNRC or licensee?

4) Do you consider LPSD (low power shutdown) PSA in risk assessment?

5) Is risk assessment result the only concern in determining safety significance? If not, what are the supplementary considerations?

6) What is the connection between ROP and the Risk-Based Inspection Program performed in 1980's?

7) In preparing plant-specific baseline inspection program, does USNRC perform plant-specific PSA for all plants or utilize licensee's IPE result?

Answer: 1) The NRC conducted a pilot of the revised ROP at nine reactor sites for 6 months in 1999 to test the effectiveness of the process and identify problems. The NRC incorporated the lessons learned from the pilot program, provided the necessary training to NRC staff, and began implementing the revised ROP for all plants in April 2000. NRC performs quarterly reviews of plant performance. If a plant shows signs of declining performance, NRC takes additional actions in accordance with its action matrix. There are four levels of regulatory response in the action matrix. NRC's response increases as plant performance declines. The first two levels of heightened regulatory response are managed by the regional office. The next two levels call for an agency response, overseen by senior managers from both headquarters and the regional office. In the past, the NRC tended to use fines to indicate the agency's concern and motivate licensee corrective actions. Under the ROP, the action matrix prescribes agency actions when plant performance declines.

2) NRC formed a Transition Task Force to manage the transition to the new oversight process. The Transition Task Force developed detailed implementing procedures and the necessary infrastructure. Although NRC staff roles and responsibilities have changed as a result of the ROP, the NRC organization has not changed significantly. During the initial piloting of the program, a pilot program evaluation panel (PPEP) was established by the agency to serve as an independent advisory committee to the agency. This panel was a cross-disciplinary group of managers and industry experts representing many different nuclear power interests, including the Union of Concerned Scientists, the Nuclear Energy Institute, pilot plant licensee management, and the Illinois Department of Nuclear Safety, in addition to NRC Headquarters and regional management. The purpose of the PPEP was to independently evaluate the results of the pilot program and draw conclusions regarding required process changes and the readiness for initial implementation. The results of the PPEP review were provided to the Commission. Finally, during the initial full implementation of the the ROP, an initial independent evaluation panel (IIEP) was established by the agency to serve as an independent advisory committee to the agency. The IIEP functioned as a cross-disciplinary oversight group to independently monitor and evaluate the results of the first year of initial implementation of the ROP. The IIEP provided advice and recommendations to the Director of the Office of Nuclear Reactor Regulation on reforming and revising the ROP.

3) The NRC determines the risk significance of all inspection findings by applying the Significance Determination Process. However, licensees can and often do develop and provide input for the NRC to assess.

4) The NRC assesses the risk significance of events and conditions at shutdown plants. The NRC staff monitors and inspects plants to ensure that the current level of safety is being maintained. NRC issued Generic Letter 87-12, "Loss of Residual Heat Removal While the Reactor Coolant System is Partially Filled," to provide the industry with guidance for operations at reduced inventory. The following year, Generic Letter 88-17, "Loss of Heat Removal During Non-power Operation," was issued to address the program needs for (1) prevention of accidents, (2) mitigation of accidents before they lead to core damage, and (3) control of radioactive material in the event of core damage. In response to these generic communications, the industry developed NU 91-06, "Guidelines for Industry Actions to Assess Shutdown Management," issued in December 1991. Most power reactor licensees have adopted these guidelines. Licensees have implemented various design changes, including ultrasonic level monitors and temporary instrument tubing connections, to provide information on reactor pressure, temperature, and level indication to the operators during shutdown conditions.

5) Some of the performance indicators have deterministic criteria, for example, the performance indicators for barrier integrity, which use increased radioactivity in the coolant and the reactor coolant leak rate indicate fuel problems.

6) There is no connection.

7) The NRC staff selects systems and activities in each inspectable area to inspect during the next 12 months. The staff uses generic guidelines to select systems and activities. The staff may also consider site-specific information from sources, such as the licensee's IPE.

Question Number: 06.14

Question: Experiences with Risk Informed Regulation: Did the US-NRC experience or foresee any disadvantages in the transition from the traditional oversight process to the Risk Informed and Performance based oversight process?"

Answer: A number of issues became evident during the transition from deterministic regulation to the risk-informed ROP. The most significant issue was that not all inspection findings could be analyzed with existing probabilistic risk assessment (PRA) tools. This issue complicates the NRC's significance determination process, used to determine the risk significance of inspection findings. NRC has continued to develop and refine the significance determination process for inspection findings in the security/safeguards, radiation protection, and emergency preparedness areas. NRC is also struggling to overcome the contradictions between its regulations, based upon deterministic criteria, and its risk-informed oversight process. NRC is looking at ways to minimize the regulatory burden of some performance indicators by standardizing the definitions used by the NRC and other industry bodies.

Question Number: 06.15

Question: 1) On Corrective actions: What measures were taken by the US-NRC, besides issuing of a red finding, after Indian Point 2 SGTR?

2) How will a repetition of such an event anywhere in the USA be avoided?

3) Was this event reported to INES?

Answer: 1) A "red" finding indicates that reduced safety margins warrant increased NRC oversight. A red finding or a "multiple degraded cornerstones" finding does not mean that the plant is unsafe to operate. NRC's ROP provides for NRC inspections and oversight based on licensee performance. As a plant with multiple degraded cornerstones, Indian Point 2 has been the recipient of increased NRC inspection and oversight. NRC's goal is to ensure that the nature and extent of the underlying problems are fully understood and addressed. NRC's ROP will ensure that adequate corrective actions are taken to restore safety margins to an acceptable level.

An NRC team conducted a special inspection from March through July 20, 2000 to investigate the causes of the failure of the steam generator tube. The NRC team included NRC steam generator experts and contractors with steam generator expertise. The special inspection revealed weaknesses in Consolidated Edison's (Con Ed) steam generator management program, which became the focus of corrective actions by Con Ed.

The NRC staff also reviewed the steam generator condition-monitoring and operational-assessment reports prepared by Con Ed for Indian Point 2 to determine the acceptability of the steam generators for continued operation. During the review period, Con Ed decided to replace the steam generators, and the NRC review ended.

2) The goal of the steam generator inspection program is to have steam generators operate without failures. This is a goal, and it is recognized that some tube failures may occur. Operators are well trained to respond to such failures using established procedures. When failures occur at plants, NRC reviews the failure data to learn how to minimize future failures.

As part of the overall evaluation of the Indian Point 2 tube failure, the NRC staff prepared a report on lessons-learned from the event to evaluate the NRC staff's technical and regulatory processes for assuring steam generator tube integrity and to identify areas for NRC and/or industry improvement. The NRC staff met with industry to discuss the areas for improvement identified in the NRC's lessons-learned report, and industry activities resulting from the industry's own lessons- learned evaluation.

The NRC staff prepared an integrated action plan that considers all generic steam generator activities after the Indian Point 2 tube failure. In developing the plan, the staff considered the recommendations of the lessons-learned report, the recommendations of an Office of the Inspector General audit of the Indian Point 2 tube failure, the recommendations of the Advisory Committee on Reactor Safeguards review of a differing professional opinion on steam generator issues, and issues arising from a generic safety issue related to steam generators. The action plan has resulted in a revision to the steam generator inspection procedure, preparation of guidance for inspectors overseeing plants with primary-to-secondary leakage, training of regional inspectors on the new inspection procedure, and issuance of a regulatory issue summary. The NRC staff also sponsored a public workshop on steam generator issues, attended by headquarters and regional NRC staff and interested external stakeholders.

3) Yes. The International Nuclear Event Scale (INES) Event Rating Form was completed on April 13, 2000. The event was assigned an INES rating of level 0/below scale. The event occurred on February 15, 2000. As part of the U.S. transition to full participation in the INES program by May 2002, NRC has tentatively proposed the goal of issuing future INES Event Rating Forms for events that rated INES level 2 or higher within 2 business days of the NRC being notified of the event.

Question Number: 06.16

Question: When the implementation of the Revised Reactor Oversight Process started to be implemented and to what plants?

Answer: The NRC conducted a pilot of the revised ROP at nine reactor sites for 6 months in 1999 to test the effectiveness of the process and identify problems. The NRC incorporated lessons learned from the pilot program and began the initial implementation of the revised ROP for all plants in April 2000.

Question Number: 06.17

Question: 1) An overview is given in section 6.2.2 of the new Reactor Oversight Process. As the NRC is focussing very hard on the safety cornerstones and the performance indicators, is there a risk that the licensees focus their safety work on these cornerstones as well, and put too little effort on other areas which are known to be important to safety?

2) How long would it take NRC to detect more fundamental deficiencies in the safety work of a licensee, such as understaffing and inadequate organisational arrangements?

Answer: 1) The ROP addresses three strategic performance areas of reactor safety, radiation safety, and security. NRC has developed cornerstones of safety in each strategic performance area. Acceptable licensee performance in the safety cornerstones provides reasonable assurance of adequate protection of public health and safety. The ROP was designed to focus attention on areas that both the NRC and the industry agree are important to safety, so NRC is not concerned that licensees will pay too much attention to these areas.

Performance indicators, together with risk-informed baseline inspections, provide a broad sample of data for assessing licensee performance in the risk-significant areas of each cornerstone. Performance indicators are not intended to provide complete coverage of every aspect of plant design and operation. Licensees have the primary responsibility for ensuring the safety of their facilities. NRC uses objective thresholds to help determine the level of regulatory response appropriate to licensee performance in each cornerstone area. Based on past experience, NRC expects that a few risk-significant events will continue to occur with little or no indication of declining performance. When such events occur, NRC will conduct followup inspections to ensure that the causes of these events are well understood and that licensee corrective actions are adequate to prevent recurrence. NRC also conducts inspections to follow up on allegations. NRC assesses the results of such followup inspections along with performance indicators and risk-informed baseline inspections. If a plant shows signs of declining performance, NRC takes additional actions in accordance with its action matrix. There are four levels of regulatory response in the action matrix. NRC's response increases as plant performance declines. The first two levels of heightened regulatory response involve the regional offices. The next two levels call for an agency response, overseen by senior managers from both headquarters and the regional offices.

2) Since the ROP is performance based, the NRC does not ordinarily assess staffing or organizational arrangements as part of the baseline inspection program. Licensees are responsible for dealing with organizational and staffing issues. After performance declines, NRC begins to assess such issues through supplemental inspections. The more a licensee's performance declines, the broader and more diagnostic the supplemental inspections become.

Question Number: 06.18

Question: 1) Which efforts are planned to evaluate the new full size oversight process?

2) Have any concerns been identified so far requiring modification of the process?

Answer: 1) NRC believes that the ROP has met the goal of developing an oversight process that is more objective, risk-informed, understandable, and predictable. The NRC recognizes that the ROP needs further improvements and has established a self-assessment program that will identify those areas for improvement. The NRC staff reports on an annual basis to the Commission on the results of the self-assessments and any significant changes to the ROP.

2) Since the initial implementation of the ROP, the basic structure of the ROP has remained the same. The NRC has revised many of the baseline inspection procedures and some of the performance indicators. There have also been extensive improvements made in the significance determination process. As NRC gains experience with the process, it continually assesses the need for additional changes.

Question Number: 06.19

Question: It is mentioned in section 6.2.7. that the Reactor Safety Research Programme is directly aligned with the NRC performance goals. A possible interpretation of this is that the research must be of immediate practical use. As a consequence, is there a risk that the "anticipatory research" will be given too little resources in order to prepare NRC for new regulatory challenges?

Answer: The Reactor Safety Research Program budget is developed using an established planning, budgeting, and performance management process for setting strategic directions and budgeting resources. One of the initial steps in this process is to assess internal and external stakeholder needs, legislative mandates, and Commission direction to develop a set of planning assumptions upon which to base budgeted resource allocations. The NRC ranks and prioritizes all research projects and activities (both confirmatory and anticipatory research) in terms of their contribution to meeting the agency's performance goals: maintaining safety; increasing public confidence; reducing unnecessary burden; and making NRC activities and decisions more effective, efficient and realistic. The consistency between the resource allotment, the planning assumptions, and the prioritized ranking of the activities with respect to the four performance goals, is tested throughout the development and execution of the budget. Our current practice is to allocate approximately 20% of our budget for anticipatory research.

Question Number: 06.20

Question: The report states that the [NRC] will only impose additional requirements consistent with the Commission's Backfit Rule. How is the requirement for a periodic review of a safety case consistent with this statement?

Answer: The backfit rule (10 CFR 50.109) requires that backfits to ensure adequate protection of public health and safety must be imposed regardless of cost. Some backfits are not necessary to ensure adequate protection of public health and safety. NRC can impose such a backfit only if NRC determines that the backfit substantially increases the overall protection of the public health and safety and the increased protection justifies the direct and indirect costs of implementation. The backfit rule is only one piece of the NRC's overall regulatory process. The overall process provides continuous oversight of nuclear power plants and ensures that requirements are revised if necessary. NRC does not perform periodic safety reviews but believes that its ROP meets the objectives of periodic safety reviews.

When the original operating license was issued, the NRC made a comprehensive determination that the design, construction, and proposed operation of the nuclear power plant satisfied the NRC's requirements and provided reasonable assurance of adequate protection to the public health and safety. However, the licensing basis of a plant does not remain fixed for the term of the operating license. The licensing basis evolves throughout the term of the operating license because of the continuing regulatory activities of the NRC, as well as the activities of the licensee.

The NRC engages in a large number of regulatory activities which, when considered together, constitute a regulatory process that provides ongoing assurance that the licensing basis of nuclear power plants provide an acceptable level of safety. This process includes research, inspections (both periodic regional inspections as well as daily oversight by the resident inspector), audits, investigations, evaluations of operating experience, and regulatory actions to resolve identified issues. The NRC's activities may result in changes to the licensing basis for nuclear power plants through promulgation of new or revised regulations, acceptance of licensee commitments for the modification to nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. Operating experience, research, or the results of new analyses are also issued by the NRC through documents such as bulletins, generic letters, regulatory information summaries, and information notices. Licensee commitments in response to these documents also change the plant's licensing basis. In this way, the NRC's consideration of new information provides ongoing assurance that the licensing basis for the design and operation of all nuclear power plants provides an acceptable level of safety. This process continues for plants that receive a renewed license.

In addition to NRC required changes in the licensing basis, a licensee may also seek changes to the current licensing basis for its plant. However, these changes are subject to the NRC's formal regulatory controls with respect to the changes (such as 10 CFR 50.54, 50.59, 50.90, and 50.92). These regulatory controls ensure that a documented basis for licensee-initiated changes to the licensing basis for a plant exists and that NRC review and approval is obtained prior to implementation if changes to the licensing basis raise safety questions. The plant's FSAR is periodically updated to reflect changes to the licensing basis.

The strict regulatory controls that exist for design changes proposed following issuance of the initial operating license and the ongoing NRC regulatory processes that impose new requirements needed to maintain safety meet the objectives of a periodic safety review.

ARTICLE 7. LEGISLATIVE AND REGULATORY FRAMEWORK

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

2. **The legislative and regulatory framework shall provide for:**

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

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

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

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

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

Questions and answers pertaining to this section follow below.

Question Number: 07.01

Question: 1) What is the exact list of nuclear installations that are exempt (see p. 7-2 of the USA report) from licensing by the NRC?

2) Is the list of such installations, given on page 8-16 of the US report (penultimate paragraph), complete?

3) Are any of these installations concerned by the Convention on Nuclear Safety?

Answer: 1) No nuclear installations in the U.S. are exempt from licensing by the NRC. A nuclear installation is defined in Article 2 of the Convention as "any land-based civil nuclear power plant under [the Contracting Party's] jurisdiction, including such storage, handling, and treatment facilities for radioactive materials as are on the same site and are directly related to the operation of the nuclear power plant." All such installations are licensed by the NRC. Indeed, if the U.S. Department of Energy (DOE) constructed and operated a demonstration nuclear power plant that produced electricity for commercial use, the plant would be licensed by the NRC. The parenthetical text on page 7-2 of the U.S. National Report (which apparently prompted the question) is not intended to say that some nuclear installations are exempt from licensing by the NRC. It says that some government facilities other than nuclear installations are exempt from licensing, meaning government nuclear facilities operated by or for DOE (e.g., weapons facilities and research reactors located at national laboratories operated for the DOE). The U.S. report lists these "facilities" on page 7-2 along with licensed facilities other than civil nuclear power plants to give a fuller picture of how nuclear materials in the U.S. are regulated.

2) The list of facilities on pages 8-16 is not a list of "nuclear installations," as that phrase is defined by the Convention, but of other types of nuclear facilities run by or for DOE and not regulated by the NRC. NRC does not license such facilities, and so does not keep a complete list. However, a full account of these facilities (as of 1996) is given on DOE's web site at the following Internet address:

http://www.em.doe.gov/acd/rpt1esum.html

3) No. As noted in the responses to Questions 7.1(1) and 7.1(2), they are not "installations" as defined by the Convention.

Question Number: 07.02

Question: We have noticed the Price Anderson Act in the list of statutes bearing substantially on the practices and procedures of the NRC on Art.7-1 of your report. We would like to know whether there is recent progress in the legislation related to the nuclear liability.

Answer: The Commission submitted to the Congress in August 1998, a report containing recommendations regarding the renewal of the Price-Anderson Act. The Act presently expires on August 1, 2002. Even if Congress fails to renew the Act, however, existing indemnification agreements, requirements for insurance of currently NRC-licensed facilities and various other provisions, would continue. In its report, the Commission provided current detailed information that Congress sought about nuclear power production, available insurance, and experience under Price-Anderson. Congress also requested and the Commission provided its views as to whether Congress should renew the Act, and if so, what modifications should be enacted.

Hearings were held in the House and in the Senate on the recommendations in the report, which was entitled "The Price-Anderson Act-Crossing the Bridge to the Next Century: A Report to Congress." The House passed a bill to renew the Act for an additional fifteen years in late 2001. The Senate held hearings again in January 2002, but as yet has not passed a bill. In addition to the extension of the Act, the House bill increases the annual retrospective premium from the current \$10 million per reactor per incident per year to \$15 million, with an inflationary adjustment provision. The current retrospective premium of \$83.9 million would be increased in the House bill for inflation to approximately \$92 million. All of the other provisions presently in the Act would remain unchanged.

Question Number: 07.03

Question: How does NRC regulate management issues which may affect safety such as deregulation and organisational changes?

Answer: The NRC does not regulate such issues directly. It is expected that management issues will manifest themselves in performance. If a licensee has a poor "safety culture" or poor problem identification and corrective action processes, the licensee will cross thresholds for various performance indicators, or the licensee's problems will emerge during baseline inspection activities, or both. The NRC evaluates licensees problem identification and corrective action processes through the baseline inspection program, NRC indirectly gauges the health of a licensee's safety culture. The NRC also evaluates allegations from plant workers regarding safety culture issues. Lastly, the NRC's verification of implementation of the Maintenance Rule, also part of the baseline inspection program, provides assurance that deficiencies in risk-significant safety equipment are being effectively resolved. In short, no separate and distinct assessment of licensee safety culture is needed because it is subsumed by either the performance indicators or baseline inspection activities.

ARTICLE 8. REGULATORY BODY

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

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

This section of the U.S. National Report explained the establishment of the U.S. regulatory body, the NRC. It also explained how the functions of the NRC are separate from those of bodies responsible for promoting and using nuclear energy (i.e., the U.S. Department of Energy).

Questions and answers pertaining to this section follow below.

Question Number: 08.01

Question: What are the relations between the NRC and the DOE for regulatory inspection and enforcement activities on the Hanford site, in Washington State, where there are DOE installations and a NPP (Columbia Generating Station) regulated by the NRC?

Answer: The local government planned to build and operate three nuclear installations (as defined by Convention) at DOE's Hanford reservation. Only one, Columbia Generating Station, was completed and began commercial operation. It was constructed as a commercial nuclear power plant under NRC license. It remains subject to NRC inspection and enforcement.

Question Number: 08.02

Question: Most of the NRC's budget is based on the fees/fines to be collected from applicants and/or licensees.

1) Is the budget affluent enough to cover the cost for R & D conducted by NRC?

2) Can NRC maintain an effective separation of the regulatory body's function between those of organization concerned with utilization of nuclear energy by recovering the cost for regulation from licensees?

Answer: NRC's activities, including confirmatory research and development, rely on general Treasury funds, rather than on the revenue stream from the payment of fees to the Treasury. Therefore, the appropriations from Congress are sufficient for research and development identified in the budgeting process. For some years, the U.S. budget and appropriations legislation has required that (with a few exceptions) NRC's budget allocation be recovered through user fees. As outlined in Article 8, the NRC has established a regulatory structure to recover fees based on the cost of reviews for certain permits and licenses or on an annual charge for holders of licenses. The appropriations act permits the NRC to incur obligations and make payments out of the U.S. Treasury. The fees charged under Parts 170 and 171 are paid to the U.S. Treasury, not to the NRC.

The NRC is independent of organizations concerned with utilization of nuclear energy because Congress (with input from the NRC), not licensees, determines both the size of the NRC's budget and how much of the budget is paid for by fees imposed on licensees.

Question Number: 08.03

Question: 1) Are there any overlap between NRC and EPA concerning the regulatory responsibility to nuclear energy utilization, other than examples shown in page 8-13?

2) How do you coordinate the overlap in the enforcement of regulatory responsibility?

Answer: 1) Yes, though the overlaps on page 8-13 of the U.S. National Report are the most important. Under Reorganization Plan No. 3 of 1970, the U.S. Environmental Protection Agency (EPA) was given the authority to "establish generally applicable environmental standards for the protection of the general environment from radioactive material. As used herein, standards mean limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material."

NRC has overlapping authority under several sections of the Atomic Energy Act of 1954, as amended, to regulate these same matters. EPA's standards take priority. If the EPA has issued regulations under the authority cited above, any regulations the NRC issues on the same subject must be consistent with the EPA's. If the EPA has not issued such regulations, the NRC's regulations govern the subject.

EPA's authority overlaps NRC's in a number of areas besides those listed on page 8-13 of the U.S. National Report: emergency planning guidelines, emissions standards under the Clean Air Act, standards governing hazardous radioactive and chemical waste, and environmental risk assessment. For example, (as discussed in Article 15), in 10 CFR Part 20, Subpart D (§20.1301, "Dose limits for individual members of the public"), the NRC recognizes EPA's generally applicable radiation standards in 40 CFR Part 190 and states that a license holder is also subject to those requirements. EPA has other statutory authorities. Under the Federal Water Pollution Control Act (also known as the Clean Water Act), EPA (or a State government by delegation) establishes the environmental protection requirements for utilization facilities and issues the pollution discharge permits. As discussed in Article 17 of the U.S. National Report (see Yellow Creek Decision), the NRC accepts EPA's determinations without independent inquiry in NRC licensing reviews.

Generally speaking, EPA has no authority to regulate what happens inside the boundaries of sites under the control of NRC licensees. NRC alone establishes the standards that govern most of the details of the design, construction, and operation of nuclear installations.

2) NRC and EPA coordinate the establishment and the enforcement of standards by reviewing each other's rulemakings, by participating in interagency groups representing Federal agencies with responsibilities for nuclear installations, and by implementing Memoranda of Understanding.

The NRC requires that licensees maintain the currency of the necessary permits required by Federal, State, and Tribal agencies; in the case of environmental protection permits, the issuing agencies generally have permitting and enforcement provisions. The NRC ROP and inspection program (discussed in Article 6), and the enforcement program, (discussed in Article 9), confirm that licensees comply with NRC regulatory requirements. NRC incorporates the EPA's generally accepted radiation standards" into NRC's regulatory requirements. NRC solely conducts inspections and takes enforcement actions.

Question Number: 08.04

Question: Independence of the Commissioners: Enforcement is a competence of the commissioners. As such they act like a judge. Are commissioners, like judges independent of political influences, and is this independence guaranteed by law?

Answer: In the U.S. legal system, enforcement is usually an executive function, not a judicial function. The Commissioners sometimes act as judges because they are called upon to render opinions in adjudicatory hearings. Their independence is preserved by statutory provisions that protect them from arbitrary removal. Under Section 5841 of Title 42 of the U.S. Code, a Commissioner serves for a fixed term of 5 years, and cannot be removed from office during that term except by the President, and then only for "inefficiency, neglect of duty, or malfeasance in office." The President cannot remove a Commissioner merely because they disagree. Although this is not as much protection as given judges appointed under Article III of the U.S. Constitution, it is more protection than is given most heads of agencies in the executive branch of the U.S. government, who generally serve at the pleasure of the President and can be removed at any time. No Commissioner has ever been removed from the Commission by the President.

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 each licensee meets its primary responsibility for safety. 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, its Reactor Oversight Process, discussed in Article 6.

Questions and answers pertaining to this section follow below.

Question Number: 09.01

Question: 1) Article 9.2.1 mentions that civil penalties are not usually applied for violations associated with the Reactor Oversight Process (ROP). This is somewhat confusing since one might imagine that all operations fall under the ROP - even if they are not closely scrutinised. Thus could not all incidents and violations be seen to be associated with the ROP?

2) Is it possible to give an example of violations that have and have not fallen in this category of attracting a penalty?

Answer: 1) Some more-than-minor violations, for example, willful violations and violations that can adversely affect the NRC's ability to monitor licensee activities, cannot be evaluated using risked-informed methods. These violations call for the traditional enforcement approach, using the guiding principles and examples in the NRC's Enforcement Policy. If the NRC concludes that the violations are significant, the NRC carefully considers whether civil penalties are appropriate. These types of violations are currently not addressed in the NRC action matrix. The NRC is evaluating ways to integrate these types of violations into the ROP. For additional information about enforcement and the ROP, see the discussion in Section 6.2.2.5 of the U.S. National Report. All inspection findings are reviewed to determine if a violation of regulatory requirements has occurred. Violations fall into three categories: minor violations that can be evaluated using risk-informed methodologies, and violations that cannot. Licensees must rectify minor violations, but NRC does not focus additional regulatory attention on these violations. More than minor violations that are associated with inspection findings and that can be assessed using risk-informed methodologies are addressed within the action matrix of the ROP to determine the level of agency response. NRC does not normally propose civil penalties for these violations because they are being addressed in the action matrix. However, a violation that can be evaluated under the ROP may still warrant a fine because of its particularly high safety significance (e.g. an accidental criticality).

2) To date, the NRC staff has not proposed any civil penalties for highly significant violations evaluated through the ROP's significance determination process. NRC continues to impose civil penalties for discriminatory acts or failure to provide complete and accurate information. On June 27, 2001, for example, NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty of $55,000 for a Severity Level III violation to Nuclear Management Company, LLC, the licensee for the Palisades Nuclear Generating Station. The action was based on the

licensee's failure to provide complete and accurate information in letters to the NRC requesting enforcement discretion and an exigent technical specification change.

Question Number: 09.02

Question: It is reported that the violations are either 1) assigned to the severity level, or 2) associated with the findings of the assessment thru the significance determination process. Does this mean any violation not assigned to the severity level is assigned to the assessment in ROP process?

Answer: Yes. Violations that are not assigned severity levels are associated with findings evaluated under the ROP's significance determination process.

Question Number: 09.03

Question: Enforcement. In case a licensee disagrees with the imposed penalty a hearing can be requested. Which parties participate in this hearing and which party or person judges if the complaint is justified or not?

Answer: Hearings are conducted in accordance with the Rules of Practice established in 10 CFR Part 2 of the NRC's regulations. The parties to the hearing are usually the NRC and the licensee that received the civil monetary penalty. The NRC's regulations provide that any person whose interest may be affected by a proceeding and who desires to participate as a party may file a petition for leave to intervene. However, a person who files a petition to intervene is unlikely to be admitted as a party to the proceeding.

Administrative law judges from the NRC's Atomic Safety and Licensing Board Panel (ASLBP) conduct these hearings. The ASLBP's law judges are employees of the NRC; however, under NRC rules and under the Administrative Procedure Act, they are independent from the NRC staff. The judges have no stake in the outcome of a proceeding, and reach objective decisions based on the record.

After the ASLBP renders a decision, a party may file a petition for review with the Commission. Subsequent to the Commission's decision, a licensee or individual may seek judicial review by appealing the administrative hearing decision to the United States Court of Appeals (part of the judicial branch of the U.S. Government).

Question Number: 09.04

Question: Although in Articles 9 and 10 the word safety culture is not mentioned, it is assumed that safety culture forms an important issue in the USA. In chapter 9 much attention is given to the NRC enforcement program. Do you agree that stimulation by the regulatory body is helpful for a good and open safety culture at a plant and/or within a utility, whereas too strict enforcing actions can work counterproductive? In that respect, can the strong enforcement program in the USA give rise to conflicting situations with regard to safety culture? If yes, how is the NRC dealing with these kind of situations?

Answer: The NRC agrees that open and candid discussions of regulatory issues improve safety culture. Although safety culture is a broad concept, there is general agreement that it includes licensee management emphasis on safety as the highest priority; training for all staff, at all levels, to ensure that they understand their responsibilities for ensuring safe operations; conservative, safety-conscious decisionmaking; a philosophy of continuous self-assessment and improvement; and a willingness to address problems promptly and effectively when they arise. The NRC's regulatory program promotes an industry environment in which the highest standards of quality, integrity, and safety are understood to be in the licensee's self-interest. Such a regulatory scheme demands that nuclear licensees bear the primary responsibility for safely operating their facilities. Consistent with this responsibility, a licensee's safety culture is an integral part of the regulatory framework.

Although the NRC's enforcement program and Enforcement Policy are designed to emphasize the importance of compliance with NRC requirements, they are also designed to encourage prompt identification, and prompt, comprehensive correction of violations, which are consistent with a strong safety culture. For example, the NRC Enforcement Policy includes multiple provisions to encourage licensees to identify and correct problems. As stated in Section 9.2.1 of the National Report, most of the violations identified in the nuclear industry are of low risk significance. Provided certain criteria are met (such as identification and corrective action), the NRC normally refrains from issuing a Notice of Violation. These minor violations are called Non-cited Violations (to establish public records). They are not subject to enforcement action and are not normally described in inspection reports. Sometimes the NRC even refrains from issuing civil penalties or Notices of Violation for more risk-significant violations. The criteria for exercising this "enforcement" discretion are specified in Section VII.B of the NRC Enforcement Policy. During fiscal year 2001 (October 1, 2000 through September 30, 2001), the NRC exercised enforcement discretion for approximately 9 percent of significant enforcement cases.

The goal of the Enforcement Policy is not to minimize the number of violations, but to foster a strong safety culture by encouraging licensees to identify problems at their facilities, and correct them promptly and effectively. All violations, regardless of their significance and how the NRC handles them, must be corrected.

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) as a major element of a policy giving due priority to safety. Specifically, this section covered the policy, safety goals and objectives, and applications of PRA. The applications discussed were (1) the use of safety goals to resolve severe accident issues and evaluate new and existing regulatory requirements and programs, (2) the implementation plan for risk-informed regulation, (3) activities that improve data and methods of risk analysis, (4) industry activities and pilot PRA applications, and (5) 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 Revised Reactor Oversight Process in Article 6.

Questions and answers pertaining to this section follow below.

Question Number: 10.01

Question: The NRC is planning on developing a Human Reliability Analysis program. Please provide more detail.

Answer: The objectives of NRC's Human Reliability Analysis Research Program are to: (1) develop improved human reliability analysis methods, tools, and data, (2) develop human reliability analysis results and insights, and (3) provide human reliability analysis support to other NRC programs. The fiscal year 2001-2005 tasks are to develop improved methods and data for human reliability analysis quantification, perform technical analyses supporting PRA studies of various engineering issues (e.g., the risk of pressurized thermal shock), develop improved methods for certain human reliability analysis problems (e.g., the treatment of latent errors), and develop user guidance documents for a variety of user audiences. The research program is described in a paper, "The NRC Human Reliability Analysis Research Program." The paper was presented at the NEA workshop, "Building the New Human Reliability Analysis: Errors of Commission from Research to Application," in Rockville, Maryland, May 7-9, 2001.

Question Number: 10.02

Question: The answer to this article relies exclusively on the Risk-informed approach and the use of PSA. Although it is clear that this approach is an important input for the demonstration of a high safety level, other aspects could be also described. Could the United States of America give more information about the actions carried out by the utilities in order to ensure and to maintain a high safety level?

Answer: The use of PRA or PSA in NRC's regulatory system is described in general terms in the 1995 policy statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities." The policy ensures that PRA would be implemented in the regulatory process in a manner that promotes regulatory stability and enhances safety. Regulations are not based on risk insights alone but are risk-informed such that the NRC and the industry pay a safety issue a level of attention warranted its significance.

It is necessary to realize that when many NRC regulations were originally formulated, the NRC did not yet have much practical experience with commercial reactors. As a result, the Commission generally proceeded very cautiously, relying on conservative engineering judgment and defense in depth. As the industry has matured, we have learned a great deal, have improved PRA techniques and have accumulated well over 2,000 years of operational experience in the U.S. alone. We now recognize that some of our regulatory requirements are not necessary to provide adequate protection of public health and safety. In these cases, NRC will and has taken action to remove or reduce the requirement. We have also found areas in which risk-significant systems or processes currently are not adequately addressed by our regulations, and have developed new rules to cover these areas, such as the Station Blackout and the Anticipated Transient Without Scram Rules.

The regulations themselves are not risk-based. They are in general the same rules that were originally formulated, containing both prescriptive and performance based requirements. The NRC uses risk insights to determine which areas warrant more or less attention. We have effectively sharpened our focus to those areas that are safety-significant. By using risk-informed insights, the regulation process is more scrutable, objective, consistent and transparent to the public.

Aside from the Maintenance Rule (10 CFR 50.65), which requires licensees to assess the risks incurred while performing maintenance activities before they are conducted, and 10 CFR Part 52, which requires that PRA techniques be used to optimize the design of new reactors, licensees are not required to use PRA techniques to prove compliance with the regulations.

Question Number: 10.03

Question: 1) In addition to PRA, how does the NRC supervise the safety culture of management, managerial structures and licensee organisations with respect to nuclear safety?

2) What does NRC do to prevent possible consequences of inadequate safety culture before severe incidents occur?

Answer: The NRC does not regulate such issues directly. The importance of safety culture is similar to, if not integral with, the role of licensee problem identification and corrective action processes. Within the ROP, an assumption was made regarding the role of safety culture and problem identification and corrective action processes in NRC assessments of licensee performance. Specifically, if a licensee had a poor safety culture or poor problem identification and corrective action processes, problems and events would continue to occur at the facility and performance would degrade at the plant to the point where the performance indicators of the ROP would cross indicator thresholds, or the problems would emerge during NRC baseline inspection activities of the ROP, or both. Since the baseline inspection program covers licensee problem identification and corrective action processes, NRC indirectly gauges the health of a licensee's safety culture. The NRC also evaluates allegations from plant workers regarding safety culture issues, and regulations prohibit the licensees from firing or taking adverse actions against employees who raise safety issues. Lastly, the NRC's inspection of licensee's maintenance activities provides assurance that deficiencies in risk-significant safety equipment are being effectively resolved. In short, no separate and distinct assessment of licensee safety culture is needed because it is subsumed by either the performance indicators or baseline inspection activities.

Question Number: 10.04

Question: 1) We believe that the fostering of a safety culture at nuclear power plants is becoming increasingly important mission. In 1998, NRC implemented the survey of the safety culture of NRC itself, and issued the detailed report. We have few reports on the safety culture evaluation in USA. What kind of other activities on the safety culture evaluation do you have?

2) How would you develop the safety culture study in future?

Answer: 1) NRC is not evaluating licensee safety culture at this time. Safety culture is fundamental to problem identification and corrective action. In designing the ROP, NRC assumed if a licensee had a poor safety culture or poor problem identification and corrective action processes, problems and events would continue to occur at the facility and performance would degrade at the plant to the point where the performance indicators of the ROP would cross indicator thresholds, or the problems would emerge during NRC baseline inspection activities of the ROP, or both. And since the baseline inspection program covers licensee problem identification and corrective action processes, NRC indirectly gauges the health of a licensee's safety culture. The NRC also evaluates allegations from plant workers regarding safety culture issues, and regulations prohibit the licensees from firing or taking adverse actions against employees who raise safety issues. Lastly, the NRC's inspection of licensee's maintenance activities provides assurance that deficiencies in risk-significant safety equipment are being effectively resolved. In short, no separate and distinct assessment of licensee safety culture is needed because it is subsumed by either the performance indicators or baseline inspection activities.

2) In March 2002, the Office of the Inspector General (OIG) announced that it had initiated a special evaluation to assess the NRC's current safety culture and climate and compare it to a benchmark established in 1998. In 1998, OIG sponsored the first NRC Safety Culture and Climate Survey, which was developed and administered by an independent contractor, International Survey Research. The OIG has again hired this firm to measure the agency's organizational safety culture and climate. International Survey Research is recognized for its expertise in conducting surveys, and the use of an outside firm is considered the most objective way to determine employees' attitudes while ensuring anonymity. The contractor will interview a sample of employees (individually or in focus groups) to update the questionnaire.

NRC has concluded that a separate evaluation of licensee safety culture would be superfluous because the performance indicators and baseline inspection already cover licensee safety culture.

Question Number: 10.05

Question: Regarding Risk-Informed Regulation Implementation Plan (RIRIP) of USNRC, your answer to the following questions would be appreciated:

1) What is the process inside USNRC in implementing the RIRIP?

2) Have you invented additional organization or committee for implementing the RIRIP? If so, please describe them briefly.

3) What are the benefits of the implementation of RIRIP so far, not only for the regulator but also for the licensee?

4) USNRC has taken initiative in applying the PRA to regulatory program and it is recognized there has been considerable achievements. What is your perspective for international cooperation in this area and what is your plan for that?

Answer: 1) & 2) The NRC PRA Steering Committee, made up of directors of major NRC offices, determines NRC's overall PRA policy and the major objectives of NRC's PRA activities. The PRA Steering Committee (1) reviews inter-office RIRIP activities, (2) resolves policy issues identified during RIRIP activities, (3) chooses new activities to add to the RIRIP (and the office-specific operating plans), and (4) interacts with the public and senior industry management on topics of common interest. The NRC designates a lead office for each activity in the RIRIP. The lead office is responsible for completing the activity. The Office of Nuclear Regulatory Research periodically updates the status of RIRIP activities. The Risk Management Operating Team, an interoffice management team oversees the RIRIP activities. The Risk-Informed Licensing Panel, a group of division-level managers, meets as necessary to make technical decisions on plant-specific issues related to risk-informed licensing actions.

3) The RIRIP showed relationships between activities and showed that many activities should be coordinated and integrated to get results more quickly with fewer resources, benefitting both NRC and its licensees.

4) Many foreign regulators have expressed interest in learning more about the NRC's risk-informed ROP. When requested, NRC discusses the ROP at international meetings whenever possible. NRC is also developing risk-informed special treatment requirements and risk-informed technical requirements, and will discuss them with foreign regulators. The NRC Office of Nuclear Regulatory Research has an extensive international cooperative research program, the Cooperative Probabilistic Risk Assessment Program. The Cooperative Probabilistic Risk Assessment Program focuses on four general areas of research: (1) PRA methods for fire risk, equipment aging, human reliability, and digital systems reliability and risk, (2) analysis of operating events, (3) development of advanced PC-based PRA software, and (4)

regulatory applications of PRA. Korea has participated in this program since November 1998 and the cooperative agreement extends to November 2003.

The NRC Office of Nuclear Regulatory Research staff also actively participates in the international working group sponsored by the Nuclear Energy Agency (NEA). The objective of the working group is to advance the understanding and utilization of PRA in ensuring continued safety of nuclear installations in member countries.

Question Number: 10.06

Question: Concerning the last paragraph of article 10.3.1, what kind of action does the NRC consider to take for the nuclear power plants with core damage frequencies in the range of 1E-3 to 1E-4?

Answer: NRC regulatory actions are based not just on the calculated core damage frequencies but whether the licensed facility is designed, operated, and maintained in accordance with existing requirements. The NRC assesses whether new requirements should be imposed on existing licensees by applying the criteria in the Backfit Rule (10 CFR 50.109). The Backfit Rule requires that backfits to ensure adequate protection of public health and safety must be imposed regardless of cost. For potential backfits that are not necessary to ensure adequate protection of public health and safety, the Backfit Rule indicates that the NRC shall impose a backfit only when it determines that there is a substantial increase in the overall protection of the public health and safety to be derived from the backfit and that the direct and indirect costs of implementation are justified in view of this increased protection. The NRC applies the criteria in the Backfit Rule using the approach described in NUREG/BR-0058, Revision 3, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," July 2000. Actions may include design changes to the plant, such as hardening the vents of BWR Mark 1 containments to lower the probability of containment failure in the event of the loss of decay heat removal. This backfit was imposed on all BWR Mark 1 plants.

Question Number: 10.07

Question: The last paragraph of article 10.3.1 describes that NRC considered prompt action when the analyses results showed a core damage frequency of 1E-3 per reactor-year or greater. What kinds of actions are included in the prompt action?

Answer: NRC regulatory actions are based not just on the calculated core damage frequencies but whether the licensed facility is designed, operated, and maintained in accordance with existing requirements. The NRC assesses whether new requirements should be imposed on existing licensees by applying the criteria in the Backfit Rule (10 CFR 50.109). The Backfit Rule requires that backfits to ensure adequate protection of public health and safety must be imposed regardless of cost. For potential backfits that are not necessary to ensure adequate protection of public health and safety, the Backfit Rule indicates that the NRC shall impose a backfit only when it determines that there is a substantial increase in the overall protection of the public health and safety to be derived from the backfit and that the direct and indirect costs of implementation are justified in view of this increased protection. The NRC applies the criteria in the Backfit Rule using the approach described in NUREG/BR-0058, Revision 3, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," July 2000. Actions may include design changes to the plant, such as hardening the vents of BWR Mark 1 containments to lower the probability of containment failure in the event of the loss of decay heat removal. This backfit was imposed on all BWR Mark 1 plants.

Question Number: 10.08

Question: The last paragraph of article 10.3.1 describes that NRC established a subsidiary objective of a core damage frequency of 1E-4 per reactor-year. What is the technical basis of this subsidiary objective?

Answer: The NRC established the CDF subsidiary objective to minimize the likelihood of a core damage accident at a U.S. plant over the life of the plant. The PRA Policy Statement makes it clear that any core damage accident at a U.S. nuclear power plant is unacceptable, regardless of whether a radiological release occurs or how few persons are exposed. The subsidiary objective is consistent with the agency's policy of defense-in-depth in that both the frequency of a core damage accident and the probability of a radiological release must be very low.

Question Number: 10.09

Question: Concerning the industry activities of PRA applications in article 10.3.5, how many NPPs have been approved by the NRC to implement the Graded QA program, RI- In-service Testing program, RI- In-service Inspection program, and RI- Technical Specification Changes program by the end of 2001?

Answer: In 2001, NRC issued an exemption to South Texas Project to implement a risk-informed graded quality assurance (QA) program. The program essentially incorporates the elements discussed in Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance."

Risk-informed inservice testing programs have been implemented at four plants, and NRC is reviewing amendments to allow two other plants to implement these programs. Risk-informed inservice inspection has been implemented at 43 plants. Risk-informed changes to technical specification allowed outage times have been implemented for various safety systems at 41 plants.

Question Number: 10.10

Question: An important tool for risk informed regulation is the use of PRAs. However, there is a large variety in quality and scope of the existing PRAs which were made under the IPE and IPEEE framework. Also the PRA-standardisation activities (ASME and ANS) are not yet finished. How is NRC dealing with this variety in quality of the risk insights? E.g., is the penalty for having a low quality PRA an increased regulatory oversight?

Answer: NRC's general approach for evaluating the scope and quality of PRAs used by licensees to inform regulatory decisions is documented in NRC Regulatory Guide 1.174, Standard Review Plan Chapter 19, and a Commission paper, SECY-00-0162. The NRC, in making a regulatory decision on whether to approve a licensee's amendment request, focuses only on those parts of the PRA that are relevant to the request. In general, high-quality PRA information submitted with a license amendment request allows the NRC to make a more risk-informed decision in granting the request. Thus, the reward to the licensee for providing high quality risk information is NRC's approval of a request that NRC may reject for a licensee with a low quality PRA. The NRC plans to develop a regulatory guide and standard review plan to address the use of PRA standards and industry peer review programs to support risk-informed regulatory applications.

Question Number: 10.11

Question: The success of risk informed regulation is highly dependent on the quality of PRAs. Because organizational factors are not yet treated in PRAs, e.g. under the umbrella of Human Reliability Assessments, PRA techniques are not suitable to assess safety culture aspects within a NPP (as long as there is no sudden drastic change of failure frequencies). Can we therefore assume that the supplementary oversight process based on the cornerstones of safety and associated safety indicators can tackle safety culture related issues? If yes, is there something more to tell how this is done? How do you treat e.g., issues where, due to deregulation of the electricity market, less money is spent for safety, like the tendency to outsource more and more support functions which effect on safety is subtle and hardly to quantify. If not, is there another program to assess safety culture?

Answer: Safety culture is fundamental to problem identification and corrective action. In designing the ROP, NRC assumed if a licensee had a poor safety culture or poor problem identification and corrective action processes, problems and events would continue to occur at the facility and performance would degrade at the plant to the point where the performance indicators of the ROP would cross indicator thresholds, or the problems would emerge during NRC baseline inspection activities of the ROP, or both. Since the baseline inspection program covers licensee problem identification and corrective action processes, NRC indirectly gauges the health of a licensee's safety culture. The NRC also evaluates allegations from plant workers regarding safety culture issues, and regulations prohibit the licensees from firing or taking adverse actions against employees who raise safety issues. Lastly, the NRC's inspection of licensee's maintenance activities provides assurance that deficiencies in risk-significant safety equipment are being effectively resolved. In short, no separate and distinct assessment of licensee safety culture is needed because it is subsumed by either the performance indicators or baseline inspection activities.

Question Number: 10.12

Question: Graded QA: Is our observation correct that less safety significant systems and components get less attention than previously. Can this lesser attention increase non-nuclear risk (safety for the workers)?

Answer: Graded QA methodology is discussed in Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance." The application of graded QA methodology to safety-related components may reduce the QA controls (e.g., inspection frequency) for safety-related equipment that is categorized as having low safety significance. Therefore, the observation that less attention is given to such equipment is correct.

With respect to whether graded QA decreases nonnuclear occupational safety, worker safety regulations are under 29 CFR Part 1902, which applies the provisions of Section 18 of the Occupational Safety and Health Administration (OSHA) relating the development and enforcement of State occupational safety and health standards. These regulations are under the administration of the U.S. Labor Department.

Industrial safety programs, administered under OSHA regulations, apply to all activities of workers at nuclear plants. OSHA regulations are independent of the safety significance classification of equipment in nuclear power plants. To use the example of inspection frequency, the purpose of inspecting equipment under OSHA regulations is to ensure worker safety. The purpose of inspecting equipment under 10 CFR Part 50 regulations is to ensure the functionality of the equipment to perform its plant function. Therefore, reducing the frequency of inspections pursuant to Part 50 does not affect the frequency of occupational safety inspections conducted under a licensee's industrial safety program. Therefore, the application of graded QA methodology does not increase nonnuclear risk for workers.

This question possibly alludes to the increased possibility of a piping rupture. However, while inservice inspections of piping are less frequent for piping systems of lower safety significance, licensees are still required to assess any degradation they find, including erosion and corrosion, to ensure that piping systems will remain structurally sound for the next inspection interval.

Question Number: 10.13

Question: The US-NRC had set up a large research program on severe accident issues, lasting many years, and consuming a large budget. Much of this work was reported in the yearly Water Reactor Safety Information Meetings (and their successors). It came practically, and seemingly quite suddenly, to an end, a few years ago. Is there an evaluation document about the US-NRC severe accident research programme and its achievements?

Answer: The severe accident research program was created to resolve specific severe accident issues. There are NUREG reports and other documents on the issues that were resolved (e.g.,NUREG/CR-5423 and NUREG/CR-6025 on Mark I containment liner early failure, NUREG-1524 and NUREG/CR-5960 on alpha-mode steam explosion, and NUREG/CR-6075 and NUREG/CR 6182 on direct containment heating). There are also NUREGs and other topical reports on issues that were extensively studied, such as hydrogen combustion (NUREG/CR-6509) and core melt progression (NUREG/CR-6167). NRC is compiling the results of the severe accident research program into a single report.

Question Number: 10.14

Question: What methods for systematically assess the safety implications of age-related degradation during the period of initial license, and to support safety decisions for license renewal are used by US-NRC?

Answer: The SSCs of nuclear power plants age continuously. Licensee and NRC programs established when plants were licensed, mitigate the effects of aging to ensure continued safe operation. Nuclear power plants in the U.S. are initially licensed for 40 years. There are extensive requirements for monitoring, surveillance, detection, and preventive maintenance to ensure that nuclear power plants are operated safely. For example, Appendix H to 10 CFR Part 50 requires reactor pressure vessel surveillance; 10 CFR 50.61 contains fracture toughness requirements for the reactor vessel; 10 CFR 50.55a requires inservice inspection and testing programs for components in accordance with the American Society of Mechanical Engineers (ASME) Code; 10 CFR 50.49 requires environmental qualification of electrical equipment; and 10 CFR 50.55a requires containment inspections per the ASME Code. Licensees and NRC review plant-specific and industry-wide operating experience to assess the effectiveness of activities to manage aging and the need for additional actions. Technical specifications restrict the operation of the plant to within limits based on the design of the plant, and the plant must shut down if it cannot operate within those limits. If degradation is detected during surveillance or testing, the licensee must do a root cause analysis and take appropriate corrective action to restore the system, structure, or component to its design basis condition.

Licensees have been performing various maintenance activities on their nuclear power plants since the plants were constructed. The industry and NRC now have extensive experience with nuclear power plant maintenance. The industry and NRC understand that effective maintenance leads to decreases in the number of challenges to safety related SSCs, and consequently increases their reliability. The Maintenance Rule, 10 CFR 50.65, requires that licensees monitor the performance or condition of SSCs in a manner sufficient to provide reasonable assurance that they are capable of fulfilling their intended functions.

For license renewal, the NRC relies on its regulatory process to ensure that the licensing bases of current operating nuclear power plants provide, and will continue to maintain, an acceptable level of safety. This reliance continues for license renewal, except for the effects of aging on certain SSCs during the period of extended operation. The aging effects are reviewed as part of the license renewal process. Licensee must maintain the plant-specific licensing basis during the renewal term in the same manner and to the same extent as during the initial operating term. NRC credits existing licensee programs for managing the effects of aging, which allows the NRC to focus the renewal review on passive, long-lived SSCs where the effects of aging are not readily detectable. The degradation of active components is more apparent and is detected by required periodic testing and surveillance. Short-lived components are not reviewed for renewal because they are replaced under current programs before the effects of aging cause a loss of functionality. Each renewal applicant is required to perform an integrated plant assessment and demonstrate that the SSCs requiring aging management review have been identified and that programs and activities are in place to manage the effects of aging so that the functionality of the SSCs will be maintained in accordance with their licensing basis. The continuation of aging management activities conducted during the first 40 years and the additional activities identified during the renewal review for the 20-year extended term provide reasonable assurance that the effects of aging on the safe operation of nuclear power plants will be managed.

Question Number: 10.15

Question: Article:10, Section: 10.2 ,PRA Policy, Page:10-2 to 10-3, and Article: 10, Section: 10.3.2, Using the Safety Goals to Evaluate New and Existing Regulatory Requirements and Programs, Page: 10-4, state that to define "risk to life and health", the NRC approved the following quantitative health objectives (defines risks for death and cancer of the population in 1 mile and 10 miles ranges around NPP), ...the NRC established..."benchmark" values of 1x10-4 per reactor-year for core damage frequency and 1x10-5 per reactor-year for large early release frequency...

Broader text definitions are presented in the text at these 2 subsections, giving: 1) the definitions of risk factors to the population and 2) the estimation of reactor safety by Probability Risk Assessment.

1) Did you establish any connection between these "acceptable" quantitative health objectives for the population and the chosen "benchmark" values for core damage and radiation release?

2) Were the benchmarks defined on the basis of these health objectives? Difference in population density around different NPP sites (max. 10 miles range) would also allow use of more relaxed safety measures at NPPs in less populated areas.

Answer: The Commission's objective in publishing the Safety Goal Policy Statement was to define an acceptable level of radiological risk from Nuclear power plant operation. The Commission believed that by establishing a level of safety considered to be safe enough, public understanding of regulatory criteria an public confidence in the safety of operating plants would be enhanced. In formulating the policy, the Commission indicated that it believed that the current regulatory practice ensured compliance with the basis statutory standard of adequate protection, but that current practices could be improved to provide better means for testing the adequacy of current requirements and the possible need for additional requirements.

This policy statement was not a regulation but influenced various regulatory actions, primarily the development of Regulatory Analysis Guidelines used in backfit analyses. At a later date, the Commission directed the staff to develop subsidiary objectives that would provide guidance on minimum acceptance criteria for prevention (CDF) and mitigation (large early release frequency (LERF)) and thus assure an appropriate multi-barrier defense-in-depth balance in design. Early release is defined as one that occurs before emergency response occurs.

The LERF objective is derived from the safety goals, but the CDF objective was not. Since a plant with a high CDF but a low conditional containment failure probability would meet the safety goals, the CDF objective was not based on the safety goals. Instead, NRC established this subsidiary objective to minimize the likelihood of a core damage accident at a U.S. plant over the life of the plant. Moreover, the PRA Policy Statement makes it clear that any core damage accident at a U.S. nuclear power plant is unacceptable, regardless of whether a radiological release occurs or how few persons are exposed. The subsidiary objectives are consistent with the agency's policy of defense-in-depth in that both the frequency of a core damage accident and the probability of a radiological release must be very low.

Regulatory decisions for plants sited in areas of high population density are not based on objectives that are more strict than are those for plants sited in areas of low population density, since backfit decisions are based on, in part, the change in CDF.

Question Number: 10.16

Question: In view of reconsideration of probable threat, connected to act of terrorism, please, detail your vision of such reconsideration influence on risk-oriented approach.

Answer: After the events of September 11, the Chairman, with full support of the commission directed the staff to perform a top-to-bottom reevaluation of the Agency's safeguards and security programs. As part of this activity, NRC is considering modifications to the design basis threat, against which the licensees are required to defend the facility. NRC evaluates the licensee's performance via force on force exercises and table-top drills. At this point, there are no risk insights in the requirement or the performance evaluation.

Question Number: 10.17

Question: The priority to safety is focusing on risk informed decision taking. How are factors such as organisational change and safety culture taken into account in this process?

Answer: The importance of safety culture is similar to, if not integral with, the role of licensee problem identification and corrective action processes. Within the ROP, an assumption was made regarding the role of safety culture and problem identification and corrective action processes in NRC assessments of licensee performance. Specifically, if a licensee had a poor safety culture or poor problem identification and corrective action processes, problems and events would continue to occur at the facility and performance would degrade at the plant to the point where the performance indicators of the ROP would cross indicator thresholds, or the problems would emerge during NRC baseline inspection activities of the ROP, or both. Since the baseline inspection program covers licensee problem identification and corrective action processes, NRC indirectly gauges the health of a licensee's safety culture. The NRC also evaluates allegations from plant workers regarding safety culture issues, and regulations prohibit the licensees from firing or taking adverse actions against employees who raise safety issues. Lastly, the NRC's inspection of licensee's maintenance activities provides assurance that deficiencies in risk-significant safety equipment are being effectively resolved. In short, no separate and distinct assessment of licensee safety culture is needed because it is subsumed by either the performance indicators or baseline inspection activities.

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 resources needed for financing safety improvements that are made during a plant's operation, decommissioning, and handling claims and damages associated with accidents. This section also explained the regulatory requirements for qualifying, training, and retraining personnel.

Questions and answers pertaining to this section follow below.

Question Number: 11.01

Question: The examination of financial qualifications for Construction and Operations is described in Article 11.1.1. The document does not, however, state that such scrutiny is applied to operating license renewal applications and/or power up-grade applications. Also, this examination requires a specialist expertise. Does the NRC contract experts to do this work or does it retain such expertise on its staff? If so, is this difficult to do?

Answer: The current NRC regulations require a review of a licensee's financial qualifications when the licensee applies for license renewal. However, NRC is considering a rulemaking to eliminate financial qualification reviews as part of the license renewal evaluation process. The NRC staff believes that a formal financial qualifications review is only necessary during the initial licensing or in conjunction with license transfers, when warranted by special circumstances. There is no current requirement for financial qualifications reviews of power uprate applications, although, under current regulations, licensees are required to provide additional decommissioning funding assurance because of the higher power levels at the uprated plants. Of course, licensees whose license renewal and power uprate application requests are approved must to continue to comply with all applicable NRC regulations, including those pertaining to financial qualifications and decommissioning funding assurance.

The NRC uses its own staff for financial qualifications reviews. These staff are financial analysts with appropriate expertise. NRC has not found it difficult to hire and train such staff.

Question Number: 11.02

Question: Article 11.2 also mentions that NRC has had to examine facilities where there has been a high rate of failure in operator licencing exams. Is this seen as an increasing trend (note also Indian Point) and could this stretch resources of the NRC?

Answer: Failures on initial operator exams and requalification examinations are not increasing. Indian Point is an isolated case to which NRC has responded. NRC does not anticipate a problem with resources.

Question Number: 11.03

Question: What programs are in place to ensure adequate staff and training are available in the future for staff at the NRC and the licensee?

Answer: Last year the NRC had six times as many staff members over the age of 60 as under the age of 30. In the past year NRC identified skill gaps, and hired new staff to fill those gaps and ensure that essential technical skills are maintained and strengthened. More than 80 young, highly qualified engineers and scientists have accept entry-level positions. By the end of this fiscal year, the agency expects to have about 100 new staff. The ratio of 6 to 1 has been reduced to 4 to 1 and continues to decline. NRC is also trying to retain current staff members whose critical skills might otherwise be lost.

There has also been increased interest in nuclear engineering and related technical areas among university students. The University of South Carolina recently decided to establish a nuclear engineering program in recognition of the resurgence of interest in nuclear power. The NRC has an internship program for training new employees. The NRC encourages its staff to take the many courses it offers at its technical training center. NRC continually updates the courses.

With respect to licensees, 10 CFR 50.40, "Common Standards," ensures that licensees demonstrate that they are technically qualified to engage in nuclear activities. Paragraph 50.34(b)(6)(i) requires information about personnel qualifications. Subsections (i) through (m) of 10 CFR 50.54, "Conditions of Licenses," contain specific requirements for operators of the facility, the responsibility for directing activities of licensed operators, and senior operator availability and various reactor conditions and modes of operation. Subpart D, "Applications," of 10 CFR Part 55, "Operator Licensing," requires that operator license applications contain information about an individual's education and experience and related matters.

As stated in Article 11, 10 CFR Part 55 regulates the training requirements for licensed operators and licensed senior operators, and 10 CFR 50.120, "Training and Qualification of Nuclear Power Plant Workers," requires licensees to establish, implement, and maintain a training program derived from a systems approach to training. The training program must provide for the training and qualification of instrument and control technicians, electrical maintenance personnel, mechanical maintenance personnel, radiological protection technicians, chemistry technicians, and engineering support personnel. NRC Inspection Procedure 41500, "Training and Qualification Effectiveness," is used to ensure licensee compliance with 10 CFR 50.120. This inspection procedure describes the two methods used by the NRC staff to evaluate the effectiveness of training programs in the industry. The first is to monitor human performance and, if risk-significant plant performance issues are occurring, perform training inspections. The second method is to monitor the industry's accreditation process for training programs.

Question Number: 11.04

Question: Impact of deregulation: We note that the NRC is taking account of the impact of deregulation on NPPs. We would welcome a comment as to what exactly it is doing, in particular in relation to ensuring adequate staffing levels in NPPs.

Answer: The impact of economic deregulation on nuclear power plant safety is discussed in the NRC's "Final Policy Statement on the Restructuring and Economic Deregulation of the Electric Utility Industry" (62 FR 44071; August 19, 1997) and SECY-98-153 "Update of Issues Related to Nuclear Power Reactor Financial Qualifications in Response to Restructuring of the Electric Utility Industry" dated June 29, 1998. To summarize, the NRC believes that although economic deregulation may have potentially adverse impacts on nuclear power plant safety in some circumstances, the NRC's regulatory framework will identify and correct any safety degradations as a result of cost cutting before they can seriously affect safety. The NRC is currently considering whether rulemaking is necessary to address worker fatigue.

Question Number: 11.05

Question: We understand that the Price Anderson Act is in the process of amendment. Could you explain the purpose and numerical values under discussion?

Answer: The Commission submitted to the Congress in August 1998, a report containing recommendations regarding the renewal of the Price-Anderson Act. The Act presently expires on August 1, 2002. Even if Congress fails to renew the Act, existing indemnification agreements, requirements for insurance of currently NRC-licensed facilities and various other provisions, would continue. In its report, the Commission provided current detailed information that Congress sought about nuclear power production, available insurance, and experience under Price-Anderson. Congress also requested and the Commission provided its views as to whether Congress should renew the Act, and if so, what modifications should be enacted.

Hearings were held in the House and in the Senate on the recommendations in the report, which was entitled "The Price-Anderson Act-Crossing the Bridge to the Next Century: A Report to Congress." The House passed a bill to renew the Act for an additional fifteen years in late 2001. The Senate held hearings again in January 2002, but as yet has not passed a bill. In addition to the extension of the Act, the House bill increases the annual retrospective premium from the current $10 million per reactor per incident per year to $15 million, with an inflationary adjustment provision. The current retrospective premium of $83.9 million would be increased in the House bill for inflation to approximately $92 million. All of the other provisions presently in the Act would remain unchanged.

Question Number: 11.06

Question: Is there any regulatory requirement for surplus personnel for retraining to assure safe operation? If yes, what is the size of surplus personnel?

Answer: There are no NRC requirements for "surplus" licensed personnel, apart from the requirements in 10 CFR 50.54. The minimum staffing requirements and overtime hour limitations are also addressed in the technical specifications. Generally, the licensed staffing level consists of two crews on 12-hr shifts, or three crews on 8-hr shifts, plus two complement crews, one in training and the other to work on scheduled off days. In anticipation of staffing level changes, the licensees generally keep a few extra licenses active. The deregulation of the U.S. electric power generation industry motivates licensees to maintain adequate staffing to keep plants operating with minimum downtime.

Question Number: 11.07

Question: Introduction to the national report notes that NRC is adjusting its actions in view of the deregulation of the electricity sector market. What is the impact of electricity market deregulation on the safety of the operating US nuclear installations according to NRC view?

Answer: The impact of economic deregulation on nuclear power plant safety is discussed in the NRC's "Final Policy Statement on the Restructuring and Economic Deregulation of the Electric Utility Industry" (62 FR 44071; August 19, 1997) and SECY-98-153 "Update of Issues Related to Nuclear Power Reactor Financial Qualifications in Response to Restructuring of the Electric Utility Industry" dated June 29, 1998. To summarize, the NRC believes that although economic deregulation may have potentially adverse impacts on nuclear power plant safety in some circumstances, the NRC's regulatory framework will identify and correct any safety degradations as a result of cost cutting before they can seriously affect safety. The NRC is currently considering whether rulemaking is necessary to address worker fatigue.

Question Number: 11.08

Question: The operational organizations assume the alternative approaches in view of expenditures reducing of energy market liberalization conditions (p. XVII). Please, detail the basic approach essence and NRC reaction to them.

Answer: The NRC does have an obligation of fulfilling its regulatory responsibility without imposing needless burdens. Thus, in overseeing operating plants, the NRC needs to be intrusive, but only as required to achieve its statutory goals. NRC must avoid the pitfalls both of under-regulation and over-regulation. Unduly lax regulation could put the public at risk, whereas unduly stringent regulation could create unwarranted economic burden without any corresponding benefit.

With the use of risk insights and well over 2,000 years of operational experience in the U.S. alone, NRC now recognizes that some of our regulatory requirements may not be necessary to provide adequate protection of public health and safety. In these cases, the regulatory requirements can be modified or reduced, thereby reducing unnecessary burden on our licensees. Licensees are applying for risk-informed license amendments, following the approach described in Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (July 1998). NRC has approved amendments to extend safety system outage times and inservice testing intervals.

However, risk insights have also allowed the NRC to find areas in which risk-significant systems or processes currently are not adequately addressed by the regulations, and develop new rules to cover these areas, such as the Station Blackout and Anticipated Transient Without Scram Rules.

NRC experience with deregulation to date has generally shown that good safety performance is linked to good economic performance. Both are furthered by more attention to preventive maintenance, better training of operators, and, overall, a greater focus on fostering a safety culture. The less time required to shut down and handle maintenance problems, the higher the capacity factor.

Question Number: 11.09

Question: A GAO review reported in Nuclear Market Review (4 Jan 2002) that NRC has been asked to request guaranteed additional resources and document review of any financial information. Is NRC doing this and what has been the outcome?

Answer: The U.S. Government Accounting Office (GAO) criticized the NRC for not following its own policies in reviewing two license transfer applications. The GAO report raised concerns about the transferees' financial qualifications to operate the plants safely and their ability to provide the required funding assistance for decommissioning. The NRC disagreed with the GAO's findings, but acknowledged that it could have done a better job of documenting both reviews. In this regard, for future financial qualifications reviews, the staff intends to clearly document cases where it has independently checked such information as State restructuring laws and bilateral agreements between applicants and their affiliates that have not been included in the docketed application packages. The GAO included the NRC's comments on the draft GAO report as Appendix 1 of GAO's final report. The NRC issued its comments on GAO's final report on March 1, 2002, which are publically available in ADAMS.

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 and the 6 major areas under the program in which the NRC performs significant activities. These areas 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.

Questions and answers pertaining to this section follow below.

Question Number: 12.01

Question: Could the United States of America provide some information on the measures taken by contractors in order to ensure a sufficient competence and safety culture?

Answer: NRC regulations require licensees to have QA programs, including measures to ensure that contractor services conform to procurement documents. These measures must include provisions for source evaluation and selection, objective evidence of quality furnished by the contractor, and inspection at the contractor source. To the extent practical, NRC uses the United States National Laboratories to provide contractor services.

Within the ROP, an assumption was made regarding the role of safety culture and problem identification and corrective action processes in NRC assessments of licensee performance. Specifically, if a licensee (or a contractor) had a poor safety culture or poor problem identification and corrective action processes, problems and events would continue to occur at the facility and performance would degrade at the plant to the point where the performance indicators of the ROP would cross indicator thresholds, or the problems would emerge during NRC baseline inspection activities of the ROP, or both. No separate and distinct assessment of contractor safety culture is needed because it is subsumed by either the performance indicators or baseline inspection activities for the licensees.

Question Number: 12.02

Question: Could the United States of America provide some information about the implementation of symptom-oriented procedures and the corresponding operators training? How is the efficiency of these accidental operation procedures assessed?

Answer: Emergency operating procedures have been symptom-based for many years. Emergency preparedness is one of the seven cornerstones of safety in the ROP. The objective of the emergency preparedness cornerstone is to "ensure that the licensee is capable of implementing adequate measures to protect the public health and safety during a radiological emergency." Oversight of the emergency preparedness cornerstone is achieved through performance indicators and a supporting risk-informed inspection program. The drill and exercise performance indicator monitors timely and accurate licensee performance during drills, exercises, and actual events when presented with opportunities to classify emergencies, notify offsite authorities, and recommend protective actions. The emergency preparedness cornerstone has three inspectable areas:

- Problem identification and resolution: Inspectors evaluate the licensee's programs for problem identification and resolution as they relate to the emergency preparedness program.
- Drill and training evolution observation: Inspectors evaluate drills and simulator-based training evolutions in which shift operating crews participate.
- Biennial exercise: The Inspectors independently observe the licensee's performance in classifying events, notifying the offsite authorities, and developing recommendations for protective actions, and performing other activities during the exercise. The inspectors also ensure that the licensee's critique is consistent with the inspector's own observations.

Question Number: 12.03

Question: Recently, the many operational events related to a human performance have been reported domestically and internationally. It is reported that the NRC researches human performance issues. Do you have any programs to evaluate the human performance in these events from the safety culture standpoint?

Answer: When a human performance issue is identified NRC assesses the work environment (safety culture) at the facility, and requests or orders the licensee to conduct a survey of its safety-conscious work environment (or hires a third party to do the survey) and report the results to the NRC. Thus far the NRC has not needed to issue an order to a licensee.

With regard to research initiatives, the objectives of NRC's Human Reliability Analysis Research Program are to: (1) develop improved human reliability analysis methods, tools, and data, (2) develop human reliability analysis results and insights, and (3) provide human reliability analysis support to other NRC programs. The fiscal year 2001-2005 tasks are to develop improved methods and data for human reliability analysis quantification, perform technical analyses supporting PRA studies of various engineering issues (e.g., the risk of pressurized thermal shock), develop improved methods for certain human reliability analysis problems (e.g., the treatment of latent errors), and develop user guidance documents for a variety of user audiences. The research program is described in a paper, "The NRC Human Reliability Analysis Research Program." The paper was presented at the NEA workshop, "Building the New Human Reliability Analysis: Errors of Commission from Research to Application," in Rockville, Maryland, May 7-9, 2001.

Question Number: 12.04

Question: The first paragraph of Shift Staffing describes that the most recent amendment to 10CFR50.54(m) increased the minimum onsite staffing for a single operating unit to two senior reactor operators and two reactor operators. What are the bases or reasons for that?

Answer: The basis for the rule was published in the United States Federal Register on July 11, 1983. The requirements of 10 CFR 50.54(m) were a result of the accident at Three Mile Island 2. The requirements ensure that all operating nuclear power plants are adequately staffed with licensed personnel. The addition of the second senior reactor operator is required to give the shift supervisor freedom to move about the plant during normal and emergency situations and relieve the senior reactor operator in the control room if he or she has to leave the control room.

Question Number: 12.05

Question: 1) Article 12, Section 12.1, Page 12-1 states "Human performance is a critical element of nuclear power plant safety. More than half of the incidents that are reported by licensees of commercial nuclear power plants have human performance as a root cause.... many incidents at nuclear power plants often result from incorrect human actions. Consistent with the NRC's mission is the view that human performance should not contribute to undue risk in using nuclear materials." In the background statement the importance of human factor is discussed supported by data of the operating experience. The discussion is concentrated to incident causes. Contrary to that, please could you give your opinion about the human factor's treatment in the framework of accident management, especially because it is expected, that the operators would make more faulty actions in the severe and stress conditions during accidents?

2) Is the balance between the automatic plant response and operator action appropriate or there is a room for some more automation? What are the main conclusions of such analysis if it is performed?

3) Importance of Human factor safety significance is quite uncertain especially in the area of Beyond Design Basis Accidents and Severe accidents. What are the principles and criteria for risk informed decision-making in such low probability uncertain conditions?

Answer: 1) NRC has no conclusive evidence that operators make more faulty actions during accidents. This conclusion is partially based on NRC observations of emergency preparedness activities. Emergency preparedness is a major component of the ROP and is one of the seven recognized cornerstones of safety in the process. The objective of the emergency preparedness cornerstone is to "ensure that the licensee is capable of implementing adequate measures to protect the public health and safety during a radiological emergency." Oversight of the emergency preparedness cornerstone is achieved through performance indicators and a supporting risk-informed inspection program. The performance indicator for drill and exercise performance monitors timely and accurate licensee performance in drills, exercises, and actual events when presented with opportunities to classify emergencies, notify offsite authorities, and recommend protective actions. The inspectable areas of the emergency preparedness cornerstone include the following:

- Problem identification and resolution: Inspectors evaluate the licensees' programs for problem identification and resolution as they relate to the emergency preparedness program.

- Drill and training evolution observation: Inspectors evaluate drills and simulator-based training evolutions in which shift operating crews participate.

- Biennial exercise: The Inspectors independently observe the licensee's performance in classifying events, notifying the offsite authorities, and developing recommendations for protective actions, and other activities during the exercise. The inspectors also ensure that the licensee's critique is consistent with the inspector's own observations.

2) The NRC finds the current balance acceptable. The requirements for control room staffing in 10 CFR 50.54(k) and (m) are cognizant of the current level of automation. To use an alternative level of operator staffing, a licensee must justify an exemption from the regulation by performing a detailed function and task analysis, followed by demonstrations on a control room simulator or control room prototype of all activities expected of the operators during normal, abnormal, emergency, and accident conditions. In order to do these activities, the licensee would have to first develop a concept of operations, considering the following factors:

- Role of the operator - Is the operator to be an active participant in reactor operation or a passive monitor or troubleshooter?

- Level of automation - Is the system to be fully automatic, fully manual, or some combination thereof?

- Control room design - Describe the overall design of the control room? How many workstations are there? What are they for? How are individual workstations designed?

- Personnel categories and qualifications - Should operators be licensed as they are today or will they need different qualifications (e.g., knowledge of refueling operations, computer expertise)?

- Procedures - Are they symptom based? Are they interactive? Are they computerized or hard copy?

3) In observing emergency preparedness activities, the NRC has determined that operators do not make more mistakes during accidents. Early protective actions for various sets of emergency conditions are predetermined during planning. Operators may need to adjust planned actions to suit the local conditions. Early evacuation of nearby areas is the most beneficial protective action, and for the most severe accidents, early evacuation is the only available action to protect the public living near the plant (i.e., within 3.2 to 4.8 km (2 to 3 miles).

The technical basis and guidance for determining protective actions for severe (core damage) reactor accidents are given in NUREG-0654, "Criteria for Protective Action Recommendations for Severe Accidents," Supplement 3, and EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents." These documents are based on the conclusions of severe accident studies, such as NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants."

Only a reactor accident that causes core damage and failure of the containment could result in doses sufficient to have early significant health effects (injuries or deaths). In a severe accident, the control room staff would know (1) that the core is damaged and (2) that a large amount of fission products in the containment atmosphere could be released if the containment fails. However, the performance of the containment cannot be predicted with great certainty under severe accident conditions.

Studies of severe reactor accidents and the effectiveness of protective actions have reached the following conclusions:

- To substantially reduce risk, evacuation must begin before, or shortly after, a release.
- Moving people even short distances substantially reduces risk.

Question Number: 12.06

Question: Article: 12, Section 12.2.3.1, Page 12-3 states, "Governing Documents and Processes, The NRC staff evaluates the human factors engineering design of the main control room and control centers outside of the main control room using NUREG-0800, Revision, Chapter 18..." Is it planned to introduced the new Chapter 18 of SRP dedicated to Human factor for operating plants?

Answer: NRC will update Chapter 18 of the Standard Review Plan to address the latest technologies. Revision 2 of NUREG-0700, "Human System Interface Design Review Guideline," and Revision 1 of NUREG-0711, "Human Factors Engineering Program Review Model," both soon to be published, will be the bases for this update and will be available in ADAMS. The NRC staff will use the updated Chapter 18 only to review future applications. No backfit is planned.

Question Number: 12.07

Question: Article 12, Section 12.2.3.2, Page 12-4 states "This section discusses human factor activities related to emergency operating and plant procedures. Licensees must have programs for developing, implementing and maintaining such procedures." Please could you explain, what are the main hardware modifications coupled with the procedures and guidelines changes, which are set up with the aim to decrease the operators workload during accident management.

Answer: The NRC has not mandated any hardware modifications beyond the ones in the Three Mile Island Action Plan. The Three Mile Island Action Plan included requirements for the addition of a Safety Parameter Display System to continuously display information on reactivity control, reactor core cooling and heat removal, reactor coolant system integrity, radioactivity control, and containment condition. The plan also required each licensee to conduct a Detailed Control Room Design Review to identify, assess, and correct significant human engineering discrepancies in the control room and the remote shutdown panel. NUREG-0700 provides guidelines for good practices.

Question Number: 12.08

Question: Please, could you describe if any influence of the maintenance rule requirements fulfillment is observed on human factor performance in US plants and is it evaluated in safety analysis and whether it is evaluated in PRAs.

Answer: In accordance with the Maintenance Rule (10 CFR 50.65), licensees are required to assess and manage risk in performing maintenance. These risk assessments typically use the nominal human performance reliability estimates used in the licensee's PRA. Within the ROP, an assumption was made regarding the role of safety culture and problem identification and corrective action processes in NRC assessments of licensee performance. Specifically, if a licensee had a poor safety culture or poor problem identification and corrective action processes, problems and events would continue to occur at the facility and performance would degrade at the plant to the point where the performance indicators of the ROP would cross indicator thresholds, or the problems would emerge during NRC baseline inspection activities of the ROP, or both. Since the baseline inspection program covers licensee problem identification and corrective action processes, NRC indirectly gauges the health of a licensee's safety culture. The NRC also evaluates allegations from plant workers regarding safety culture issues, and regulations prohibit the licensees from firing or taking adverse actions against employees who raise safety issues. Lastly, the NRC's inspection of licensee's maintenance activities provides assurance that deficiencies in risk-significant safety equipment are being effectively resolved. In short, no separate and distinct assessment of licensee safety culture is needed because it is subsumed by either the performance indicators or baseline inspection activities.

Question Number: 12.09

Question: What are the main characteristics of the supplemental inspection procedure related to the human performance - crosscutting element Revised Reactor Oversight Process?

Answer: NRC Inspection Procedure 71841, "Human Performance," addresses the human-system interface, the environment, communication, coordination of work and supervision, work practices, procedure use and adherence, training and qualifications, and fitness for duty.

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 Revised Reactor Oversight Process, augmented QA, and graded QA.

Questions and answers pertaining to this section follow below.

Question Number: 13.01

Question: Augmented quality program- PSA studies and operating experience can lead to implement design modifications at the nuclear plants. Could the United States of America give some information on the requirements concerning the quality assurance of these modifications?

Answer: Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," discusses the use of PSA studies. Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance," provides guidance to licensees on determining the relative safety significance of plant equipment and on applying graded QA.

Section 13.4.3 of the U.S. National Report addresses augmented quality programs for fire protection, station blackout, and anticipated transients without scram and cites the following regulatory guidance documents.

- Branch Technical Position CMEB 9.5-1, "Guidelines for Fire Protection for Nuclear Power Plant for Nuclear Power Plants," Revision 3, July 1981.
- Regulatory Guide 1.155, "Station Blackout," August 1988.
- Generic Letter 85-06, Quality Assurance Guidance for Anticipated Transients Without Scram Equipment That Is Not Safety-Related," April 16, 1985.

Licensees follow these guidance documents in implementing plant modifications. NRC has not issued more recent regulatory guidance on QA requirements for such modifications.

Question Number: 13.02

Question: Graded QA - Could the United States of America indicate if the graded QA methodology will be apply to all US nuclear reactors?

Answer: Graded QA methodology is discussed in Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance". This regulatory guide provides guidance to licensees, both on determining the relative safety significance of plant equipment and on applying graded QA controls.

Implementation of graded QA methodology is voluntary. Whether a reactor owner adopts the graded QA methodology depend primarily on the owner's cost-benefit analysis. The graded QA methodology may not prove to be beneficial for every U.S. nuclear reactor.

Question Number: 13.03

Question: Which additional measures for the quality assurance of components are planned in connection with the lifetime prolongation of NPPs?

Answer: NRC has issued the license renewal rule, 10 CFR Part 54, to provide assurance that the effects of aging on the functionality of long-lived passive SSCs, such as pipes, tanks, and heat exchangers, are adequately managed in accordance with the plant-specific current licensing basis so that their intended functions are maintained during the period of extended operation.

To address the effects of aging during the lifetime of the plant, licensees have developed a number of aging management programs. Both the license renewal application and the plant safety analysis report contain a summary description of programs and activities for managing the effects of aging. Aging management programs are generally of four types: prevention, mitigation, condition monitoring, and performance monitoring. Prevention programs prevent the aging effect from occurring; for example, coating programs prevent external corrosion of a tank. Mitigation programs slow the effects of aging, for example, chemistry programs mitigate internal corrosion of piping. Condition-monitoring programs inspect for the presence of and determine the extent of aging effects; for example, concrete structures are visually inspected for cracking, and pipe walls are examined by ultrasound for erosion-corrosion-induced wall thinning. Performance monitoring tests the ability of a structure or component to perform its intended function; for example, the heat balances on heat exchangers are monitored to ensure that the tubes transfer heat properly. In some instances, licensees have implemented more than one type of aging management program to ensure that an intended function is maintained during the period of extended operation.

All activities, including aging management programs, associated with safety-related SSCs and non-safety-related SSCs that may affect the operation of safety-related SSCs or are credited in the licensee's safety analysis of record, are subject to the QA requirements of 10 CFR Part 50 Appendix B.

Question Number: 13.04

Question: The section 13.4.4 describes 4 essential elements by which the requirements of 10CFR50 Appendix B are graded. What is the criterion to decide whether a problem is subject to root-cause analysis or not?

Answer: Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 requires nuclear plant licensees to establish measures to assure that conditions adverse to quality are promptly identified and corrected. In the case of "significant conditions adverse to quality," the measures must assure that the root cause of the condition is determined and corrective action taken to prevent reoccurrences.

Licensee corrective action processes use plant-specific criteria to determine the levels of significance for conditions adverse to quality. The criteria may be based on traditional engineering approaches or on a risk-based methodology. Root cause analysis is generally required above a certain significance level.

The NRC evaluates the effectiveness of licensees' corrective action programs, including their root cause analysis processes, through inspections under the ROP and through review of licensee performance and operating history as reported through regulatory processes such as the licensee event report (LER) system. An effective root cause process generally results in a low incidence of problem recurrence and high equipment reliability and availability.

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. It also discussed experience and lessons-learned from performing safety assessments. 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.

Questions and answers pertaining to this section follow below.

Question Number: 14.01

Question: Article 14.1.2 states that a "change, test or experiment" at a facility requires NRC approval if it would result in more than "minimal increase in frequency of occurrence of an accident previously evaluated in the final safety analysis report". The expression "minimal increase" is rather imprecise given the probabilistic nature of NRC safety assessments. Is there a figure associated with this term?

Answer: The term "minimal increase" is not quantified in NRC guidance on implementing 10 CFR 50.59. A licensee may use a calculation to quantify the change in likelihood of a malfunction of an system, structure, or component (SSC) important to safety, if a calculation is available and practical. To exceed the more than "minimal increase" standard, the effect of a proposed activity on the likelihood of a malfunction must be discernable and attributable to the proposed activity. A proposed activity is considered to have a negligible effect on the likelihood of a malfunction when the change in likelihood is too small to conclude that the likelihood has actually changed. A proposed activity that has a negligible effect satisfies the minimal-increase standard.

This guidance is contained in NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," dated November 2000. This guidance was endorsed by NRC Regulatory

Guide 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," also dated November 2000.

Question Number: 14.02

Question: The intent of the article is very much related to the (quite static) Final Safety Analysis Report and to the detailed safety verification activities. However, in several points of the U.S. report, there are examples where different reasons may lead to a need to re-examine safety; while the first initiative on such an item may be taken by the utility or by the regulator. Concerning the whole safety picture of a nuclear power plant, IAEA has issued guidelines for Periodic Safety Reviews; and the licensee may be expected to perform periodic "self assessments" of this kind. Has USNRC considered this from the regulatory rulemaking/ oversight standpoint?

Answer: NRC relies on its regulatory process rather than periodic safety reviews to oversee nuclear power plants and upgrade requirements as they are determined necessary. When issuing the original operating license, the NRC made a comprehensive determination that the design, construction, and proposed operation of the nuclear power plant satisfied NRC's requirements and provided reasonable assurance of adequate protection to the public health and safety. However, the licensing basis does not remain fixed but evolves throughout the term of the operating license in response to NRC regulatory activities of the licensee activities.

Considered together, NRC regulatory activities provide ongoing assurance that the licensing basis of nuclear power plants ensure an acceptable level of safety. NRC's activities include research, inspections (periodic regional inspections and daily oversight by the resident inspector), audits, investigations, evaluations of operating experience, and regulatory actions to resolve identified issues. NRC's activities may result in changes to the licensing basis for nuclear power plants through the promulgation of new or revised regulations, acceptance of licensee commitments to modify nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. NRC also issues documents such as bulletins, generic letters, regulatory information summaries, and information notices. Licensee commitments in response to these documents also change a plant's licensing basis. In this way, NRC's consideration of new information provides ongoing assurance that the licensing basis for the design and operation of all nuclear power plants provides an acceptable level of safety. This process continues for plants that receive renewed licenses.

A licensee may also request changes to the current licensing basis for a plant. Such changes are subject to NRC's regulatory controls on changes (e.g., 10 CFR 50.54, 50.59, 50.90, and 50.92). These regulatory controls ensure that there is a documented basis for licensee-initiated changes to the plant licensing basis and that NRC review and approval is obtained before implementation if a change to the licensing basis raises safety questions. The plant FSAR is periodically updated to reflect changes to the licensing basis.

NRC meets the objectives of periodic safety reviews through strict regulatory controls on proposed design changes after issuance of the initial operating license and the ongoing NRC regulatory activities that impose new requirements needed to maintain safety.

A plant's FSAR is not static. It is periodically updated to reflect changes to the licensing basis. NRC regulation 10 CFR 50.71(e) requires that updates be submitted annually or within 6 months of each refueling outage provided that the interval between successive updates does not exceed 24 months. The updates must include the effects of all changes made to the facility or procedures described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that the changes did not require a license amendment; and all analyses of new safety issues performed by or on behalf of the licensee at the NRC's request.

The NRC is aware of the recommendations of the IAEA safety guide on performing periodic safety reviews for operational nuclear power plants. However, NRC has strict regulatory controls on design changes proposed after issuance of the initial operating license, and NRC's ongoing regulatory activities impose new requirements needed to maintain safety. NRC therefore achieves the objectives of a periodic safety review on a continuing basis.

Question Number: 14.03

Question: 1) Are there any requirements to prefer either conservative methods or best-estimate methods for safety demonstration?

2) Is the quantification of uncertainties mandatory when applying best-estimate methods?

Answer: 1) Traditionally, conservative analyses have been performed, but NRC current regulations are ambivalent about whether a licensee used a conservative or a best-estimate methodology as long as the requirements for the chosen methodology are met. With regard to LOCA analyses, for example, both 10 CFR 50.46 and Appendix K to Part 50 make it clear that either approach is acceptable.

2) Yes. This is explicitly stated in 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-water Nuclear Power Reactors."

Question Number: 14.04

Question: 1) Under which conditions does the necessity arise to perform an update of safety analyses?

2) Do such analyses consider e.g. new site evaluation aspects, new evaluation according to the state of the art in science and technology of the original earthquake design, of the design against external impacts (e.g. extreme weather conditions, high tides, aircraft crash etc.), consideration of low power and shutdown conditions, fuel management with increased burn-up, increased enrichment and other such aspects?

Answer: 1) Safety analyses are updated when the licensee makes a change to the plant design or operation or when significant changes are made to or errors are discovered and corrected in the models used to perform analyses for loss of coolant accidents required by 10 CFR 50.46. Usually the change is a physical change to the plant, such as the replacement of a pump or a steam generator in a pressurized-water reactor or the use of a new fuel design. Recently, licensees have voluntarily performed reanalyses using state-of-the-art methods to gain additional margin and uprate power.

2) Yes, the analyses include such considerations if they are relevant to the plant under review. Licensees are not required to analyze new design features that were not considered in the original licensing design basis.

Question Number: 14.05

Question: 1) 10CFR 50.71 requires periodic updating of FSAR. Please provide information about the maximum time interval for each updating.

2) Is updating only needed if the licensee intends to perform plant modifications?

Answer: 1) As required by 10 CFR 50.71(e)(4), licensees are required to submit a periodic FSAR update annually, or within 6 months of each refueling outage, provided the interval between successive updates does not exceed 24 months. Licensees may request an exemption from this requirement from the NRC. The NRC has granted exemptions allowing licensees to submit a single, combined periodic update for a multi-unit facility.

2) No. Updating is required per the schedule described above even for power reactors that have permanently ceased operation. Regulatory Guide 1.181, issued in September 1999, endorses NEI 98-03, "Guidelines for Updating Final Safety Analysis Reports," dated June 1999. This guidance document states that a licensee must evaluate new regulatory requirements, changes to the facility or procedures, and new safety issues to determine whether to include them in the FSAR. If no FSAR changes have been made, the update submittal can so state.

Question Number: 14.06

Question: 1) Almost all licensees in the U.S.A. are expected to seek renewal of their licences in the future, if they have not already received renewed licenses up to now. Do applicants for renewed licences find themselves faced with higher demands concerning selected safety issues compared to the first license because of the further development of safety regulations particularly in connection with future NPPs?

2) If yes, which are typical issues?

Answer: NRC relies on its regulatory process rather than periodic safety reviews to oversee nuclear power plants and upgrade requirements as they are determined necessary. When issuing the original operating license, the NRC made a comprehensive determination that the design, construction, and proposed operation of the nuclear power plant satisfied NRC's requirements and provided reasonable assurance of adequate protection to the public health and safety. However, the licensing basis does not remain fixed but evolves throughout the term of the operating license in response to NRC regulatory activities of the licensee activities.

Considered together, NRC regulatory activities provide ongoing assurance that the licensing basis of nuclear power plants ensure an acceptable level of safety. NRC's activities include research, inspections (periodic regional inspections and daily oversight by the resident inspector), audits, investigations, evaluations of operating experience, and regulatory actions to resolve identified issues. NRC's activities may result in changes to the licensing basis for nuclear power plants through the promulgation of new or revised regulations, acceptance of licensee commitments to modify nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. NRC also issues documents such as bulletins, generic letters, regulatory information summaries, and information notices. Licensee commitments in response to these documents also change a plant's licensing basis. In this way, NRC's consideration of new information provides ongoing assurance that the licensing basis for the design and operation of all nuclear power plants provides an acceptable level of safety. This process continues for plants that receive renewed licenses.

A licensee may also request changes to the current licensing basis for a plant. Such changes are subject to NRC's regulatory controls on changes (e.g., 10 CFR 50.59, 50.90, and 50.92). These regulatory controls ensure that there is a documented basis for licensee-initiated changes to the plant licensing basis and that NRC review and approval is obtained before implementation if a change to the licensing basis raises safety questions. The plant FSAR is periodically updated to reflect changes to the licensing basis.

NRC meets the objectives of periodic safety reviews through strict regulatory controls on proposed design changes after issuance of the initial operating license and the ongoing NRC regulatory activities that impose new requirements needed to maintain safety.

Question Number: 14.07

Question: Has there been international participation of U.S.A. NPPs in safety assessments?

Answer: Yes. U.S. NRC staff and utility personnel participate in safety missions organized by the IAEA. For example, the U.S. participates in missions of Operational Safety Review Teams (OSARTs), International Probabilistic Safety Assessment Review Teams, International Regulatory Review Teams, and Assessment of Safety Significant Events Teams. Most recently, the North Anna nuclear power plant hosted an IAEA OSART mission (January-February 1999). This was the fourth mission in about 10 years to a U.S. plant.

U.S. utility and plant experts also participate in OSARTs sent to other Member States outside the U.S.

Question Number: 14.08

Question: The Report, Articles 6 and 14, states that safety assessments of nuclear installations are being performed throughout NPP lifetime to maintain the licensing basis. Three questions arise in this connection: Do they perform periodic [planned] in depth safety assessments of the operating nuclear installations, including those constructed to older designs?

Answer: NRC relies on its regulatory process rather than periodic safety reviews to oversee nuclear power plants and upgrade requirements as they are determined necessary. When issuing the original operating license, the NRC made a comprehensive determination that the design, construction, and proposed operation of the nuclear power plant satisfied NRC's requirements and provided reasonable assurance of adequate protection to the public health and safety. However, the licensing basis does not remain fixed but evolves throughout the term of the operating license in response to NRC regulatory activities of the licensee activities.

Considered together, NRC regulatory activities provide ongoing assurance that the licensing basis of nuclear power plants ensure an acceptable level of safety. NRC's activities include research, inspections (periodic regional inspections and daily oversight by the resident inspector), audits, investigations, evaluations of operating experience, and regulatory actions to resolve identified issues. NRC's activities may result in changes to the licensing basis for nuclear power plants through the promulgation of new or revised regulations, acceptance of licensee commitments to modify nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. NRC also issues documents such as bulletins, generic letters, regulatory information summaries, and information notices. Licensee commitments in response to these documents also change a plant's licensing basis. In this way, NRC's consideration of new information provides ongoing assurance that the licensing basis for the design and operation of all nuclear power plants provides an acceptable level of safety. This process continues for plants that receive renewed licenses.

A licensee may also request changes to the current licensing basis for a plant. Such changes are subject to NRC's regulatory controls on changes (e.g., 10 CFR 50.54, 50.59, 50.90, and 50.92). These regulatory controls ensure that there is a documented basis for licensee-initiated changes to the plant licensing basis and that NRC review and approval is obtained before implementation if a change to the licensing basis raises safety questions. The plant FSAR is periodically updated to reflect changes to the licensing basis.

NRC meets the objectives of periodic safety reviews through strict regulatory controls on proposed design changes after issuance of the initial operating license and the ongoing NRC regulatory activities that impose new requirements needed to maintain safety.

NRC has done an in-depth assessment of facilities constructed to older designs. In 1977 the NRC initiated the Systematic Evaluation Program to review the designs of older operating nuclear reactor plants and confirm and document their safety. The program evaluated licensees' compliance with current licensing requirements for certain safety issues, provided a basis for resolving the discrepancies in an integrated plant review, and documented the evaluation of plant safety.

Question Number: 14.09

Question: Which older plants were covered by the in depth safety assessments?

Answer: Eleven older plants were reviewed under the Systematic Evaluation Program: Palisades, Ginna, Oyster Creek, Dresden 2, Millstone 1, Yankee Rowe, Haddam Neck, La Crosse, Big Rock Point, San Onofre 1, and Dresden 1.

Question Number: 14.10

Question: What is the frequency of the planned safety assessments of the operating nuclear installations during their lifetime?

Answer: The NRC relies on its regulatory process to provide continuous oversight of nuclear power plants and upgrading of requirements as they are determined necessary rather than utilize periodic safety reviews.

Question Number: 14.11

Question: It is not directly stated but is obvious from the text that regulatory requirements regarding quantitative safety criteria (PSA CDF and LRF frequencies.) remain the same in life extension (license renewal). Does this mean that also the relevant requirements for new NPPs are the same as for present NPPs?

Answer: The CDF and large early release frequency values were developed to support the NRC Safety Goals and are the same for new and current facilities. However, these values are not used directly as quantitative safety criteria. Consistent with the Commission's Severe Accident Policy Statement, the NRC expects new reactor designs to achieve a higher level of safety for certain technical and severe accident issues than currently operating nuclear power plants.

NRC reviews applications for approval or certification of new designs in accordance with10 CFR Part 52. The NRC staff uses the review guidance in the Standard Review Plan (NUREG-0800) to determine if the design meets the applicable regulations, regulatory guidance, and industry codes and standards. NRC also requires applicants to demonstrate by testing and/or analysis that new design features will perform their intended functions.

For new designs, such as the pebble bed modular reactor, the NRC conducts pre-application reviews to identify potential safety issues that need to be addressed in the license application. In some cases, NRC conducts confirmatory research to reach independent conclusions on safety issues. The NRC does a detailed and comprehensive assessment of new designs to ensure that appropriate safety margins are established and maintained.

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.

Questions and answers pertaining to this section follow below.

Question Number: 15.01

Question: The "Standards for Protection against Radiation" states in the third paragraph on page 15.4 that there is provision for "planned special exposures". Does the License Holder have to submit details of the dose rates in areas in which such "planned special exposure" would be required for NRC consideration and approval, prior to access of any workers?

Answer: No. But licensees are required to keep employees' lifetime dose records. When an employee receives the planned special exposure, the licensee must submit records to the NRC within 3 days. 10 CFR Part 20 specifies the types of records that must be submitted.

Question Number: 15.02

Question: Is the effect of releases from nuclear facilities under normal operation evaluated as regard the exposure to critical groups of population in their vicinity? If so, specify the models used and how they reflect changes of the actual weather situation throughout the year.

Answer: The NRC developed a specific methodology for licensees to calculate the maximum dose received by any individual, not the "critical group," from the radioactive gaseous and liquid effluents released from nuclear power plants. The methodology is described in Regulatory Guide 1.109, "Calculation of Annual Doses to Man From Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I." This dose calculational methodology is based on the ICRP-2 methodology. For calculating dose from routine radioactive effluents, the NRC continues to use the whole-body and critical-organ concept of International Commission on Radiological Protection (ICRP-2). Licensees are required to use either actual meteorological data or conservative values based on historical meteorological data.

Question Number: 15.03

Question: Could the United States of America explain how the principle expressed page 10-3 (the risk of fatalities from cancer to the population in the area near a NPP that might result from NPP operation should not exceed one tenth of one percent of the sum of cancer fatality risks resulting from all other causes) is combined with the various limits mentioned in chapter 15.

Answer: The requirements for keeping radiation exposures as low as reasonably achievable (ALARA) are based on a linear, no-threshold model for predicting cancer risk from radiation exposure. The requirements assume that no level of radiation exposure is absolutely safe and impose strict limits on liquid effluents, airborne effluents, and dose to keep public exposures well below the local range in doses from natural sources. The limits are consistent with the agency's safety goal that the risk of fatalities from cancer to the population in the area near a nuclear power plant as a result of plant operation should not exceed 0.1 percent of the sum of cancer fatality risk from all other causes. It should be noted that the principles regarding health risks are a reflection of broad Commission policy guidance, and do not reflect regulatory requirements.

Question Number: 15.04

Question: It is reported that NRC may consider and elect to implement a new international standard (e.g., ICRP-60). Could you explain what will be your schedule to implement ICRP-60 to your regulatory systems?

Answer: NRC currently complies with ICRP-26, and will consider adopting ICRP-60 after the planned revision of the standard in 2005.

Question Number: 15.05

Question: The Summary Report of first review meeting welcomes contracting parties to evolve the trends in collective doses and effluent releases in[this] report. Could you suggest any reports that show us these trends in recent years?

Answer: For occupational doses, see NUREG-0713, Vol. 22, "Occupational Radiation Exposure at Commercial Nuclear Power Plants and Other Facilities," (33rd annual report), September 2001.

Question Number: 15.06

Question: It is reported that the regulation 10CFR 50 Appendix I suggests $10,000 per person-Sv (maybe not $10 in the report) as a figure of merit for ALARA requirement. What concept and quantitative assessment were discussed to deduce this figure?

Answer: $10 is a misprint. Appendix I to 10 CFR Part 50, was issued in the 1970s. The "$1000 per total body man-rem" estimate was considered a best estimate at the time. Part 50 states that the ALARA dose criteria were adopted as an interim measure until better values or criteria could be developed. The Commission believed that operational experience would provide sufficient data to calculate a better value. However, the power reactor industry quickly complied with the ALARA criteria and even reduced doses below Appendix I limits. As a result, NRC has not revised the Appendix I criteria for the current nuclear power reactors. The NRC is considering a revision to Appendix I that would apply to future nuclear power reactors.

Question Number: 15.07

Question: 1) ALARA and Adequate Level of Safety - In Europe there is a tendency that deregulation of the electricity market can lead to a decrease in utility initiatives to further reduce risk, while the general safety philosophy of the regulatory bodies in Europe more or less require a risk reduction to a level which is as low as reasonably practicable (ALARP). Is the fact that in the USA reversed ALARA/ALARP is allowed (allowing small risk increases in some situations and under strict conditions) a factor that deregulation is a lesser issue? Especially, when compared with countries where reversed ALARA/ALARP is not, or only partially, allowed.

2) What is the meaning of ALARA in situations where an 'Adequate Level of Safety' is reached?

3) Is ALARA still a driving principle to decrease the risks to even lower scales?

Answer: 1) The NRC Safety Goal Policy Statement defines "how safe is safe enough," that is, what is reasonably practicable or reasonably achievable, in terms of the health impacts on the population in the area near a nuclear power plant. Subsidiary objectives expressed in terms of CDF and LERF have also been established. NRC Regulatory Guide 1.174 describes acceptance guidelines for assessing the impact of proposed licensing basis changes on the basis of engineering issues and risk insights using CDF and LERF as benchmarks. These acceptance guidelines are consistent with the policy statement. So far, NRC has seen no evidence that deregulation affects ALARA. The industry currently spends as much as in the past on keeping doses ALARA. Nonetheless, the NRC continues to monitor the industry as deregulation proceeds to ensure that safety is not impacted by economic considerations.

2) Several licensees have said that they have no threshold for stopping efforts to keep doses ALARA. If a decision is questionable, licensee may do a cost-benefit analysis. Licensees know that saving doses saves money.

3) ALARA is still a driving principle. The original value of the achievable dose for pressurized-water reactors in the U.S. was 100 person-rem/year/plant. The new goal is 65 person-rem/year/plant. Licensees are striving for lower levels.

Question Number: 15.08

Question: 10CFR Part 20, Subpart C, "Occupational Dose Limits"..establishes annual dose limits for adults of 0.05 Sv (5 rem),....Please specify, what is the percentage of workers who received higher doses than the limit prescribed with the IAEA Basic Safety Standards (i.e. 20 mSv per year).

Answer: In the year 2000, 99.5 percent of individuals received total doses less than 2 rem (20 mSv per year). This data is based on Table 3.3 "Summary of Annual Dose Distributions for Certain NRC Licensees, 1968-2000" in NUREG-0713, Vol. 22, "Occupational Radiation Exposure at Commercial Nuclear Power Plants and Other Facilities". (33rd annual report), September 2001.

Question Number: 15.09

Question: What specific procedures, operational controls and safety features do licensees adopt to ensure that doses are ALARA?

Answer: The procedures, operational controls, and safety features are specified in Regulatory Guide 8.8, Revision 3, "Information Relative to Ensuring That Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable," June 1978. Technological advances in remote monitoring, teledosimetry, and remote cameras over the years have helped licensees reduce occupational dose.

Other useful documents on procedures, operational controls, and safety features are the Proceedings of the 2002 International ALARA Symposium, February 17-20, 2002, Orlando, Florida; "Occupational Exposures at Nuclear Power Plants, 10th Annual Report of the ISO Program, 2000," NEA, Paris 2000; and "Work Management in the Nuclear Power Industry," NEA, Paris, 1997.

Question Number: 15.10

Question: In the absence of numerical ALARA criteria for occupationally exposed persons, how does NRC judge the extent to which doses to those people are ALARA?

Answer: All licensees review jobs with estimated collective doses of 1 person-rem or greater. As part of its baseline inspection program under the ROP, the NRC evaluates whether a licensee meets its planned dose estimate for a given job. If a licensee exceeds planned dose estimates, NRC evaluates the licensee more closely, and takes regulatory action if warranted.

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) responsibilities of the plant operator, state, and local governments; (5) emergency response centers; (6) recommendations for protection in severe accidents; (7) inspection practices and regulatory oversight; (8) the Federal response; and (9) international arrangements.

Questions and answers pertaining to this section follow below.

Question Number: 16.01

Question: Is the emergency planning zone in the vicinity of nuclear power plants specified as a special area with predefined actions for a severe (beyond design basis) accident? If so, what criteria are used to define this emergency planning zone?

Answer: The emergency planning zone is not specified as a special area for a severe (beyond design basis) accident. With regard to "predefined actions," NRC and the U.S. Federal Emergency Management Agency (FEMA) added Supplement 3 to NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," to provide updated guidance for use in developing protective action recommendations for severe reactor accidents involving actual or projected core damage with the potential for loss of containment. That guidance is founded on extensive studies of severe accidents, which clearly indicate that for all but a very limited set of conditions, the preferred initial action to protect the public from a severe reactor accident is to immediately evacuate about 2 miles in all directions from the plant and about 5 miles downwind from the plant, barring any constraints to evacuation. However, sheltering may be the appropriate protective action for controlled releases of radioactive material from the containment if there is assurance that the release is short term (puff release) and the area near the plant cannot be evacuated before the plume arrives. Persons in the remainder of the 10-mile plume exposure pathway emergency preparedness zone should be directed indoors and instructed to listen to the designated Emergency Alert Stations (e.g., radio,television) while the situation is further assessed.

Question Number: 16.02

Question: Is the public living in the vicinity of a nuclear plant informed on the protective actions included in the emergency plans?

Answer: NRC requires each nuclear power plant licensee to provide information (at least annually) to the public living within the 10-mile plume exposure pathway emergency preparedness zone. At a minimum, this information must include how the public will be notified if a plant event should occur; what actions they should take during the emergency; educational information on radiation; the name, address, and phone number of the contact person or organization who can provide additional information; protective measures such as evacuation routes and relocation centers, methods of sheltering, respiratory protection, and/or radioprotective drugs; and special accommodations for the handicapped. Licensees may distribute this information in phone books, utility bills, and/or annual publications such as calendars or other mailings. Licensees must also make information available to the transient population (visitors) within the 10-mile plume exposure emergency preparedness zone through the use of signs, decals, or other notices posted in hotels, motels, gasoline stations, phone booths, and other public facilities. Such information should refer the transient population to the primary source of emergency information (e.g., phone book) and guide them to appropriate radio and television stations. Additionally, each nuclear power plant licensee shall coordinate annual programs to acquaint the local news media with emergency plans, information regarding radiation, and points of contact for release of public information in an emergency.

Question Number: 16.03

Question: Has the final FDA guidance on potassium iodide prophylaxis been issued? Which are the major proposals of this guidance?

Answer: The U.S. Food and Drug Administration (FDA) issued its final guidance on potassium iodide in December 2001. As of the publication date of these NRC responses, the FDA guidance document is accessible on the Internet at:

http://www.fda.gov/cder/guidance/4825fnl.pdf

The major "proposals" of the guidance relate to the recommended potassium iodide doses for different risk groups. The FDA recommended specified doses on the basis of the previous guidance after incorporating the rationale derived from the data collected in the wake of the Chernobyl accident.

Question Number: 16.04

Question: Does the U.S.A. now fully participate in the INES (international nuclear event scale) programme?

Answer: In May 2001, NRC reevaluated its level of participation in the INES and concluded that full participation is appropriate. Since that time, the NRC staff has been developing internal policies and procedures to incorporate full INES participation into existing work processes. NRC intends to complete all activities (including training staff members in the rating methodology) necessary to implement full INES participation by May 2002.

Question Number: 16.05

Question: As a condition of licensing, the submission of the radiological emergency response plans of State and local governments are requested to applicant. Since the State and local government emergency response plan for the outside site are to be provided by State and local governments, these plans are out of control of applicant and licensee. What is the purpose and/or background of this regulatory requirement?

Answer: The objective of a nuclear power plant's emergency response plan is to protect the health and safety of the public. To fulfill this objective, the regulations require, in part, that licensees coordinate their plans with those of the relevant State and local agencies. The guidance provided by FEMA recommends that State and local governments formalize their emergency response plans in support of those developed by nuclear power plants. Nonetheless, NRC (rather than FEMA) confers an operating license upon the licensee (not upon the State and local agencies). As such, even though the State and local plans are not directly controlled by the licensee, the licensee is responsible for ensuring adequate protection of public health and safety. In other words, NRC imposes the license condition upon the licensee, but the State and local agencies forward their plans to FEMA for review. If deemed acceptable by FEMA, NRC will accept the State and local plans through a memorandum of understanding which formally establishes the relationship between FEMA's review and the NRC's requirements.

Question Number: 16.06

Question: As was mentioned in the paragraph next to the bottom in Chapter 16.8, the evacuation is one of the two primary protective actions and it is important to evacuate the population near a plant in a severe accident promptly. What is the applicable and/or acceptable method and tool for the evacuation time estimate?

Answer: The analysis used to estimate the evacuation time is an emergency planning tool that can be used to assess, in an organized and systematic fashion, the feasibility of developing emergency plans for a site. Guidance on performing the analysis is given in Appendix 4 to NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants." Additional guidance on performing the analysis is given in NUREG/CR-4831, "State-of-the-Art in EvacuationTime Estimate Studies for Nuclear Power Plants."

Question Number: 16.07

Question: For the effective control of the performance indicator for Drill and Exercise Performance as was referred in the last paragraph in page 16-8, Chapter 16.9, the appropriateness of the exercise scenario would be considered as one of key elements. Who is leading the development of the exercise scenario and what is the role of the NRC in this? Is there an approval procedure and/or a guideline for the development of the scenario?

Answer: As stated in 10 CFR 50.47(b)(14), "Periodic exercises are (will be) conducted to evaluate major portions of emergency response capabilities, periodic drills are (will be) conducted to develop and maintain key skills..." Licensees develop these exercises and drills, in accordance with the requirements in Section IV.F.2 of Appendix E to 10 CFR Part 50. Guidance regarding the types, content, and frequency of exercises and drills is contained in Section II.N, "Exercises and Drills," of NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants." The NRC's focus is to evaluate the licensee's self-critique of the Emergency Response Organization performance. In conducting this evaluation, NRC emphasizes the licensee's assessment of the activities by the Emergency Response Organization to develop classification, notification and protective action recommendations. NRC reviews a scenario (typically 30 days before the exercise date) to determine whether the scenario constitutes a sufficient test of the plan as defined by Section IV.F.2 of Appendix E to 10 CFR Part 50. NRC also reviews previously used scenarios to ensure that the currently proposed scenario is sufficiently different from those previously used. NRC inspection guidance is provided in NRC Inspection Manual procedure IP71114.01, "Exercise Evaluation."

Question Number: 16.08

Question: What is the recent policy on distribution of potassium iodide for in case of emergency?

Answer: 10 CFR 50.47(b)(10) directs that a range of protective actions are developed for the plume exposure pathway emergency preparedness zone for emergency workers and the public. The recent change to this regulation adds that in developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide, as appropriate. Thus, even though it is up to the offsite agencies to give consideration to the use of potassium iodide, it is the obligation of the licensees to confirm that this consideration has been made. Additionally, it requires the licensees to use this information in developing protective action recommendations for offsite agencies. The NRC is providing funding for a supply of potassium iodide for states that choose to incorporate it into their emergency plans.

Question Number: 16.09

Question: What are the specific measures adopted to inform to the population and to the competent authorities of the surrounding States about the emergency plans of the nuclear installations?

Answer: NRC requires each nuclear power plant licensee to provide information (at least annually) to the public living within the 10-mile plume exposure pathway emergency preparedness zone. At a minimum, this information must include how the public will be notified if a plant event should occur; what actions they should take during the emergency; educational information on radiation; the name, address, and phone number of the contact person or organization who can provide additional information; protective measures such as evacuation routes and relocation centers, methods of sheltering, respiratory protection, and/or radioprotective drugs; and special accommodations for the handicapped. Licensees may distribute this information in phone books, utility bills, and/or annual publications such as calendars or other mailings. Licensees must also make information available to the transient population (visitors) within the 10-mile plume exposure emergency preparedness zone through the use of signs, decals, or other notices posted in hotels, motels, gasoline stations, phone booths, and other public facilities. Such information should refer the transient population to the primary source of emergency information (e.g., phone book) and guide them to appropriate radio and television stations. Additionally, each nuclear power plant licensee shall coordinate annual programs to acquaint the local news media with emergency plans, information regarding radiation, and points of contact for release of public information in an emergency.

The competent authorities of the surrounding States (i.e., those within the 10-mile plume exposure pathway emergency preparedness zone and 50-mile ingestion pathway emergency preparedness zone), are informed through their participation in exercises. NRC requires licensees to coordinate with State and local agencies in conducting full participation exercises, which test as much of the licensee, State and local emergency plans as is reasonably achievable, without mandatory public participation. Additionally, each licensee must obtain State and local approval before making a proposed change to an Emergency Action Level (those levels at which predetermined actions are taken). Also, licensees are required to review the Emergency Action Levels on an annual basis with the State and local agencies. These measures enable State and local authorities to remain cognizant of the licensee's current assessment actions, so that they can ensure that their offsite plans are current.

Question Number: 16.10

Question: What is the required schedule for emergency drills and exercises in the US?

Answer: NRC requires licensees to coordinate with State and local agencies in conducting biennial full participation exercises, which test as much of the licensee, State and local emergency plans as is reasonably achievable, without mandatory public participation. A full-participation exercise means, along with onsite licensee personnel, appropriate offsite State and local authorities and licensee personnel physically and actively take part in testing their emergency plans and their integrated capability to adequately assess and respond to a nuclear power plant accident. Licensees must conduct the exercise within 2 years before the issuance of the first license for full power (>5% power) operation, and must include participation by each State and local government within the 10-mile plume exposure pathway emergency preparedness zone and each State within the 50-mile ingestion exposure pathway emergency preparedness zone. Subsequently, each licensee at each site shall conduct an exercise of its onsite emergency plan every 2 years. These exercises may be included in the full-participation biennial exercise. In addition, each licensee must conduct drills and take whatever other actions are necessary to ensure that adequate emergency response capabilities are maintained during the interval between biennial exercises. At least one such drill must involve a representative combination of the major elements of the licensee's emergency response capabilities; however, such drills need not activate all of the licensee's emergency response facilities. Such drills may focus on onsite training objectives.

Offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the plan. Where the offsite authority has a role under a radiological response plan for more than one site, it shall fully participate in one exercise every 2 years and shall, at least, partially participate in other offsite plan exercises in this period. Partial participation means that offsite authorities shall participate in the exercise sufficiently to test direction and control functions, including (a) protective action levels and (b) capabilities for communication among affected State and local authorities and the licensee. A State should fully participate in the ingestion pathway portion of such exercises at least once every 6 years.

ARTICLE 17. SITING

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

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

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

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

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

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

Questions and answers pertaining to this section follow below.

Question Number: 17.01

Question: While deciding the siting and/or construction of nuclear facilities, are the acceptance criteria for exposure to members of the critical group of population at emergencies (up to design basis accident) identical to dose limits for members of the public at normal operation? If different, provide specification.

Answer: The role of dose guidelines for siting nuclear power reactors has evolved over time, as discussed in greater detail below. However, the siting dose guidelines differ from both the dose criteria that are considered for normal operations and those specified in the protective action guidelines (PAGs) in the event of an accident.

For normal nuclear power operations, the dose to any individual member of the public must not exceed the maximum limit of 0.25 mSv (25 mrem) specified by the EPA standard (see also 40 CFR Part 190 "Environmental Radiation Protection Standards for Nuclear Power Operations") and the maximum limits of 1 mSv (100 mrem) in a year specified by 10 CFR Part 20. The maximum dose rate in any unrestricted area (see also Article 15) is 0.02 mSv (2 mrem) in any hour. (See also Article 15) By contrast, the PAGs are intended to provide dose savings in the case of an accident. As discussed in Article 16, a PAG is the projected dose from an unplanned release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. PAGs do not generally include the dose already incurred prior to the initiation of protective actions; rather, they focus on the protective action to avoid subsequent doses.

The EPA published its recommended protective actions, linked to the projected dose in 1980 and again in 1991 in "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" (most recently, EPA 400-R-92-001, October 1991). The 1980 version was based on the external gamma dose to the whole body from plume exposure and the committed dose to the thyroid from inhalation. The 1991 version was based on the whole body dose comprising the sum of the effective dose equivalent resulting from external exposure to the plume and the effective dose equivalent from inhalation.

For a projected dose to the public below 1 rem to the whole body and below 5 rem to the thyroid, the 1980 version recommended no planned protective actions; however it specified that a State may issue an advisory to have the public seek shelter and await further instructions while the State monitors environmental radiation levels. For a projected dose to the public of 1 to 5 rem to the whole body and 5 to 25 rem to the thyroid, the 1980 version recommended that the State consider evacuation (evacuate unless constraints make it impractical), monitor environmental radiation levels, control access, and (at a minimum) advise the public to seek shelter. For a projected dose to the public of above 5 rem to the whole body or 25 rem to the thyroid, the 1980 version recommended that the State conduct a mandatory evacuation (adjusting the evacuation area consistent with the dose level), monitor environmental radiation, and control access.

For nuclear power reactor accidents, the change from the 1980 PAGs to the 1991 PAGs generally has little impact on protective action decisions because the thyroid dose is the controlling factor and the PAG levels for the projected thyroid dose did not change. For a projected effective dose equivalent to the public of 1 to 5 rem resulting from exposure to external sources and the committed effective dose equivalent incurred from all significant inhalation pathways, the 1991 version recommends evacuation (unless sheltering provides protection equal to or greater than evacuation). For a projected committed effective dose to the thyroid from radioiodine to the public greater than 25 rem, the 1991 version recommends administering stable iodine, which requires the approval of State medical officials.

With respect to siting, NRC evaluates radiological consequences that a hypothetical individual might be expected to sustain as a result of a hypothetical design-basis accident under conservative conditions (i.e., poor atmospheric dilution). Compared to the current era, the design-basis accident analysis had greater relevance during the 1960s, in terms of providing insight on the types of exposures that could result from a nuclear power reactor. The NRC's defense-in-depth philosophy encompasses the regulatory framework of 10 CFR Part 100 (described in Article 17), the assessment of radiological consequences from postulated accidents to hypothetical individuals at the exclusion area boundary and in the low population zone, and remote siting. Since the mid-1970s, the United States has used this approach to identify sites with large tracts of undeveloped areas away from urban centers, thereby achieving the desired outcome of remote siting.

For siting purposes, the NRC examines postulated accidents to establish the design and performance characteristics of the reactor. Dose guidelines for siting purposes do not refer to real exposures; rather, they are used to assess the efficacy of the design. More specifically, the exclusion area boundary and the low population zone are the two important locations where dose guidelines are applied. The exclusion area boundary is that area surrounding the reactor where the license holder has the direct authority (either through ownership or binding arrangements) to determine all activities (including exclusion or removal of personnel and property). The low population zone is the inhabited area immediately surrounding the exclusion area where there is a reasonable probability that appropriate protective measures could be taken in their behalf in the event of a serious accident.

The dose guidelines that NRC used for the initial licensing of all existing nuclear power reactors are that (1) the total radiation dose to the whole body will not exceed 0.25 Sv (25 rem) and (2) the total radiation dose to the thyroid (from iodine) will not exceed 3 Sv (300 rem). These guidelines were considered at the exclusion area boundary for the first 2 hours after a postulated major accident because the source term decreases monotonically and in the low population zone for the first 30 days.

By contrast, the dose guideline that NRC will use for all future nuclear power reactor licensing is 0.25 Sv (25 rem) total effective dose equivalent. This guideline will be considered at the exclusion area boundary for the two-hour period that could result in the highest estimated dose because after a postulated major accident the alternate source term fluctuates as a function of time and in the low population zone for the first 30 days. This dose guideline is not an "acceptable dose," but rather is a reference value that NRC can use to evaluate design features with respect to postulated reactor accidents, in order to ensure that such designs provide reasonable assurance that accidents will not pose a significant risk of prompt fatalities.

Question Number: 17.02

Question: Is the probability and acceptability of a particular (accident) scenario used as prerequisite to determine the design basis accident? If so, what probabilities are considered?

Answer: For future power reactor licensing, NRC has established a regulatory framework in Subpart B of 10 CFR Part 100, "Reactor Site Criteria," as discussed in Article 17. Since the early 1960s and continuing through the 1997 rule change that introduced more realistic insights into the evaluation of the consequences of postulated accidents, the in-containment accident source term has been the result of a stylized set of assumptions. Consequently, PRAs contributed to the insights that have shaped the bases for the development of the design basis accident and, as discussed in Article 10, NRC has established safety goals that have certain quantitative safety objectives. However, there is no specific probability or acceptability of a particular scenario that serves as a reference value.

As noted in the 1962 reactor site criteria rule in 10 CFR 100.11 and again in the 1997 rule in 10 CFR 50.34, the fission product release should be based upon a hypothetical major accident that is postulated from possible accidental events. To support the earlier version of the rule, the

Atomic Energy Commission provided guidance on the source term in some of its earliest Safety Guides (see Regulatory Guides 1.3 and 1.4, Assumptions Used for Evaluating the Potential Radiological Consequences of a LOCA for Boiling-and Pressurized-Water Reactors, respectively).

For future site and design approvals for light-water reactors, the current guidance for the development of the design-basis accident source term is provided in NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," and Regulatory Guide 1.183, "Alternative Radiological Source Terms for Evaluating Design-Basis Accidents at Nuclear Power Plants." These reflect risk insights from the body of work since the Three-Mile Island accident, including NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants." In general, the release stages (coolant, gap, early in-vessel, ex-vessel, and late in-vessel), release fractions and timing of the releases described in these documents were intended to be representative, rather than bounding values, for low-pressure core melt accidents. For the purposes of calculating the consequences of a design-basis accident, NRC considers only the coolant, gap, and early in-vessel stages of the severe accidents described in NUREG-1465. Since the completion of the NRC Reactor Safety Study (see WASH-1400), further progress in developing PRA and in accumulating relevant data has led to a recognition that it is feasible to begin using quantitative safety objectives for limited purposes. However, sizable uncertainties still remain in the methods and the data base lacks essential elements that are needed to gauge whether the objectives have been achieved. Consequently, the quantitative objectives should be viewed as target points or numerical benchmarks of performance. In particular, because of the present limitations in the state of the art of quantitatively estimating risks, the objectives for quantitative health effects are not a substitute for existing regulations.

The United States recognizes the importance of mitigating the consequences of a core-melt accident and continues to emphasize features such as containment, siting in less populated areas, and emergency planning as integral parts of the defense-in-depth concept associated with its accident prevention and mitigation philosophy.

Question Number: 17.03

Question: 1) The NUREG 1465 document defines a source term based on the fission product release following a representative core melt accident. Could United States of America give more information on the assumptions used to evaluate the source terms defined in Regulatory guide 1.183, "Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Plants" (July 2000)?

2) Is a core melting postulated?

Answer: 1) The source terms in Tables 1 and 2 of Regulatory Guide 1.183 were taken from the corresponding Tables 3.12 and 3.13 of NUREG-1465. The basis for Tables 3.12 and 3.13 are described in NUREG-1465 and the numerous documents listed in its bibliography. Briefly summarized, the NUREG-1465 source terms were based on an extensive series of evaluations of various risk-significant severe accident sequences to obtain a source term that is believed to be appropriately conservative in the evaluation of design-basis LOCAs. All four release phases are considered, as appropriate, in assessments of severe accidents. However, the United

States has determined that the probability of the occurrence of the precursors to ex-vessel and late in-vessel releases are sufficiently low for the releases not to be considered in design-basis LOCA analyses.

The source terms in Tables 1 and 2 of Regulatory Guide 1.183 reflect events that affect the entire core. Table 3 of Regulatory Guide 1.183 provides gap release fractions for use in analyzing events that do not result in core melting. These design-basis events involve the release of the gap inventory of a relatively small number of fuel pins. Since the gap inventory strongly depends on local neutron flux and heat flux, the gap inventory of the maximum number of fuel pins will be greater than that provided for the gap release associated with a LOCA. The values in Table 3 were established through expert judgment guided by information in the open literature.

In addition to Regulatory Guide 1.183, NRC has provided other guidance on accident analysis tools. Examples of these tools are the HABIT computer model described in NUREG/CR-6210, "Computer Codes for the Evaluation of Control Room Habitability (HABIT V1.1)," by Pacific Northwest Laboratory, dated October 1998, and the RADTRAD computer model described in NUREG/CR-6604, "RADTRAD, a Simplified Model for Radionuclide Transport and Removal and Dose Estimation," by Sandia National Laboratory, dated April 1998.

2) In the United States, applicants and licensees are required by 10 CFR 50.46 to evaluate a spectrum of LOCA events to ensure that the performance of the emergency core cooling systems is adequate to prevent fuel clad perforation and the release of substantial quantities of fission products. The radiological consequences of the most limiting LOCA are then evaluated to assess the performance of the containment systems and release mitigation systems. Although a design-basis LOCA would not result in substantial core damage, in the interest of defense-in-depth, applicants and licensees are required to assume a substantial release of fission products from possible accidental events that would result in potential hazards not exceeded by those from any accident considered credible, including substantial meltdown of the core.

For various non-LOCA design-basis events, core melt and/or fuel clad perforation is postulated only if thermal-hydraulic analyses indicate that it may occur. Generally, a small amount of localized core melt is postulated for reactivity insertion accidents. For the remainder of the non-LOCA design-basis events, fuel damage, if it occurs at all, is limited to fuel clad perforation. For many non-LOCA events, only the radioactive material suspended in the reactor coolant from fuel clad leakage during normal operations is released.

Question Number: 17.04

Question: Could the United States of America indicate if it is required that the utilities reassess their design earthquake by using the Regulatory Guide 1.165, "Identification and characterization of seismic sources and determination of Safe Shutdown Earthquake Ground Motion?

Answer: Existing license holders are not required to reassess their design bases as a direct result of the change to10 CFR Part 100, "Reactor Site Criteria," which NRC implemented in

1997. Notably, as discussed in Article 17, NRC left in place the Part 100 framework that existed since the early 1960s to preserve the structure for license holders to make changes to their current licensing bases. The rule change that introduced 10 CFR 100.23 is for prospective applicants seeking a site approval for a new construction permit, an early site permit, or a combined license, and Regulatory Guide 1.165 provides guidance to applicants on acceptable approaches to comply with requirements.

Question Number: 17.05

Question: What kind of site-related factors are re-evaluated for the license renewal?

Answer: The generic evaluation contained in NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," assesses the scope and impact of environmental effects that would be associated with license renewal at any nuclear power plant site in the United States. For certain issues, the staff concluded in NUREG-1437 that the impacts were small for all plants. The staff looks for new and significant information related to these issues, but does not otherwise perform a plant-specific review. For any of the remaining 23 issues that apply to a given plant, the NRC's regulations in 10 CFR 51.95(c) require preparation of a site-specific environmental impact statement, which is a supplement to NUREG-1437, in connection with the renewal of an operating license. Issues requiring site-specific evaluation are identified in 10 CFR Part 51, Table B-1 of Subpart A, Appendix B, as Category 2 and include ground water use, entrainment and impingement of fish and shellfish (once-through cooling systems), heat shock (once-through cooling systems), threatened or endangered species, refurbishment impacts on terrestrial resources, historic and archaeological resources, and severe accidents, among others.

Question Number: 17.06

Question: Based on the regulation of 10 CFR Part 100 "Population center distance", let me know if there is any total integrated population dose limits to evaluate a proposed site in USA. If any, please provide total integrated population dose limits and the background of selecting that value of limits.

Answer: The United States does not use a specific total integrated population dose limit in siting nuclear power plants, although it is an element in determining the acceptability of a site where very large cities are involved. Remote siting, that is, siting nuclear power plants away from population centers, is one of the underlying philosophies for considering new facilities in the United States. However, this philosophy recognizes that the load center may very well be the beneficiary of the new power supply, and line losses over long distances from remote sites may jeopardize the economic viability of the proposal. The NRC's defense-in-depth philosophy encompasses the regulatory framework of 10 CFR Part 100 (described in Article 17 of the U.S. National Report), the assessment of radiological consequences from postulated accidents to hypothetical individuals at the exclusion area boundary and in the low population zone, and remote siting. Since the mid-1970s, the United States has used this approach to identify sites with large tracts of undeveloped areas away from urban centers. In the intervening years, however, urban sprawl and suburban development resulted in population increases around nuclear power plants. This issue is considered in the development and maintenance of emergency planning for operating nuclear power reactors (as described in Article 16 of the U.S. National Report).

More specifically, with respect to the dose criteria for siting, the low population zone is derived directly from the "population center distance." The dose guidelines that NRC used for the initial licensing of all existing nuclear power reactors are that (1) the total radiation dose to the whole body will not exceed 0.25 Sv (25 rem), and (2) the total radiation dose to the thyroid (from iodine) will not exceed 3 Sv (300 rem). These guidelines were considered at the exclusion area boundary for the first 2 hours after a postulated major accident because the source term decreases monotonically and in the low population zone for the first 30 days. By contrast, the dose guideline that NRC will use for all future nuclear power reactor licensing is 0.25 Sv (25 rem) total effective dose equivalent. This guideline will be considered at the exclusion area boundary for the 2-hour period that could result in the highest estimated dose because after a major postulated accident the alternate source term fluctuates as a function of time and in the low population zone for the first 30 days.

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."

Questions and answers pertaining to this section follow below.

Question Number: 18.01

Question: Could the United States of America provide detail concerning the implementation of severe accident management features in the plant design in order to reduce the probability of large off-site releases requiring short term off-site response (as indicated in INSAG 12)?

Answer: NRC has not required the implementation of any hardware features to address large early releases from containment during postulated severe accidents where "early" is defined as being within the time period not allowing for emergency response. However, as part of the severe accident management program, the U.S. nuclear industry has developed and implemented severe accident management guidance, procedures, and training to reduce the probability of large releases in general. As part of this program, licensees have identified systems (including non-safety-related systems) that could be effective in preventing or mitigating large off-site releases and have developed procedures for employing those systems. In general, these vary from plant to plant, depending on plant-specific features.

The NRC assessed the need for generic containment hardware improvements as part of the Containment Performance Improvement program. This program identified a number of potential improvements for each containment type; however, with the exception of hardened containment vents for Mark I containments, the risk reduction associated with these changes was not sufficient to require licensee implementation. Consequently, NRC required licensees with Mark I containments to install a hardened vent (which actually addresses late rather than early containment failures). NRC also requested (but did not require) that licensees with other containment types consider the potential improvements identified through the Containment Performance Improvement program as part of the individual plant examination (IPE), essentially a PRA, that were being performed at that time.

Question Number: 18.02

Question: Are there any programmes to evaluate that systems needed to cope with beyond-design events can fulfil their function under the ambient conditions typically of such events, including the necessary I&C systems and support systems?

Answer: At present, NRC Regulatory Guide 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants To Assess Plant and Environs Conditions During and Following an Accident," identifies requirements for equipment survivability. NRC is currently evaluating whether additional requirements are needed in this area.

Question Number: 18.03

Question: Are there any regulatory requirements regarding the quality assurance and test procedures for ensuring function and reliability of digital I&C systems?

Answer: 10 CFR 50.55a(h) and Appendix B provide the regulatory requirements for qualification of all systems important to safety including digital I&C systems. Chapter 7, Instrumentation and Control, of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," contains the NRC's review criteria for I&C systems, in general, and digital computer-based I&C systems of nuclear power plants, in particular. The NRC continues to perform research activities related to digital I&C systems to gain better understanding of how the systems might respond in accidents and to establish the technical bases for functional requirements.

ARTICLE 19: OPERATION

Each Contracting Party shall take appropriate steps to ensure that:

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

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

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

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

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

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

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

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

This section of the U.S. National Report stated that the NRC relies on regulations in Title 10, "Energy," of the *U.S. Code of Federal Regulations* (10 CFR) and internally developed 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.

Questions and answers pertaining to this section follow below.

Question Number: 19.01

Question: Which specific problems did the industry encounter when implementing the new section 10 CFR 50.65 (a) (4) of the maintenance rule?

Answer: The U.S. nuclear industry encountered two categories of problems. The first category includes problems that licensees encountered in establishing their programs under Paragraph (a)(4) of the Maintenance Rule and the second category includes problems that have come to NRC's attention as a result of flaws in licensees' programs and/or in their implementation. For many licensees, the implementation of Paragraph (a)(4) of the Maintenance Rule was a relatively straightforward transition from the voluntary maintenance risk assessment programs that they had already established under the old rule (Paragraph (a)(3)), in order to address the additional elements specified by Paragraph (a)(4).

In establishing the new requirements in Paragraph (a)(4), the revision to 10 CFR 50.65 clarified that the regulation applied when a plant is shut down as well as when it is operating. Consequently, one of the first challenges licensees faced was to find or adapt tools to analyze shutdown risk. Because many tools were based on Level-1, internal-event, at-power PRAs, additional work was needed to account for external events, internal flooding hazards, and containment issues. Many licensees developed an approach that blended quantitative and qualitative methods using an expert panel (or equivalent). Specifically, the qualitative methods involved defense-in-depth, barriers, and preservation of key safety functions, particularly for shutdown conditions.

The other major new requirement in Paragraph (a)(4) was risk management. The challenge caused by this requirement was the need to develop a program of graduated, systematic risk management. In addressing this challenge, some licensees followed industry guidance and established three risk categories based on levels of incremental core damage probability. Specifically, only normal work controls would be required at or below 1.0×10^{-6} incremental core damage probability, risk management actions would be required above 1.0×10^{-6} incremental core damage probability, and no voluntary entry would be allowed into a condition in which incremental core damage probability would go above 1.0×10^{-5}. About half of the licensees adopted an alternative four-band system based on multiples of CDF. For example, from baseline to (perhaps) double baseline, CDF would be considered the green band, which would require only normal work controls. Twice the baseline CDF up to (perhaps) 10 times baseline would be considered the yellow band, which would require risk management actions of at least heightened awareness measures. From 10 to 20 times the baseline would be considered the orange band, which would require various compensatory measures, and above 20 times baseline would be considered the red band, into which no voluntary entry would be permitted.

Licensees have experienced failures in the following areas in implementing their programs: (1) performing risk assessments when required, including (a) when plant conditions change, and (b) before maintenance is started; (2) performing adequate risk assessments that (a) account for all risk-significant systems or components, (b) consider the possible effect of temporary alterations and modifications, and (c) account for existing or imminent relevant external events and conditions, internal flooding or fire, and containment issues; (3) using the selected risk assessment tool within its capabilities and limitations; (4) managing risk by adequately implementing management actions when required. For example, when taking a key piece of safety equipment out of service, measures should be taken to prevent its counterpart in the other train from being taken out, rather than simply assuming that risk is minimized by not taking out the counterpart, and (5) preserving key safety functions.

Question Number: 19.02

Question: The safety comerstones and performance indicators of the NRC Reactor Inspection & Oversight Program do not directly indicate that adequate engineering and technical support is available for a nuclear installation. Which criteria are used for the judgement that the licensee has sufficient and qualified personnel at his disposal and that the necessary technical competence of personnel of the nuclear installation and of the contractors is ensured?

Answer: The NRC's regulations require licensees to have QA programs. These regulations include requirements that licensees must establish measures to ensure that their own personnel are adequately trained for their duties, and that contractor services conform to procurement documents. These measures related to contractors must include provisions for source evaluation and selection, objective evidence of quality furnished by the contractor, and inspection at the contractor source. Also, as part of the NRC's baseline inspection program, a design engineering team inspection is conducted to provide insights into the adequacy of licensee engineering and technical support. Should performance issues occur at a facility, NRC performs supplemental inspections to ensure that the licensee has determined the root causes, which might involve such issues as inadequate staffing or technical competency.

Question Number: 19.03

Question: What is your event rating system to help the public understand the significance of reported events easily and how do you implement it?

Answer: The NRC's regulations establish four classes of emergencies, in order of increasing severity. Specifically, these are (1) Unusual Event, (2) Alert, (3) Site Area Emergency, and (4) General Emergency. The specific class of emergency is declared on the basis of plant conditions that trigger the Emergency Action Levels. NRC has also used these classifications as a method of helping the public understand the significance of events.

In May 2001, NRC reevaluated its level of participation in INES and concluded that full participation is appropriate. Since that time, the NRC staff has been developing internal policies and procedures to incorporate full INES participation into existing work processes. The NRC intends to complete all activities (including training staff members in the rating methodology) necessary to implement full INES participation by May 2002.

Question Number: 19.04

Question: What are the tools for evaluation of operational experience feedback, besides Accident Sequence Precursor Program stated in the report?

Answer: NRC screens operational safety data for safety significance. In doing so, the agency investigates significant operational events in a timely, objective, systematic, and technically sound manner; documents the facts pertaining to each event; and ascertains the cause(s) of the event. NRC Management Directive 8.3, "NRC Incident Investigation Program," provides deterministic and risk-based criteria for determining the appropriate level of response required (i.e., an incident investigation team or less formal responses by an augmented inspection team or a special inspection team). The staff also uses the significance determination process of the ROP to analyze the risk-significance of events or conditions.

In addition, NRC screens operational safety data for generic implications and uses the agency's generic communications program to inform the industry about generic issues. The revised generic communications program uses bulletins, generic letters, regulatory issue summaries, and information notices. Bulletins request information and/or action from licensees on urgent safety-significant issues. Generic letters request information and/or action from licensees on non-urgent, potentially safety-significant issues. Regulatory issue summaries (1) document NRC endorsement of the resolution of issues addressed by industry-sponsored initiatives, (2) solicit voluntary licensee participation in staff-sponsored pilot programs, (3) inform licensees of opportunities for regulatory relief, and (4) announce staff technical or policy positions not previously communicated to the industry or not broadly understood. Information notices inform the nuclear industry of significant, recently identified, operating experience. Recipients are expected to review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems.

Question Number: 19.05

Question: Had the introduction of standard Technical Specifications any measurable positive contribution to the safety of the operating plants, e.g., less incidents or operational occurrences?

Answer: During the time that plants were converting to standard technical specifications, NRC noted numerous positive effects from licensees' performance improvement programs, including scram reduction, use of performance indicators, and implementation of the Maintenance Rule. However, NRC has not tried to identify any specific impact of improved standard technical specifications on these types of operational statistics. Nonetheless, NRC would expect that improved standard technical specifications help avoid scrams and plant shutdowns or power reductions, since they generally provide more appropriate surveillance testing and longer times to correct problems before requiring a plant to change modes. Other benefits include the improved understanding between the licensee and the regulator, which reduces the burden on both parties.

Question Number: 19.06

Question: 1) Accident Sequence Precursor Program The US-NRC uses for many years the Accident Sequence Precursor Programs. Produced this program insights, findings, etc. which were not gained in any other way? 2) Could and were these findings used in other regulatory programs/actions to reduce the happenings of similar precursors, (ab)normal operational occurrences in the future?

Answer: The Accident Sequence Precursor Program involves a detailed risk assessment of all events and conditions reported by licensees and NRC inspection reports. A Commission Paper (SECY-01-0034), entitled "Status Report on Accident Sequence Precursor Program and Related Initiatives," dated March 1, 2001, describes the uses of the program and gives examples of results being used in risk-informed regulatory activities. The following paragraphs summarize information from that paper.

Historical Trends and Insights

The program results are used to monitor the NRC's performance against the agency's two Strategic Plan goals for maintaining safety, which are no more than one event per year that is a significant precursor, and no statistically significant adverse industry trends in safety performance.

In the first of these goals, a "significant precursor" is defined as an event that has a probability of at least 1.0×10^{-3} of leading to a reactor accident. No potential precursors identified during Fiscal Years 1999 and 2000 had a conditional core damage probability greater than or equal to 1.0×10^{-3}. On the average, precursors with a conditional core damage probability greater than or equal to 1.0×10^{-3} have occurred about once every 4 years. The events in this group do not appear to involve any common failure modes, causes, or systems.

With regard to the second goal, the occurrence of precursors has exhibited a statistically significant decreasing trend from 1993 through 1999. The number of precursors has decreased over the period by a factor of 2 to 3.

Support of Risk-Informed Regulatory Activities

NRC uses results and insights from the program analyses to support various risk-informed activities. For example, the staff used results of the analysis of plant deficiencies at D.C. Cook to support the NRC's inspection program during the restart of that plant. The staff also used program results to support senior management decisions to dispatch augmented and special inspection teams, issue generic communications, resolve generic safety issues, assess regulatory effectiveness, and determine the safety significance of potential regulatory issues.

APPENDIX A: ACKNOWLEDGMENTS

The project manager for this report was Merrilee Banic, of the NRC's Office of Nuclear Reactor Regulation. Contributors included the following technical and regulatory experts at the NRC:

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APPENDIX B: LIST OF ACRONYMS

ADAMS	Agencywide Documents Access and Management System
ALARA	as low as reasonably achievable
ALARP	as low as reasonably practicable
ANS	American Nuclear Society
ASLBP	Atomic Safety and Licensing Board Panel
ASME	American Society of Mechanical Engineers
BLI	baseline inspection
CDF	core damage frequency
CFR	*Code of Federal Regulations*
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
EPR	European Pressurized Reactor
FDA	U.S. Food and Drug Administration
FEMA	U.S. Federal Emergency Management Agency
FSAR	Final Safety Analysis Report
GAO	U.S. Government Accounting Office
I&C	instrumentation and control
IAEA	International Atomic Energy Agency
INES	International Nuclear Event Scale
ICRP	International Commission on Radiological Protection
INSAG	International Nuclear Safety Advisory Group
IPE	Individual Plant Examination
IPEEE	Individual Plant Examination for External Events
ISO	International Standards Organization
LERF	Large Early Release Frequency
LOCA	loss-of-coolant accident
LPSD	low-power shutdown
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NPP	nuclear power plant
OSART	Operational Safety Review Teams
OSHA	Occupational Safety and Health Act
PAG	Protective Action Guide
PI	performance indicator
PRA	probabilistic risk assessment
PSA	probabilistic safety analysis
QA	quality assurance
RI	risk-informed
RIC	Regulatory Information Conference
RIRIP	Risk-Informed Regulation Implementation Plan
ROP	Reactor Oversight Process
SGTR	steam generator tube rupture
SSC	system, structure, and component

APPENDIX C: FIGURES AND TABLES OF INTEREST

Figure 1: Reactor Oversight Process Framework

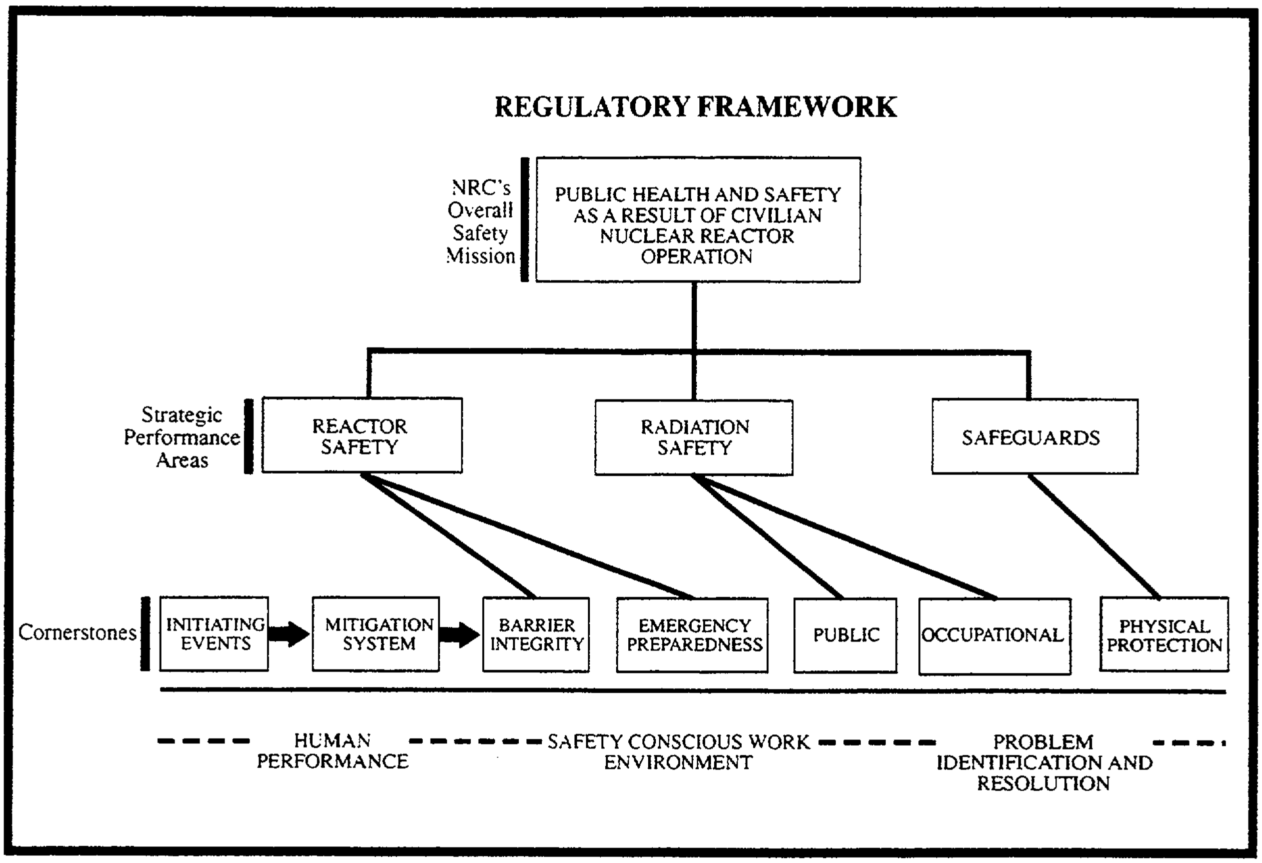
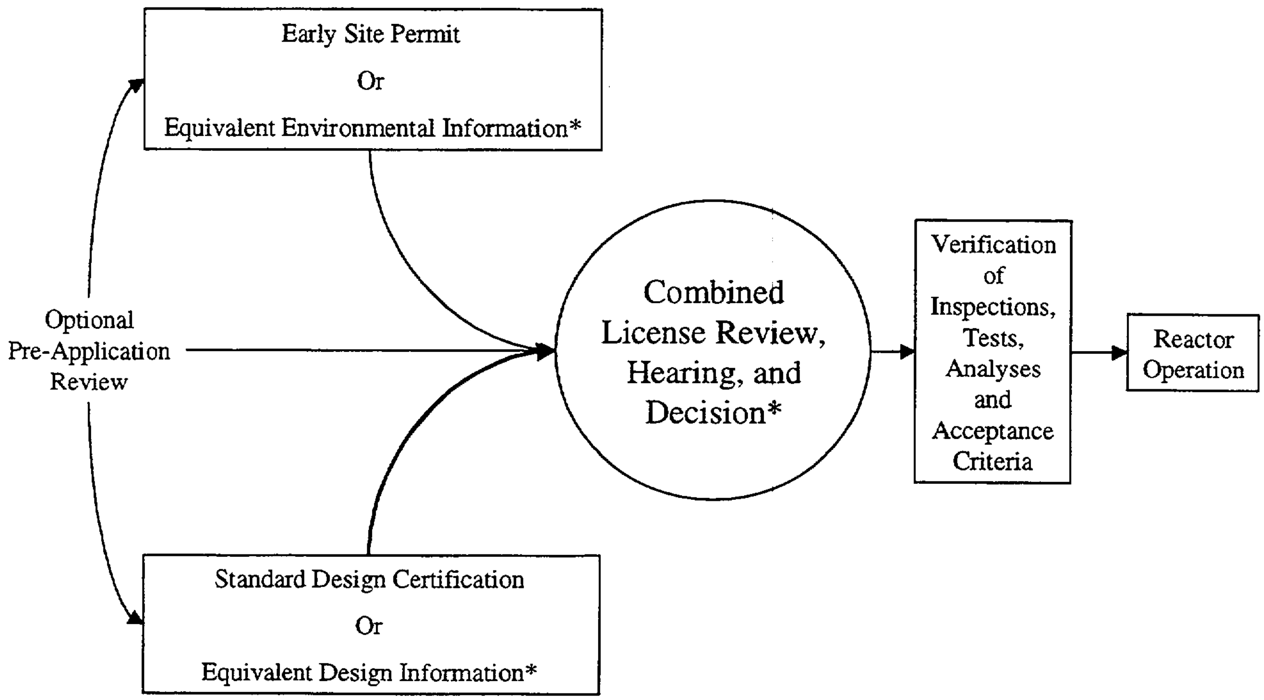


Figure 2: 10 CFR Part 52 Licensing Process



* A combined license application can reference an early site permit, a standard design certification, both, or neither. If an early site permit and/or a standard design certification is not referenced, the applicant must provide an equivalent level of information in the combined license application.

Table 1: Performance Indicators by Cornerstone

Safety Cornerstone	Performance Indicator
Initiating Events	Unplanned reactor shutdowns (automatic and manual)
	Loss of normal reactor cooling system following unplanned shutdown
	Unplanned events that result in significant changes in reactor power
Mitigating Systems	Safety system not available • specific emergency core cooling systems • emergency electric power systems
	Safety system failures
Integrity of Barriers to Release of Radioactivity	Fuel cladding (measured by radioactivity in the reactor cooling system)
	Reactor cooling system leak rate
Emergency Preparedness	Drill and exercise performance
	Emergency response organization drill participation
	Alert and Notification System Reliability
Public Radiation Safety	Effluent release requiring reporting under NRC regulations and license conditions
Occupational Radiation Safety	Compliance with requirements for the control of access to areas of the plant with dose rates greater than one rem/hr (10 mSv/hr.) Unintended radiation exposures to workers greater than a specified fraction of the dose limits in 20.1201, 20.1207, and 20.1208.
Physical Protection	Security system equipment availability
	Personnel screening program performance
	Employee fitness-for-duty program effectiveness

Table 2: NRC Response Plan or "Action Matrix"

Assessment of Plant Performance (In order of increasing safety significance)	NRC Response
I. All performance indicators and cornerstone inspection findings GREEN • Cornerstone objectives fully met	• Routine inspector and staff interaction • Baseline inspection program • Annual assessment public meeting
II. No more than two WHITE inputs in different cornerstones	**Response at Regional level** • Staff to hold public meeting with licensee management • Licensee corrective action to address WHITE inputs • NRC inspection followup on WHITE inputs and corrective action
III. One degraded cornerstone (two WHITE inputs or one YELLOW input or three WHITE inputs in any strategic area • Cornerstone objectives met with minimal reduction in safety margin	**Response at Regional level** • Senior regional management to hold public meeting with licensee management • Licensee to conduct self-assessment with NRC oversight • Additional inspections focused on cause of degraded performance
IV. Repetitive degraded cornerstone, multiple degraded cornerstones, or multiple YELLOW inputs, or one RED input • Cornerstone objectives met with long-standing issues or significant reduction in safety margin	**Response at Agency level** • Executive Director for Operations to hold public meeting with senior licensee management • Licensee develops performance improvement plan with NRC oversight • NRC team inspection focused on cause of degraded performance • Consideration of Demand for Information, Confirmatory Action Letter, or Order
V. Unacceptable Performance • Unacceptable reduction in safety margin	**Response at Agency level** • Plant not permitted to operate • Commission meeting with senior licensee management • Order to modify, suspend, or revoke license

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11. ABSTRACT *(200 words or less)*

This report documents the U.S. Nuclear Regulatory Commission's answers to questions raised by contracting parties to the Convention on Nuclear Safety in their peer reviews of the U.S. National Report for the Convention on Nuclear Safety (NUREG-1650). Contracting parties have two obligations - submit a national report for peer review and review the national reports of other contracting parties. The U.S. National Report was submitted for peer review in September 2001 to the second review meeting of the Convention, which was held at the International Atomic Energy Agency in Vienna, Austria in April 2002. Specifically, the questions and answers resulting from the peer reviews concern the safety of existing nuclear installations, the legislative and regulatory framework, the regulatory body, responsibility of the licensee, priority to safety, financial and human resources, human factors, quality assurance, assessment and verification of safety, radiation protection, emergency preparedness, siting, design, construction, and operation.

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