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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

THE UNITED STATES OF AMERICA

Washington D. C.

17 to 29 October 2010

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated Regulatory Review Service

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
THE UNITED STATES OF AMERICA

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Mission date: *17 to 29 October 2010*
Regulatory body: *USNRC*
Location: *Washington D.C., USA*
Regulated facilities and *Nuclear power plants*
Organized by: *International Atomic Energy Agency (IAEA)*

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The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of the United States of America, an international team of twenty senior safety experts visited the United States Nuclear Regulatory Commission (NRC) from 18 to 29 October 2010, to conduct an Integrated Regulatory Review Service (IRRS) Mission.

The purpose of this IRRS mission was to review the regulatory framework for safety of the operating nuclear power plants in the United States and the effectiveness of regulatory functions implemented by NRC. The review compared NRC standards against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS Review Team and the US counterparts in the areas covered by IRRS.

The IRRS Review Team consisted of 14 senior regulatory experts and 3 observers from 14 IAEA Member States, 3 staff members from the IAEA and an IAEA administrative assistant. The IRRS Review Team carried out the review in the following areas: responsibilities and functions of the Government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; regulations and guides; management systems; emergency preparedness and response; periodic safety review; feedback of operating experience; and interfaces with nuclear security.

The IRRS mission also included the following Regulatory Policy Issues for discussion: NRC's Transparency and Openness; Long-term Operation and Aging Management of nuclear power plants; and Human Resources and Knowledge Management at the regulatory body. In addition, the White Paper on "Approach to Safety" was discussed by the IRRS team. Two thematic areas were also covered, the Periodic Safety Review and Feedback of Operating Experience of nuclear power plants.

The mission included observations of regulatory activities at the operating nuclear power plants and a series of interviews and discussions with NRC staff and other organizations to help assess the effectiveness of the regulatory system. These activities included the following visits: NRC Region I Office; Limerick nuclear power plant in Limerick, Pennsylvania; Salem nuclear power plant in Hancock Bridge, New Jersey; the Headquarters Operations Centre during an emergency exercise; and direct observations of the working practices during inspections carried out by the NRC including discussions with the licensee personnel such as plant managers and executives.

NRC provided the IRRS Review Team with advanced reference material and documentation including the results of the initial and the complementary self-assessment. Throughout the mission, the IRRS Review Team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular the staff of NRC provided the fullest practicable assistance.

The IRRS Review Team identified a number of good practices, made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with the IAEA Safety Standards.

The main observations of the IRRS Review Team were the following:

- The NRC has a comprehensive and consistent regulatory system that has been developed in a determined manner and pursuing clearly defined Strategic Goals, NRC's organizational values and the Principles of Good Regulation. The Strategic Goals adopted around mid 1990´s emphasize strict verification of compliance with regulations and objective assessment of the licensee performance. The regulatory system has today reached a maturity and provides safety regulation

that meets its goals. The process of sharing lessons learned between the two NRC Offices dealing with operating and new reactors is very well controlled, including establishment of formal links, and provides for systematic future utilization of broad experience gained from supervision of operating reactors. There are effective ways to support inspection activities and share inspection findings between and within the regions and HQ. This assures that generic inspection findings can be identified and adequately addressed with the licensees and also taken into account in different regulatory processes. The NRC has established several ways for inspectors and experts conducting safety reviews to share experience and compare practices. This enables development of inspection practices and promotes consistency in the implementation of the inspection programme.

- The NRC has a strong drive for continuous improvement in its own performance and has well achieved its goals. Industry performance has also shown improvements as demonstrated by improved operational performance and reductions in risk profiles. However, there are indications that licensees have not been as proactive in making voluntary measures to upgrade systems, structures, and components with improved technology as many foreign countries have done to enhance safety. It is important that the licensees not rely solely on the NRC's regulations, generic communications, and inspections, but demonstrate on their own, initiatives and high standards of work quality.
- The NRC's information exchange programmes and its active participation in the multilateral and bilateral cooperation programmes are providing a strong contribution to worldwide development of nuclear safety practices. The NRC has developed and continuously updates a system of both procedural and technical guidance documents for safety review and assessment and inspections, and these have been made available to other regulatory bodies worldwide. In the same spirit, the NRC has developed and disseminated computer codes for safety analysis. These codes provide other regulators an opportunity to conduct independent audit calculations. In view of the increasingly international nuclear industry, it is important that the NRC continues its active involvement in the international harmonization of the nuclear safety standards and practices. Of special importance is the NRC's contribution to the development of the IAEA Safety Standards. In the same context the NRC should consider increased implementation of the safety principles and practices defined in those standards into its own regulations.

Among the good practices identified by the IRRS Review Team are the following:

- NRC has proactive, systematic and integrated human capital planning. Training of the staff at all levels is conducted following a strong systematic programme and using of state of the art tools and full scope simulators. The new staff members receive extensive training that culminates in examination of their knowledge and work skills. Much emphasis is given to understanding the NRC's basic values and principles of good regulation to new staff. Individuals receiving training of particular scope and depth are the resident inspectors. An effective method for building competence is organized interaction between review staff and inspectors. Reviewers have a complete set of guides such as standard review plans to assure adequate and consistent safety reviews, and the inspectors have tools and guides that direct their focus to issues of most relevance to controlling risks and maintaining proper safety culture. The guides and tools at the disposal of staff are useful not only for assuring quality in the conduct of work but also for knowledge management in the long term. All of these items taken together provide a high level of competence among the staff.
- NRC has developed and implemented a robust operational experience feedback programme, including guidance for safety enhancement and corrective actions recommended on the basis of lessons learned. The programme and a well developed database are available for sharing

experiences with all interested parties both nationally and internationally. Lessons are learned also from events reported from other countries. In order to ensure aging management of the systems, structures, and components, the NRC provides for documented collection of generic lessons learned from all US nuclear power plants, and offers to share this with nuclear community through the IAEA and other international channels. It thus makes a useful contribution to maintaining safety in the long term operation of all NPPs of the world.

- The rulemaking process is well-documented and organized. It provides ample opportunities for different stakeholders to make their contribution to the process. Furthermore, it entails an analysis of the impact on the licensees, the public and the NRC
- The licensing process, and in particular the license renewal process, is carried out in a very transparent manner, providing opportunities for hearing and public involvement. A number of meetings are held in the vicinity of the plants to provide the public with information on the license renewal process, solicit input on the environmental review, and to provide the results of the NRC's inspections.
- The inspection programme of the operating nuclear power plants has clear goals and a logical structure to verify that plants are operated in compliance with the NRC regulations and licence conditions. NRC inspection procedures, plant specific inspection reports and assessment results are publicly available.
- A sound and detailed on-site and off-site emergency exercise programme has been developed over the last thirty years, for a variety of scenarios with well balanced and comprehensive set of objectives. Achieving the objectives is tested – based on previously defined evaluation criteria - by a series of exercises over a six year period.

The IRRS Review Team identified certain issues in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system.

- NRC has today a number of separate programmes and processes that are useful elements of a strong management system. However, documentation of a fully integrated management system is not in place. As a move toward developing such a system, the NRC has a draft Management System Description Document. The IRRS team encourages the NRC to continue its development, and to identify/confirm and describe its organizational wide core processes and support processes. The NRC should also develop a process map in order to confirm and document a fully integrated Management System. Furthermore, the NRC should develop methods for a holistic Management System Review at planned intervals to ensure the continuing effectiveness of the system and to implement the review process.
- The NRC should prioritize the development and issue of a formal procedure for the development and revision of regulatory guides. In addition, the NRC should consider establishing a procedure to guide the periodic systematic review for its regulations and guides, based on operating experience feedback and the development of international safety standards.

Future updates of the NRC's Standard Review Plans should take into account scientific and technological developments in the area of safety assessment as reflected in the relevant IAEA safety standards.

- NRC should consider implementation of the ALARA principle in setting up the radiological acceptance criteria for design basis accidents as well as in assessment of acceptability of the results of relevant safety analysis.
- NRC should assess whether the current regulations adequately provide for an independent verification of the safety assessment under the responsibility of the licensee before its use or

submittal to the regulatory body and whether this verification is adequately confirmed by the NRC.

- NRC has in place separate programmes for periodically assessing the state of safety relevant items and provisions for industry self-assessments. However, there is no requirement on the licensee to conduct with regular intervals its own comprehensive review of whether adequate safety margins have been maintained, whether the safety margins have been verified with best available methods, and whether the management processes with relevance for safety have been kept current. Such Periodic Safety Reviews are generally carried out in other countries and have been found useful, both for maintaining and enhancing safety and for training younger generations to understand and take into account the relevant safety issues. Although the NRC utilizes an alternate approach to meet the PSR safety factors, NRC should incorporate lessons learned from Periodic Safety Reviews performed in other countries as an input to the NRC's assessment processes.
- NRC's Operational Experience procedures need to consider the collection and evaluation of non nuclear information to understand its impact to safety or security which may inform the safety security interface. Further attention should be given in order to encourage industry to take actions for ensuring the effective co-ordination of the safety/security interface issues.
- It is important in all countries of the world to get prompt and accurate information on a possible emergency at a nuclear power plant, and therefore the NRC procedures for the IAEA emergency notification (ENAC) should be improved. The emergency exercise programme should include routine testing of ENAC reporting to the IAEA.
- It can be expected that during an emergency a number of organizations are monitoring radiation situation in the surroundings of the nuclear power plant. If the results of these measurements are reported through a variety of channels, official and unofficial, it is possible that confusion could be created among the public and those responding to the emergency if false results appear and are not promptly corrected. The NRC should discuss with its Federal partners the consideration of a proposal for creating a system where all field measurements performed during an emergency by different stakeholders could be submitted into a single database and analyzed for relevance and credibility. This database should be made available online for decision making purposes.

The IRRS Review Team findings are summarized in Appendix V.

An IAEA press release was issued at the end of the mission.

I. INTRODUCTION

At the request of the Government of the United States of America, an international team of 20 safety experts visited the Nuclear Regulatory Commission (NRC) from 18 to 29 October 2010 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the US nuclear regulatory framework and its effectiveness. There were two preparatory missions during 2009 and 2010 carried out in NRC's Washington Headquarters to discuss the objective, purpose and consequently the preparations of the review as well as its scope in connection with the areas covered by NRC and selected safety aspects.

The IRRS Review Team consisted of 17 senior regulatory experts (14 reviewers and 3 observers) from 14 IAEA Member States, 3 staff members from the IAEA and an IAEA administrative assistant. The IRRS Review Team carried out the review of the NRC in the following areas: responsibilities and functions of the Government; global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; regulations and guides; emergency preparedness and response; periodic safety review; feedback of operating experience; and interfaces with nuclear security.

The IRRS review addressed the US nuclear power plants in operation regulated by NRC.

In addition, policy issues were addressed, including: a White Paper on the Approach to Safety; Human Resources and Knowledge Management at the regulatory body; and Openness and Transparency. Two thematic areas were also covered, the Periodic Safety Review, and Long-Term Operation and Aging Management of nuclear power plants.

NRC prepared substantial documentation as advance reference material and a well prepared self-assessment. During the mission the IRRS Review Team performed a systematic review of all topics using the advance reference material, held interviews with management and staff from NRC Headquarters, NRC Region I Office, Limerick nuclear power plant, Salem nuclear power plant, and the Federal Emergency Management Agency (FEMA), and performed direct observation of the working practices during inspections carried out by NRC.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the United States nuclear regulatory framework and regulatory activities as applied to operation of nuclear power plants to review its regulatory effectiveness and to exchange information and experience in the areas covered by IRRS. The review was carried out by comparison against IAEA safety standards as the international benchmark for safety.

It is expected that the IRRS mission will facilitate regulatory improvements in the United States and throughout the world from the knowledge gained and experiences shared by NRC and the IRRS reviewers and through the evaluation of the effectiveness of the US nuclear regulatory framework and its good practices.

The key objectives of this mission were to enhance nuclear safety and emergency preparedness:

- ✓ Providing NRC, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against international safety standards;
- ✓ Providing the United States of America (NRC) with a review of their regulatory programmes and policy issues relating to nuclear safety and emergency preparedness;
- ✓ Providing the United States of America (NRC) with an objective evaluation of its nuclear safety and emergency preparedness regulatory activities with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting the sharing of experience and exchange of lessons learned;
- ✓ Providing reviewers from Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field;
- ✓ Providing key staff with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing the United States of America (NRC) with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the United States' government authorities, preparatory meetings for the Integrated Regulatory Review Service (IRRS) were conducted in October 2009 and March 2010. The preparatory work for the mission was carried out by the IRRS IAEA Team Coordinator Mr Gustavo Caruso, the appointed Team Leader Mr Jukka Laaksonen and the Deputy Team Leader Mr Kunihisa Soda.

The NRC prepared for the mission based on the IAEA "Guidelines for the Preparation and Conduct of IRRS Missions, Edition 2010". For the preparation of the IRRS in US, the NRC established the following organization:

- NRC IRRS Mission organization chart: composed by the NRC staff with key roles during all preparations:
    - Senior Executive Manager: Mr Marty Virgilio, Deputy Executive Director for Reactor and Preparedness Programmes.
    - Liaison Technical Officer, Mr Bruce Boger, Deputy Director for Reactor Safety Programmes Office of Nuclear Reactor Regulation. Support Staff: Mr Jake Zimerman, Branch Chief and Mr Jon Hopkins, Senior Project Manager.
    - Liaison Organizational Officer, Mr Scott W. Moore, Deputy Director, Office of International Programmes. Support Staff: Ms. Jennifer Schwartzman, International Relations Specialist.
    - Communication Team Lead, Ms Beth Hayden, Senior Level Advisor on Public Affairs. Support Staff: Mr Scott Burnell, Public Affairs Officer
- IRRS Senior Management Board:
    - Mr Marty Virgilio, Chair
    - Seven USNRC Staff with experience on IRRS missions in other countries: Mr Bruce Mallett, Mr Luis Reyes, Mr Victor McCree, Mr George Pangburn, Mr William Dean, Mr Bruce Boger and Mr Mark Satorius.
- The Office of Nuclear Reactor Regulation
    - Mr Eric Leeds, Office Director
    - Associate Directors:
        - For Engineering and Safety Systems, Mr John Grobe and Support Staff, and
        - For Operating Reactor Oversight & Licensing, Mr Bruce Boger and Support Staff
- The NRC Region I Office
    - Mr Marc Dapas, Acting Administrator
    - All involved staff of Region I

The IRRS Review Team representatives had extensive discussions regarding the NRC regulatory programmes and policy issues with the top management of NRC represented by Mr Gregory B. Jaczko, USNRC Chairman, Mr Dale Klein, Former Chairman, Mr William Borchardt, Executive Director for Operations, Mr Marty Virgilio, Deputy Executive Director for Reactor and Preparedness Programmes, Senior Management Staff and Support Staff.

The discussions resulted in the following areas to be covered by the IRRS mission:

- Nuclear power plants in operation;
- Emergency preparedness and response;
- Interfaces with nuclear security;
- Selected policy issues.

NRC Management Staff made comprehensive presentations on the self-assessment results and other advanced reference material. IAEA presented the IRRS principles and methodology, including the self-assessment phase. This was followed by a discussion on the work plan for the implementation of the IRRS in the United States in October 2010.

The proposed IRRS Team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS Review Team was confirmed. Logistics including meeting and work space, counterpart identification, lodging and transportation to accommodate site visits and observations were also addressed.

In July 2010, NRC provided IAEA with the advance reference material for the review, including the self-assessment report (Appendix VI).

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards used as review criteria are: GSR Part 1, Safety Requirements on Governmental, Legal and Regulatory Framework for Safety, GS-R-2, Preparedness and Response for a Nuclear or Radiological emergency and GS-R-3, Safety Requirements on The Management System for Facilities and Activities. The complete list of IAEA publications used as the reference for this mission is given in Appendix VII.

C) CONDUCT OF THE REVIEW

An opening IRRS Review Team meeting was conducted on Sunday, 17th October 2010 in Washington by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

The Technical and Organizational Liaison Officers were present at the opening IRRS Review Team meeting, in accordance with the IRRS guidelines. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 18th October 2010, with the participation of NRC senior management and staff. Opening remarks were made by Mr G. Jaczko, Chairman of NRC, Mr B. Borchardt, Executive Director for Operations, the IRRS Team Leader, Mr B. Boger and the IRRS Coordinator.

During the mission, a systematic review was conducted for all the review areas with the objective of providing NRC with recommendations and suggestions as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to NPPs and direct observations regarding the national practices and activities.

The IRRS Review Team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday 29th October 2010. The opening remarks at the exit meeting were presented by Mr B. Boger. The results of the IRRS mission were presented by Mr J. Laaksonen. The closing remarks were made by Mr D. Flory, Deputy Director General of the IAEA Department of Nuclear Safety and Security and Mr G. Jaczko, Chairman of NRC.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

The US has a well established national policy and strategy for nuclear safety. The basic policy aim is to ensure safety of civilian use of radioactive materials. The basic strategy is licensing of facilities and activities and the regulatory oversight with an objective to verify continuing compliance with safety regulations.

The policy and strategy are codified in major statutes which establish the regulatory framework for the safety of facilities and sources, radiation protection, safe transport of radioactive material, the safe management of waste, decommissioning, emergency planning, and financial indemnification arrangements for third parties in the event of a major accident.

- The Atomic Energy Act of 1954 establishes the regulatory apparatus and the basic licensing requirements, covering essentially all areas having to do with public health and safety and the environment, including facility safety, radiation protection, waste management, and transportation. Financial indemnification arrangements for third parties are covered by the Price-Anderson Act, which is part of the Atomic Energy Act of 1954 as amended.
- Reorganization Plan No. 3 of 1970 reassigns responsibility for generally applicable environmental standards to the then newly established U.S. Environmental Protection Agency (EPA). The Energy Reorganization Act of 1974 establishes the U.S. Nuclear Regulatory Commission (NRC) and reassigns the chief safety regulatory responsibility to the NRC.
- Reorganization Plan No. 1 of 1980 clarifies the role of the Chairman in day-to-day administration of the agency while preserving the Commission’s policymaking role and provides the Chairman clear authority to manage NRC’s response to emergencies.
- The Nuclear Waste Policy Act of 1982 establishes a programme to develop a national high-level waste repository, and the Act assigns regulatory responsibilities in this area to both the NRC and the EPA.
- The Low-Level Radioactive Waste Policy Amendments Act of 1985 aims at the development of low-level waste facilities.
- The Hazardous Materials Transportation Uniform Safety Act of 1990 assigns basic regulatory authority over the transportation of hazardous radioactive material to the U.S. Department of Transportation.
- Presidential Executive Order 12148, ”Federal Emergency Management,” dated July 20, 1979, assigns to the Federal Emergency Management Agency responsibility for establishing Federal policy on emergency response, including response to accidents at civilian nuclear facilities.

These statutes and the rules and policies issued under them by the NRC provide a broad authority to regulate health and safety, adequate resources and provision for research. The framework also provides for a graded approach, most clearly manifested by the Reactor Oversight Process.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The AEA establishes the basic rationale for authorizing a given plant and requires that operation of the plant be in accord with the common defense and security and provide adequate protection to the health and safety of the public.

The AEA clearly assigns to the NRC the responsibility for regulating nuclear safety at nuclear power plants. The safety objectives are stated in general terms. The statutory authority to determine what constitutes adequate protection of health and safety of the public is given to the Commission. Under this authority, the Commission issues such orders and regulations as the Commission "may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property". These orders and regulations are issued after a process that involves public notice and opportunities to make comments.

The NRC has the legal authority to require facility operators to provide any necessary information needed to ensure safe facility operation, including information from suppliers, even if this information is proprietary.

Emergency planning is the subject of statute which gives the NRC's Chairman special authority during an emergency and regulation. The NRC works closely with States, licensees, and the Federal Emergency Management Agency to ensure that emergency plans are well developed and well rehearsed. The plans must meet Federal standards but are essentially implemented by the States.

Other statutes assign to the Environmental Protection Agency (EPA) some responsibilities for setting environmental standards for nuclear power plants and assign to the Occupational Safety and Health Administration responsibility for setting industrial safety standards at such plants.

The AEA authorizes generally the establishment of independent advisory bodies and Section 29 of the Act establishes a permanent advisory committee to the Commission, the Advisory Committee on Reactor Safeguards.

The ERA, which established the NRC, also established an Office of Nuclear Regulatory Research within the NRC, with appropriate authorities in research and development. The Act allows the Commission to engage in or contract for research and obliges other Federal agencies to provide such research services as they may reasonably be able to offer.

Other sections of the AEA provide authority for the NRC regulations to ensure proper decontamination and decommissioning of nuclear facilities, including the funding to pay for them.

Several AEA provisions and NRC regulations are devoted to regulating the export and import of nuclear equipment and materials. The NRC works closely with other agencies in the executive branch to ensure implementation of these provisions.

This extensive regulatory framework excludes other governmental authorities from entering into NRC´s mandated responsibility for technical nuclear safety judgments, but at the same time, the framework sets fundamental terms for the participation of other authorities and the public in NRC decision-making.

U.S. approach to enhancing safety was summarized in a White Paper that was provided as part of the advanced reference material to the IRRS team.

According to the paper, *"The U.S. Nuclear Regulatory Commission (NRC) assures the safety of nuclear power plants through a system of legal requirements, comprehensive operating experience evaluation and extensive on-site inspections. The NRC's statutory mandate is to assure adequate protection of public health and safety. What constitutes adequate protection can change over time as operating experience, technological understanding, significant events, and inspection findings are assessed. The NRC updates its requirements to reflect these assessments to satisfy the adequate protection mandate, which in turn enhances nuclear power plant safety. In addition, the Institute for Nuclear Power Operations (INPO), an industry sponsored oversight organization that has a Memorandum of Agreement with the NRC, provides an impetus for nuclear utilities to steadily improve performance in pursuit of excellence in operations. Furthermore, the license renewal programme provides assurance that aging management programmes are established to assure the safety of long-term operations. The result, as evidenced by industry trends*

and the Accident Sequence Precursor Programme, is an enhancement of nuclear power plant safety on a continual basis."

Aspects of this White Paper were extensively discussed between the IRRS team and the NRC during the mission which is reflected in other parts of this report.

1.3. ESTABLISHMENT OF A REGULATORY BODY

In the opinion of the team, the NRC has the legal power, staffing, and financial resources to discharge its assigned responsibilities.

1.4. INDEPENDENCE OF THE REGULATORY BODY

Team recognized the effective independence of the NRC that is established in the legislation and has been experienced in practice.

Among the evidence of the independence the team noted the following:

- The Energy Reorganisation Act of 1974 separates regulation from promotion and created the NRC as well as what would later become the Department of Energy. NRC has no role in promotion or operation of nuclear facilities of any kind.
- The decision making body heading the NRC is the five-member Commission whose members are nominated by the President and confirmed by the U.S. Senate for a 5-year term and the terms are staggered so that one term expires every year. A Commissioner can be removed from office only for inefficiency, neglect of duty, or malfeasance in office. A maximum of three Commissioners can belong to the same political party.
- The President designates one member of the Commission to serve as Chairman and can change the Chairman during his or her term but this does not influence the membership of the Commission and the Chairman cannot drive a policy without support of a majority of the Commission.
- The President cannot direct the Commission's decisions and the Congress is not able to override these decisions, except by legislative acts. Licensing decisions can be appealed to a Federal Court, but in these cases the Court only reviews whether law has been applied correctly by the agency.
- The Commission has statutory authority to issue rules in Title 10 of Code of Federal Regulations, and compliance with these rules presumptively constitutes adequate protection of public health and safety. What constitutes adequate protection can change over time. The rules with major importance to national economy have to be submitted to the Congress for its possible intervention but in practice the Congress has never used its right to contravene NRC's rules.
- The Congress has been supportive to the Commission by making amendments in the legislation in cases where the authority of the Commission has been challenged, such as the authority to grant a combined license (COL) to construct and operate a nuclear power plant.
- The executives of the staff are appointed on the basis of their professional qualifications and their political orientation is not a factor to be taken into account. The executives remain on their posts independently of the possible political changes in administration after elections.
- The Commissioners and the staff can testify in front of the Congress without a need of pre-approval by other any other branches of the administration.
- The human, financial and material resources provided to the NRC have been adequate for fulfilling its statutory obligations.

In summary, the five NRC Commissioners have considerable independence within the executive branch. Congress, Courts, other Federal Agencies, and State governmental entities generally defer to the

Commission's safety judgments and regulations. Beyond this basic separation from promotion and partisan politics, the NRC has several means for maintaining its effective independence from DOE, the licensees and other bodies that promote nuclear technology, such as industry groups (see further examples in section 3.2).

1.5. PRIME RESPONSIBILITY FOR SAFETY

The team noted that there is no provision in U.S. statute or regulation explicitly stating that the licensee/operator has the prime responsibility for safety, though some other regulatory documents do state this. The safety responsibility of the licensees is defined principally through licensing and continuing regulatory oversight, and enforcement throughout all stages in the lifetime of a facility. This means the NRC makes sure that the licensees take their safety responsibility. Under the statutory provisions for liability payments in the event of a major nuclear accident, it is clear that the industry bears the liability.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 - Requirement 5: Prime responsibility for safety states that** *"The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance."*
S1	**Suggestion: In the absence of a direct legal statement about the prime responsibility for safety, the NRC should provide a consistent, clear message to the licensees that they have responsibility to take their own initiatives to improve safety whenever reasonably practicable.**

1.6. COMPLIANCE WITH SAFETY REGULATIONS

The NRC has explained to the team that the fact of extensive regulation does not mean that the regulator takes over responsibility for safety. There are several regulations requiring actions by the licensee and also room for safety improvement initiatives by the licensees. The regulations are for the most part stated in general terms, and guidance documents explicitly leave the regulated parties room to propose alternative ways to comply with the regulations. The safety responsibility also extends to the authorized party's employees, contractors, and others, against whom the agency has authority to take enforcement action. Authorized parties are responsible for verifying that products and services supplied to them by employees and contractors in fact comply with applicable law.

1.7. COORDINATION OF DIFFERENT AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

Applicants for nuclear power plant licenses must obtain authorizations from a number of Federal, State, and local governmental bodies, and those bodies conduct continuing regulatory control over operating plants within their respective areas of responsibility.

The NRC deals in several ways with such dispersal of authority among several agencies. However, in all cases where NRC and another authority have some responsibility for operating plants, the NRC has a Memorandum of Understanding with the other party to clarify responsibilities and authorities and how interactions between the parties should be arranged. There are about 20 such memoranda which are regularly evaluated. Clear Memoranda of Understanding between agencies with shared authority could be regarded as good practice.

The regulatory framework excludes other governmental authorities from replacing the NRC's technical nuclear safety judgments with their own, but at the same time, the framework sets fundamental terms for

the participation of those authorities and the public in NRC decision-making. When another Federal authority is drafting rules that might impinge on nuclear safety practices at nuclear power plants, the NRC consults with the other agency during the rulemaking to ensure that the final rule will not have a negative impact on safety. The courts and Congress also from time to time minimize potential conflicts among authorizing agencies by drawing reasonably clear jurisdictional lines. For instance, the Supreme Court has ruled that emissions from nuclear power plants to surface water are to be regulated solely by the NRC under the AEA and not by the EPA under the Clean Water Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 - Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
GP1	**Good Practice: The NRC uses written Memoranda of Understanding with other agencies who have shared authority with the NRC.**

1.8. COMPETENCE FOR SAFETY

The NRC has an extensive programme of grants to persons and institution in order to maintain and improve the national competence in nuclear safety related fields. The agency also regulates the training of nuclear power plant personnel and conducts licensing of the reactor operating staff at the NPPs (see module 5 and 7).

Internally, the NRC maintains a high level of expertise by providing training opportunities (see section 3.3); by participating actively and routinely cooperating with technical experts outside of the agency, both domestically and internationally; and by carefully recruiting new staff with educational and experience backgrounds that match the agency's technical needs. For example, NRC staff frequently participates in international cooperative programmes sponsored by the International Atomic Energy Agency and the OECD Nuclear Energy Agency.

The NRC routinely issues contracts for research projects to gain access to independent technical expertise. The NRC's major source of this expertise is the U.S. National Laboratory system, which includes numerous separate research facilities, located throughout the United States, with extensive and varied technical capabilities. However, the NRC also contracts with other Federal agencies, universities, and commercial businesses to carry out research projects and to obtain technical expertise. The NRC can also ensure independent expertise by establishing its own research and development center, as it did in 1987 when the agency established the Center for Nuclear Waste Regulatory Analyses to help resolve issues related to a geologic repository for high-level waste. The NRC has the ability to set up and fund independent advisory bodies to provide expert opinion and advice. The Advisory Committee on Reactor Safeguards, established by law, further provides independent opinion and advice to the Commission.

1.9. PROVISION OF TECHNICAL SERVICES

In the U.S. regulatory framework, licensees are required to perform technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and calibration of equipment.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

Conduct of International Activities

The NRC's participation in international activities is pursuant to statutory mandate and takes place in coordination with US Executive Branch and other Federal Agencies, as appropriate

Since 1995 the international activities became part of the NRC core business and therefore fully integrated in the institutional activities of the Agency. NRC participation is guided by the Commission policy directions and priorities. Examples of recent policy directions are the increase of interest (more resources) for India at bilateral level, while at multilateral level, there is increase of financing to the IAEA for supporting its projects for the infrastructure development in new-comers countries and for the assistance to the implementation of the code of conduct on the radioactive sources.

An International Council, composed by NRC Office Directors, is established to discuss the NRC participations to ensure a due exchange of information within the Agency structure and to deal with specific issues identified in multilateral contexts which can imply decisions on the assignment of Staff resources to perform studies on it.

The Office of International Programmes (OIP) reporting directly to the Commission is responsible for the coordination of the international activities of the Agency.

Some of the important objectives of the NRC's international activities include:

(1) Obtaining and using non-U.S. safety and security information that will alert the NRC to potential problems and threats,

(2) Helping to identify potential accident precursors, and

(3) Providing accident and incident analyses—including lessons learned— directly applicable to the safety and security of U.S. nuclear power plants and other facilities and to the safe and secure use of nuclear material.

Among others, the international activities include the following:

(1) Assess the safety and security significance of foreign nuclear accidents or incidents for civilian power reactors and uses of radioactive materials, to understand the implications for the NRC and its licensees.

(2) Exchange information with countries having experience of special relevance to the NRC's programmes concerning the safety and security of nuclear material, waste, and reactors.

(3) Maintain appropriate levels of NRC research cooperation with countries having mature nuclear power programmes directly or through, for example, the IAEA, the OECD/ NEA, or the EU to leverage NRC resources to examine key technical issues in regulating the safety and security of existing and proposed U.S. commercial nuclear facilities and the safe and secure use of nuclear materials.

Arrangements are in place to ensure that experts participating in international work go prepared to represent the Commission position on the involved matter. Pre-trip and post-trip reports are utilized to share information and ensure alignment to the specific objectives associated with the trip. The OIP maintains an overall view of participations and provides the Commission with an annual report. Participations are ultimately defined by Offices in consultation with EDO and OIP.

Information Exchange Activities

The NRC exchanges safety-related information through both formal and informal arrangements, including conventions and treaties, codes of conduct, bilateral agreements with States, and memoranda of understanding, to help fulfill safety and security obligations and to promote cooperation.

The NRC continues to strive for excellence in the use and sharing of international operating experience (OpE), working closely with the international community to share domestic OpE and learn about international experiences. The NRC reviews international OpE information in the same manner as domestic OpE. This activity is further discussed in section 6.12 of this report. The INES and IRS of the IAEA are now integrated into the NRC's operating experience functions.

In the context of a changed international environment, the NRC is collecting experience in the licensing and construction of new reactors in France, Finland, China, the Republic of Korea, Japan and Taiwan.

Conventions and Treaties

Treaties that legally bind the NRC and the U.S. Government's peaceful uses of nuclear energy and nuclear applications include:

(1) Nuclear Non-Proliferation Treaty (1978),

(2) Convention on Physical Protection of Nuclear Material (1980),

(3) Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency (1986),

(4) Convention on Nuclear Safety (1994),

(5) Convention on Early Notification of a Nuclear Accident (1986), and

(6) Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (1997).

NRC staff members regularly participate in international meetings related to these conventions. In its bilateral work with regulatory counterparts worldwide, the NRC exchanges experience and good practices in order to further the goals of these international instruments.

In addition to these legally binding obligations, the United States has agreed to comply with certain activities to enhance the safe and secure uses of nuclear applications. For example, the United States has made a political commitment to implement the Code of Conduct on the Safety and Security of Radioactive Sources. This commitment has been codified in U.S. statute as part of the Energy Policy Act of 2005 and is reflected in the NRC's export and import regulations.

Multilateral and Bilateral Activities

For many years, the NRC has provided both regular budget and cost-free expert staff support to IAEA, as well as participants in safety and security missions, conferences, steering groups, safety and security standards committees, consultancies, and technical meetings. The NRC attends roughly 100 IAEA meetings and missions each year. The NRC also serves in various membership and leadership capacities at OECD NEA, with representation at a variety of levels on NEA's standing safety technical committees and associated working groups. The NRC similarly supports the ICRP, the UNSCEAR, and other multilateral activities. The NRC also is a party to several multinational activities, including the Multinational Design Evaluation programme (with OECD NEA).

The NRC also has bilateral technical information exchange arrangements with 40 Member States and approximately 100 research agreements.

The bilateral agreements by the NRC need the approval of the State Department.

International Assistance Programmes

The NRC is providing bilateral regulatory assistance to countries seeking to establish nuclear power programmes (emerging countries), in close consultation with the IAEA. The U.S. Government and the IAEA are both actively promoting regional cooperation and have engaged in workshops and training activities to further that goal. In 2010, the NRC hosted nine assignees from five foreign countries.

Research Programmes

The NRC conducts confirmatory regulatory research through more than 100 multilateral agreements, in partnership with nuclear regulatory agencies and technical support institutes in more than 20 countries. This research supports regulatory decisions on emerging technologies, aging equipment and facilities, seismic, severe accident, and various other safety issues. The NRC and other nuclear regulatory and safety organizations carry out cooperative research projects to achieve mutual research needs with greater efficiency.

The NRC has been actively carrying out the international activities with strong commitment to fulfil its obligations and also to promote international cooperation to enhance nuclear safety worldwide.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 – Requirement 14: International obligations and arrangements for international cooperation states that** *"The government shall fulfil its respective international obligation, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally."*
GP2	**Good Practice: The NRC's information exchange programmes, and its active participation in the multilateral and bilateral cooperation programmes are providing a strong contribution to worldwide development of nuclear safety practices and to dissemination of knowledge to other countries.**

2.2. HARMONIZATION OF U.S. REGULATIONS TO INTERNATIONAL STANDARDS

The NRC has been actively participating in the development of safety standards of the IAEA and committed to stay actively engaged in this international programme.

In the Strategic Plan for FY 2008-2013 the NRC addresses its commitment to the international cooperation in the area of safety standards. The plan states: "Participate in the development and evaluation of international standards to ensure they are soundly based and determine whether substantial safety improvements can be identified and incorporated domestically." It also reaffirms that the NRC would continuously influence the development of standards and guidance consistent with U.S. objectives.

Whenever an IAEA safety standard comes up for development or revision, the NRC performs a detailed review of the IAEA Safety Standard and creates a "Gap Analysis" that evaluates: (1) Are there relevant NRC regulations or guidance?, (2) Are there relevant other Federal Agency documents or positions?, and (3) What are the key differences which could raise issues when the IAEA document is compared to the NRC or other Federal Agencies? The Gap Analysis results are used to develop NRC positions to be represented at various IAEA safety committees and CSS. The results are also considered, as appropriate, for future revisions of the associated NRC regulations and guides. The NRC collects and organizes the information obtained from each IAEA Safety Standard review in an agency-wide Knowledge Management database. The NRC staff can access this database when considering a revision to a regulation or guide and consider any gaps to IAEA Safety Standards.

There is a draft Management Directive 6.6 entitled "Regulatory Guides" that addresses updating of regulatory guides including consideration of harmonization with international standards. It says "Endorsement of international standards is an important element in providing harmonization of

approaches to safety issues worldwide, ...When appropriate, when existing regulatory guidance is being updated, international standards such as those promulgated by the International Organization for Standardization should be considered for endorsement and/or reference. In addition, safety standards such as those promulgated by the IAEA should also be considered for use in Regulatory Guides."

With this Management Directive in draft form, the NRC management expressed its commitment to develop a methodology to upgrade Regulatory Guides as first measure to pursue harmonization to international standards at the corresponding level of the IAEA Safety Guides. The team was informed that the final approval of MD will be made in several months time.

Examples of drafting Regulatory Guides that take into account the IAEA standards give actual evidence of the NRC willingness to consider IAEA Safety Standards in the development of regulations and guides (see module 9 for specific references such as draft Regulatory Guide DG-8034 "Occupational Radiation Dose Assessment in Light – Water Reactor Power Plants Design Stage Person – Sievert (Man-Rem) Estimates").

The IRRS team was also informed that the NRC is considering updates to the 10 CFR 20, Standards for Protection against Radiation, taking into account the results of on-going IAEA work on its Basic Safety Standards for radiation protection. This example could be representative of a general process the NRC could establish to study harmonizing its regulations and guides to international standards.

Additional directions to harmonization come from an NRR Instructions Information Document on rulemaking procedure. The last Instructions Information Document was issued in 2008 and is currently under revision. This document defines a list of acceptable sources which can be used by the Staff to form the technical basis informing the proposal of rulemaking. The international standards organizations are included in such a list. The IRRS team was told that the new of version of the instructions issued by NRR and approved by EDO will provide the Staff with more direction to use international standards in the process of reviewing regulations. NRR is waiting for the finalization of MD 6.6 before of issuing the respective new instructions.

The team was also informed that the interest by the US Industry in the harmonization in a globalized market is one of the drivers towards more international standardization. In this regard the NRC representatives referred to the request which came from the Industry to use international standards for QA by updating the Appendix B to the 10 CFR 50.

With regard to other relevant international initiatives on the matter, the NRC expressed interest on the harmonization work in the WENRA context, on the EU Directive and on the ENSREG activities. A channel for the exchange of information and dialogue has already been established with the European Commission.

The team informed the NRC that especially the WENRA work for harmonization could be a useful reference to the NRC. This work was conducted as multilateral cooperation among 17 European regulatory bodies that altogether regulate more than 150 operating power reactors. These regulatory bodies identified from the IAEA Safety Standards around 600 safety topics for which they defined common reference levels, harmonized with the IAEA Standards. All regulatory body heads committed to upgrade their national regulations in line with these reference levels by the end of year 2010. Many of these regulatory bodies have now completed the committed harmonization and are applying the revised regulations. Information on the WENRA work can be found from www.wenra.org.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, para. 3.2. "***The features of the global safety regime include:---- Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S2	**Suggestion: The NRC should evaluate the added value to safety of harmonizing its regulations and guides with the IAEA safety standards and consider the possible means to take into account the IAEA Safety Standards in the regulations and regulatory guides.**

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

The NRC has a large and well established organization. Under the five-member Commission, the organization is structured in 11 offices reporting directly to the Commission (of these, the Office of the Inspector General has a special independent standing) and 14 offices reporting to the Executive Director for Operations (EDO). In addition to the HQ resources the NRC has four regional offices conducting supervision of the nuclear power plants and other nuclear facilities located in the respective region. There are daily contacts between the regional offices and the HQ as well as between the resident inspectors at the nuclear sites, regional staff and project managers at the HQ.

Below the office level the NRC organization is structured in divisions and branches reflecting the activities, functions and expertise needed to fulfill its statutory obligations. Minor organizational changes take place every year but larger changes are rare.

The NRC staff has expanded a lot over the last years in view of licensing of new reactors, licensing of the Yucca Mountain spent fuel repository and upcoming retirements. In total there are now 4052 employees, an increase of 890 over the last few years. About half of the staff has less than 5 years of working experience with the NRC.

Financial resources are made available to the NRC through enactment of appropriations by the US Congress. Every fiscal year (FY) the NRC has to submit a detailed budget justification to the Office of Management and Budget, and Congress for review and approval. The budget request is supported by detailed output measures for each business line for the coming FY as well as performance records for earlier FYs. The detailed budget process with all internal iterations takes about two years to complete. In general the NRC has received the funding it needs for all programmed activities. After an increase of allocated funds over the last years, a minor decrease is expected for FY 2011 depending on an expected decrease in NPP relicensing applications. Allocated funds for FY 2010 amounts to 1.066 billion USD About 90 percent of the funding is recovered from the licensees and paid to the government. The NRC has no authority to invoice over this limit.

The NRC has a detailed internal control over the use of allocated funds through performance metrics and internal (by OIG) and external (by GAO and OMB) audits. Funds can be re-allocated if needed and the activity planning and follow up process makes sure that resources are used according to a graded approach.

3.2. EFFECTIVE INDEPENDENCE DURING CONDUCT OF REGULATORY ACTIVITIES

The NRC has a number of staff instructions on professional conduct and ethics in order to preserve independence and integrity in relations with licensees. Also the internal staff training programmes put a large emphasis on integrity. Newly employed staff receives special training on these matters.

All NRC interactions with licensees are regulated in Management Directives and Instructions in order to clearly separate the roles and preserve regulatory integrity. Formal meetings between the regulator and industry are often conducted in public. NRC employees are not allowed to own stocks in companies belonging to the regulated industry or to have any other vested interests in that industry.

The resident inspectors are instructed not to have personal relations with licensee staff outside work.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The NRC has an advanced, comprehensive and systematic plan for staffing and competence needs. A 5-year Strategic Human Capital Plan provides the framework for the management of human resources. The current plan is valid through 2014. The plan outlines a number of strategies for recruiting, introducing and training staff as well as retaining the knowledge of retired staff or staff eligible to retire. Development of the plan was guided by the Human Capital Council, which was established in 2006 as an agency wide forum to address human capital challenges. The Council has advisory functions to EDO and the Chief Human Capital Officer.

The NRC has experienced little difficulty finding qualified applicants for open positions. Currently the agency is fully staffed. Recruitment is proactive and planned long before a vacancy occurs. Salary conditions are competitive with industry for positions below the executive level. There is no mandatory retirement age. Depending on working time in the federal government individuals normally retire between 55 and 65 years of age. Some retirements are expected in the near future.

Several advanced web based planning instruments have been developed by NRC to support the human capital strategies. Among these is a Knowledge Management Centre on the intranet consisting of electronic communities of practice designed to enable staff to collaborate, capture and share knowledge in order to build organizational memory and capture lessons learned and best practices from the most experienced staff. This centre also features Q and A modules and video and voice recordings of retired experts. NRC is also using an automated strategic workforce planning tool to capture existing staff competences as well as critical skills and knowledge needs. This tool helps the agency to determine critical skill and knowledge gaps and to target recruitment accordingly.

The NRC has dedicated training programmes and individual development plans. The Office of Reactor Regulation (NRR) has an especially well developed training programme for its technical staff. Each job category has a qualification programme including theoretical, practical and on-the job training courses which culminate in an examination before an “oral board” composed of directors and technical specialists. Newly employed staff is expected to pass this examination within 18 months after entry. Mentors are available. Experienced staff is required to take refresher courses on an annual basis. To support the technical training programmes, the NRC has a well known dedicated technical training centre in Chattanooga with four full scope simulators reflecting the US NPP designs. The centre provides extensive structured training in power plant design, systems and operations of NPPs.

More advanced and specialized training modules are also available, for instance in cooperation with universities, which can be tailored to an individual´s educational background and future job responsibilities.

Training arrangements for regional and resident inspectors are further discussed in module 7 and Emergency Preparedness training in module 10.

In order to prepare for future recruitment the NRC has several outreach programmes, such as providing scholarships to students and informing students about its technical careers at schools of different levels all over the USA. The NRC is applying diversity management principles when recruiting new staff. A University Champion has been established for 36 Universities including the University of Puerto Rico to inform students about working opportunities at the NRC. Another interesting detail is that NRC staff has met specifically with girls in primary schools to interest them in technical careers.

The proactive, systematic and integrated human capital planning of NRC supported by information technology tools can be regarded as good practice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 – Requirement 18: Staffing and competence of the regulatory body states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
GP3	**Good Practice: The proactive, systematic and integrated human capital planning of NRC supported by information technology tools.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The NRC has three independent advisory committees. The most prominent one and relevant for the IRRS is the Advisory Committee on Reactor Safeguards (ACRS) which is a statutory committee established by the Atomic Energy Act. The task of ACRS is to provide the Commission with independent technical advice on issues of public health and safety related to the generation of nuclear power and use of nuclear materials. The Committee is composed of a maximum of 15 members appointed by the Commission for up to four years with a possibility for extension. Members should have broad as well as specific technical expertise. They typically have long experience from national laboratories, universities, other federal agencies or earlier employment in the industry. The ACRS members do not work full time for the NRC but they allocate a significant part of their total working time to the Committee's work. The ACRS is supported by a full-time group of technical experts and administrative staff.

Typical issues for the ACRS are to provide an opinion on licence applications, new regulations and guidance, reactor safety standards, research projects and programmes. On its own initiative the ACRS can review any issue related to nuclear power production that it finds important to public health and safety. An ACRS review is mandatory in connection with applications for new power reactor licenses or construction permits.

The ACRS can provide its advice orally at meetings with the Commission, regulatory staff, associated stakeholders, or as letter reports that document the observations and recommendations of the Committee.

The NRC regards the advice of the ACRS as a very important input to the regulatory activities. Often recommendations of the ACRS lead to additional consideration of an issue or a redirection of a planned activity.

Hiring qualified Committee members can sometimes be a challenge due to the level of technical expertise required, the significant time commitment involved, and the potential for conflicts of interest.

With regard to other support organizations, the NRC is well equipped to contract national laboratories and consultants for specific technical advice when needed. Results of the contracted work are reviewed by NRC staff and any regulatory decisions are always taken by NRC.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Most of the regular meetings between NRC and the licensees take place at the regional level. There is daily contact between NRC´s resident inspector and the respective plant management. According to Inspection Manual Chapter 102 the regional administrator should, on average, meet with the plant management at one power reactor site per month (which approximates to a meeting with plant management at every NPP site in the region once every two years) to discuss the safety performance of the plant and related matters. Face-to-face meetings between the regional administrator and the plant management are most often conducted as public meetings. In cases of degraded performance the contacts

get more frequent and could also generate meetings between the utility corporate management and NRC headquarters management and the Commission.

NRC puts a lot of emphasis on training staff to act professionally towards licensee personnel. The relations should be formal but also frank and open. The NRC would like to be perceived as a strong regulator and believes that the licensees regard the NRC as such. The performance of NRC staff in this respect is assessed by their managers.

There are no formally established meetings between NRC´s headquarters management or Commissioners and the utility corporate management to inform about operational plans and to exchange views and expectations on safety related issues. Meetings however frequently take place on a drop in basis on the initiative of the licensees to inform about specific plans, personnel changes in corporate management, or upcoming activities that could engage NRC resources. The NRC headquarters management also periodically meet with groups of licensee executives to discuss generic issues and participate in information exchange meetings with NEI, utility groups, owners groups, citizen groups etc. Some of these are public meetings. At the meetings with NEI different industrial initiatives are discussed, such as Industry's work on safety culture.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The NRC regulatory process, especially as manifested in the Reactor Oversight Process (ROP) is a formal process, documented in detail including specified acceptance criteria and enforcement plans. This risk informed, performance based process is predictable and transparent. The publicly accessible NRC webpage for the ROP has active links to all power reactor assessments, inspection schedules and results. The input data for the facility assessments, including inspection report information and performance indicators are linked to those web pages. The NRC offices share databases that allow the offices to be linked and share information. This prevents subjectivity in decision making by individual staff members. Furthermore, NRR performs an annual performance review of the regional implementation of the ROP. In the implementation of ROP, the NRC's management provides guidance and control that emphasizes consistent use of the process at all regions and plants. Active rotation of staff contributes to consistency, objectivity and staff development.

Since implementation of the ROP, systematic processes are being used for continuous enhancement of its effectiveness. Modifications in the ROP are carefully prepared, justified and discussed with stakeholders. The NRC is much aware of the risks associated with making modifications to well established practices.

Changes to regulatory requirements may have to be justified on a cost benefit basis and all changes have to be processed according to documented procedures. However, changes necessary for adequate protection, to bring a licensee into compliance with its license or defining or redefining what is necessary for adequate protection are not subject to cost-benefit analysis. The change process is fully transparent and includes consultation with stakeholders by means of hearings, publication on the NRC website as well as in the Federal Register.

Some features of the regulatory system aiming at providing stability, consistency and predictability such as the backfit rule have a potential to work in the opposite direction, namely that the regulatory system is not responsive and flexible enough to accommodate new insights and international developments. The NRC has to be aware of this risk.

3.7. SAFETY RELATED RECORDS

The NRC has a well developed electronic documentation control system: The Agency wide Documents Access and Management System (ADAMS) where all unclassified, non-safeguards official program-related records are stored. Most of these documents are also publicly available through the NRC´s external website and the ADAMS public libraries. All program-related documents have to be put into

ADAMS as soon as they have been finalised and approved and in that way become official records. Public documents have to be made available within six days after approval.

Classified and safeguards information are kept in a different system. However, only a very small portion of the NRC´s documents have this classification.

ADAMS went into operation in the year 2000. Older documents are either scanned or kept on microfiches. If a new project requires access to historical documentation of the subject matter, these documents are scanned and put into ADAMS. Hardcopy documents coming in to the agency are now always scanned and put into the ADAMS. All correspondence with interested parties is done electronically and the original documents receive an electronic identification.

Archiving is managed according to the rules of National Archives and Records Administration (NARA) and the General Services Administration. Records are maintained, distributed, preserved or destroyed according to those rules. A large number of historical records have been transferred on microfiche to the National Archive.

There are several requirements on the licensees in 10 CFR 50 on maintaining safety related records For instance, Appendix A to the license "Technical Specifications" contains requirements on keeping records of offsite dose calculations. 10 CFR Part 20 requires records of occupational exposures and releases of radioactive effluents to the environment. 10 CFR 50.71 requires maintenance and making of records, especially subsection (e) that requires the licensee´s Final Safety Analysis Report to be kept up to date and reflect all modifications and changes which have been made to the licensing basis.

The NRC´s resident inspectors and project managers regularly check how the licensees maintain their records.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The NRC has high standards for itself and puts a lot of emphasis on openness and transparency in the conduct of regulatory activities. The most prominent communication tool is the agency´s website where major regulatory decisions, inspections reports, safety assessment reports etc. are posted. The public ADAMS library also contains most of the official documents developed by NRC since implementation of the system.

There is an established process to respond quickly to public requests made under The Freedom of Information Act. The NRC is helpful in making requested copies of official documents.

The rules and procedures on licensing and rulemaking contain mandatory consultation with interested parties in the form of hearings and publishing of drafts for comments in the Federal Register. The NRC periodically and as required, invites the public and media in the vicinity of the NPPs to informational meetings where regional staff explains how NRC is working and how safety issues are addressed. These meetings are advertised on the NRC website as well as in local newspapers.

In cases of major events at the NPPs or other issues of significant public interest, the NRC develops specific communications plans. These plans could include public meetings, in the vicinity of a nuclear facility, at the HQ or at a regional office, issuing of press releases or development of a specific webpage on the external website.

Communications with Congress take place mainly through letters and the annual Performance and Accountability Report. NRC typically receives 50-100 written inquiries per year from members of Congress, and NRC provides written answers to these. The Chairman and the Commissioners could also be called to answer questions before a Congressional committee. Communication with other federal agencies take place through planned meetings according to the MoU and sharing of public reports.

Liaison with industry organisations such as NEI and INPO are strictly regulated. Meetings with NEI and INPO are open to the public, unless there is some sensitive issue, in which case it is only the portion of the meeting that deals with the sensitive issue that is closed. There is a detailed Memorandum of Agreement with INPO specifying the roles, responsibilities, exchanges and interfaces in mutual interest activities such as exchange or operational and construction experience data, inspection and plant evaluation activities, training related activities and incident investigation activities. Regular meetings are foreseen between the parties in order to exchange information. Minutes and documents are kept in the public domain. Proprietary information should be minimized.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

Introduction

The IAEA Safety Requirements publication GS-R-3, issued 2006, defines the requirements for establishing, implementing, assessing and continually improving a Management System that integrates safety, health, environmental, security, quality and economic elements. This integration aims to ensure that safety is properly taken into account in all the activities of an organization in order to ensure the protection of people and the environment. The requirements are applicable on Management Systems for industrial nuclear facilities and activities as well as for regulation of such facilities and activities. GS-R-3 with its integrative and process based approach, emphasis on safety culture promotion and strong focus on continuous improvement can be seen as an evolution of the earlier concepts of Quality Assurance and Quality Management.

Documentation of the Management System

As an outcome of the IRRS self-assessment the NRC has identified that it does not have an overarching document describing the many complex components of the agency´s management system as required by GS-R-3. A draft such Management System Description Document is included in the advanced reference material. This draft document is a good starting point containing many elements of what is required in sections 2.8, 2.9 and 2.10 of GS-R-3 but more work is needed in order to define and describe an integrated Management System. Basically the NRC needs to confirm and describe its organizational wide core processes and support processes needed to achieve the organizational objectives and deliver the products of the organization. These process descriptions need to be organized in a map showing how the processes relate to each other and how they interact in order to deliver the expected products of the organization. There are many examples of how such a map can be arranged and there is no standard solution that fits all organizations. The map has to be tailored to the needs of each organization. The basic idea is that the map should provide a convenient overview of the processes from activity planning, over performance of activities, delivering of products to assessment of achievements and experience feedback. This overall flow should also be reflected in each specific process description together with inputs to the process and outputs (see also GS-R-3, 5.4). The core processes should be generic and supported by necessary subprocesses where the ways of doing business need to be differentiated depending on different needs. Management directives, instructions and guidance documents should be linked to each process as needed. There are examples of good information technology solutions making it possible on the intranet to navigate easily in this map structure and quickly find all relevant documents for an activity.

The NRC already has a large number of documents in a five level hierarchy that can be adapted to an integrated management system structure as described above. These existing documents are:

1. Commission level policies and papers;
2. Management Directives and associated handbooks for specific functional areas;
3. Agency level guidance spanning over multiple agency offices;
4. Office-specific implementation guidance, e.g. Office Instructions;
5. More detailed task-specific technical and administrative user guidance for implementation of activities the various divisions.

The proposed major activities and support activities in the Draft Description Document seem to be a good basis for a process map. However further processes may be relevant to consider in this context and the processes should be described in line with GS-R-3, 5.4. Other things the NRC could consider is to supplement the Draft Description Document with a message from the Chairman and provide more details

about how the Management System is assessed, especially how holistic Management System Reviews will be carried out (see below under the section assessment and improvement).

Safety culture promotion

For many years the NRC has worked to promote a strong safety culture in order to ensure achievement of its mission. Over the last few years efforts have focused on coordination and integration of different initiatives and programmes. These efforts are coordinated by the Office of Enforcement. Internally a Safety Culture Task Force in 2009 completed a series of data collection activities to solicit ideas agency wide about enhancing the safety culture. The Task Force also benchmarked external organizations. These ideas have been taken forward in staff training and a number of internal programmes. Regularly (1-4 year intervals) a number of surveys are administered to obtain feedback from employees on the organizational culture. Among these are Human Capital Surveys administered by the US Office of Personnel Management and climate surveys administered through the NRC´s Office of the Inspector General (OIG). The results of the OIG surveys have been interpreted in focus groups and resulting in an action plan. The NRC has been rated the best place to work in the Federal Government as a result of the two last Federal Human Capital surveys and also showed substantial improvement in most areas from one survey to the next.

The NRC has several programmes and processes to promote an open collaborative work environment that encourages all employees to raise concerns without fear of negative consequences. For example, the Open Door Policy allows any employee to initiate a meeting with an NRC manager at any level of the organization, including a Commissioner or the Chairman to discuss any matter of concern to the employee. The Non-Concurrence Process allows employees to have their concerns documented early in the decision making process, responded to, and attached to the document to be approved. The Differing Professional Opinions Programme is a formal process that allows employees and contractors to have their differing views on mission-related issues considered at the highest level in their organizations. This process provides managers with an independent review of the issue and also provides employees with appeal of the decision to the EDO.

Externally the NRC has increased the emphasis of safety culture issues in the ROP by instructing inspectors to be aware potential weaknesses in areas related to safety culture at the plants. Training and formal guidance have been issued to this effect. In 2009 a draft new safety culture statement was proposed to the Commission building on the earlier concept of safety conscious work environment but expanded to be applicable on all licensees and certificate holders and supplemented with new international insights and also to consider security aspects. After a first round of public comment, the statement has been published again in the Federal Register for comment and is expected to be issued in 2011. As soon as the statement is finalized the NRC will review its programme and process for oversight of licensees with respect to the expectations in the policy statement.

Graded approach

The NRC applies the graded approach in several ways. The most obvious is the risk informed, performance based Reactor Oversight Process that is designed to focus regulatory resources on the plants with the highest potential risk for the environment and the safety performance of these plants. This focus is also reflected in the detailed and extensive Management Directive and number of instructions associated with this process. Another example of the graded approach is the licensing procedures which are much more extensive and detailed for the major nuclear facilities than for facilities with less potential environmental impact.

Management commitment

Management responsibilities and authorities are well outlined and described in the comprehensive set of Management Directives (MD) which address all major regulatory and support activities of the agency.

Individual contracts exist with office and division directors on what should be achieved every year in accordance with the Strategic Plan. Management and staff performance is assessed formally on a regular basis through assessment tools developed and reviewed by the US Office of Personnel Management (OPM). NRC annually evaluates and documents executives' performance against both key programmatic objectives and leadership indicators and has received full certification from the OPM for its Senior Executive Service appraisal system.

Expectations of interested parties

As mentioned in section 3.8, the NRC conducts a large number of different meetings with its stakeholders. The meetings range from formal meetings associated with the Reactor Oversight Process and licensing of nuclear facilities to more informal information meetings conducted with the public and media in the vicinity of the NPPs. The well known Regulatory Information Conference is held in Washington every year. The public has ample opportunities to voice concerns and make recommendations at hearings and to petition the NRC. The NRC´s public website is another tool for communicating expectations. The NRC reviews and evaluates all comments from the stakeholders and provides answers.

Activities for open communication and public involvement are documented in the recently published Open Government Plan which is an initiative of the Obama administration.

Organizational policies

The NRC puts much emphasis on commitment to its corporate values and ethics. The values: Integrity, Service, Openness, Commitment, Cooperation, Excellence and Respect are advertised all over the HQ office and the staff seems highly aware of these values. The practical meaning of the values are discussed and followed up in focus groups, training and in management assessments of staff performance. There are also principles of good regulation which are similarly emphasized for the regulatory staff: Independence, Openness, Efficiency, Clarity and Reliability.

Activity planning

The NRC has a comprehensive and rigorous activity planning process which is directly connected with the budget process. The planning involves staff from all parts of the organization. It is a formal process aligned with the five year Strategic Plan (currently spanning 2008-2013). The Strategic Plan is public and widely distributed. It describes how the NRC intends to accomplish its mission and establishes the Commission´s strategic direction by defining the vision, goals and outcomes it intends to pursue. The plan focuses on the goals to be achieved within the three main areas: safety, security and organizational excellence. The goals and strategic outcomes are informed by an environmental scan of expected events and developments during the five year period. At the operating plan level the goals are quite detailed. The goals are reviewed every year but the Strategic Plan itself is not reissued. The implementation of the Plan is measured through performance measures developed for the annual Performance Budget and reported in the annual Performance and Accountability Report.

The Performance Budget (NUREG-1100) is published each year. It describes the programmes, goals and outcome measures, the budget estimates, and the distribution of the budget over the programme areas. The performance budget is translated into operating plans for each office.

Every fiscal year the NRC evaluates its own performance against the previous year´s Performance Budget. The results are presented in the Performance and Accountability Report (NUREG-1542). This report includes:

- The audited financial statements;
- The results on an evaluation of management controls;
- A report on NRC´s success in achieving its strategic and performance goals;

- The results of any significant assessments of programme activities carried out during the reporting period;
- The NRC´s Inspector General´s discussion of the most serious management challenges facing the agency and how the NRC is addressing them.

During the Fiscal Year, performance indicators are used to follow up the progress of the operating plan. The results are available on the internal website. Indicators are green, yellow or red depending on how the performance is progressing against targets. The results are discussed at a quarterly senior management meeting and reported to the EDO. This reporting lays the basis for reallocation of resources between programme areas if needed. The Office of the Inspector General has a similar planning and follow up process but completely independent from the rest of the organization.

Human resources and knowledge management

See section 3.3

Control of documents and records

See section 3.7

Assessment and improvement

Several types of independent audits are regularly done of the NRC. The US Government Accountability Office (GAO) working for Congress performs audits on an ad hoc basis on own initiative or other governmental initiative. GAO screens other audit results and initiates its own audits if there are major concerns, one example is how NRC dealt with the issue of buried piping at the nuclear sites. The US Office of Management and Budget (OMB) required the NRC to perform a self-assessment of its performance using a special tool: the Programme Assessment Rating Tool. OMB reviewed the results of this self-assessment. The Agency also established the Senior Performance Official (SPO) rating process. Under the SPO process, a formal assessment of organizational performance is conducted annually. This assessment process includes a midyear discussion between counterparts to discuss progress in meeting operating plan outcomes, progress on addressing SPO feedback from the previous year, and information regarding challenges to be addressed before the end of the current year. According to an Act from 1982, the NRC Chairman also has to certify every year with reasonable assurance the NRC meets the objectives of 1/ effective/efficient operations, 2/ reliable financial reporting and 3/compliance with laws and regulations. Each office has to provide input to this assurance.

Internal auditing is conducted by the NRC´s Office of the Inspector General (OIG) which is established by law as an independent entity. This office has its own budget, policies and procedures separate from other parts of the organization. The Inspector General reports both to the Chairman and to Congress. The office has a staff of 58 and conducts both audits and investigations.

Audits are conducted according to an annual plan concentrating on high risk areas, i.e. areas that have a high potential for not meeting programme goals. Certain audits have to be conducted on an annual basis, input to the annual plan is also provided by other offices within NRC and other stakeholders. The OIG conducts about 25 audits every year with its own resources and with contractors. Most of the auditors are analysts or accountants, but are assisted by a senior engineer/technical advisor. Contractors are used in cases where special technical expertise is needed, but not available on the OIG staff. The conduct of audits is regulated by Government Auditing Standards issued by the GAO. There is also a Management Directive on how audit results shall be processed within the agency and how deficiencies are resolved and closed. All audit reports are public documents. The whole process to close an audit takes 6-8 months.

The OIG may also initiate investigations covering a broad range of allegations concerning criminal wrongdoing, administrative misconduct or mismanagement. OIG investigators have a background in law enforcement and are supported by a senior engineer/technical advisor.

Other NRC offices occasionally carry out audits on own initiative. So called Lean Six Sigma Teams have been assigned to look into specific activities. One example is to review the hiring procedures at NRC.

GS-R-3 puts a special emphasis on regular Management System Reviews in a holistic perspective in order to ensure the continuing stability and effectiveness of the management system. The focus of the review is the results delivered and objectives achieved by the processes of the organization. Therefore the review needs to overlook the process map and check if there are any not-effective components somewhere in the system which can affect the performance of the whole system.

As understood by the team, the NRC has no formal procedure or methodology in place corresponding to the holistic Management System Reviews as intended in GS-R-3. The Reasonable Assurance Process seems to carry a similar idea but is focused more on compliance than on identifying opportunities for improvement of the internal processes. A prerequisite for a Management System Review is also to have a process map in place, something that the NRC is currently lacking. The NRC is therefore recommended to develop in due time a methodology for and implement Management System Reviews at planned intervals and to describe this procedure in its Management System Description Document.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-3 para 5.1. states that *"The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved."*
(2)	**BASIS:** GS-R-3 para 5.2. states that *"The sequence and interactions of the processes shall be determined."*
(3)	**BASIS:** GS-R-3 para 5.3. states that *"The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented."*
(4)	**BASIS:** GS-R-3 para 5.4. states that *"The development of each process shall ensure that the following are achieved:* *—Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed.* *—Hazards and risks are identified, together with any necessary mitigatory actions.* *—Interactions with interfacing processes are identified.* *—Process inputs are identified.* *—The process flow is described.* *—Process outputs (products) are identified.* *—Process measurement criteria are established."*
(5)	**BASIS:** GS-R-3 para 5.5. states that *"The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities."*
R1	**Recommendation: The NRC should identify/confirm and describe its organizational wide core processes and support processes and include process inputs, flows and outputs (e.g., develop a process map) in order to confirm and document a fully integrated Management System.**
(1)	**BASIS:** GS-R-3 para 6.7. states that *"A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished."*
(2)	**BASIS:** GS-R-3 para 6.8. states that *"The review shall cover but shall not be limited to:* *—Outputs from all forms of assessment;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	—Results delivered and objectives achieved by the organization and its processes; *—Non-conformances and corrective and preventive actions;* *—Lessons learned from other organizations;* *—Opportunities for improvement."*
(3)	**BASIS:** GS-R-3 para 6.9. states that *"Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner."*
(4)	**BASIS:** GS-R-3 para 6.10. states that *"The review shall identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and processes."*
R2	**Recommendation: The NRC should develop a methodology and implement a holistic Management System Review at planned intervals to ensure the continuing effectiveness of the management system.**
(1)	**BASIS:** GS-R-3 para 2.8. states that *"The documentation of the management system shall include the following:* *—The policy statements of the organization;* *—A description of the management system;* *—A description of the structure of the organization;* *—A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* *—A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved."*
(2)	**BASIS:** GS-R-3 para 2.9. states that *"The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use."*
(3)	**BASIS:** GS-R-3 para 2.10. states that *"The documentation of the management system shall reflect:* *—The characteristics of the organization and its activities;* *—The complexities of processes and their interactions."*
S3	**Suggestion: The NRC should continue to develop its draft Management System Description Document and accommodate in this document the results of the recommendations given above.**
(1)	**BASIS:** GS-R-3 para 2.5. states that *"The management system shall be used to promote and support a strong safety culture by:* *—Ensuring a common understanding of the key aspects of safety culture within the organization;* *—Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* *—Reinforcing a learning and questioning attitude at all levels of the organization;* *—Providing the means by which the organization continually seeks to develop and improve its safety culture."*
GP4	**Good practice: The NRC´s Open Door Policy, Non Concurrence Process and Differing Professional Opinions Programme are good instruments for reinforcing a questioning attitude at all levels of the organization and thereby promoting safety culture. [See www.nrc.gov/about-nrc/values for more information].**

5. AUTHORIZATION

This section reviews authorizations for nuclear facilities and activities using the requirements of GSR Part 1 and the associated guides as the basis.

5.1. LEGAL BASIS

Responsibility for authorization was originally assigned to the Atomic Energy Commission by the Atomic Energy Act (AEA) of 1954. However, the Energy Reorganization Act of 1974 amended the AEA and established the Nuclear Regulatory Commission, (NRC) abolished the Atomic Energy Commission and transferred all its licensing and related regulatory functions to the NRC, including those assigned to the Atomic Safety and Licensing Board Panel (ASLBP).

The AEA, as amended by subsequent legislation, remains the primary authority for the NRC's imp1ementing regulations (set forth in Title 10 of the Code of Federal Regulations) and NRC activities. The amended AEA will be called the Act in this report. The Act specified the agency's organization and the nuclear materials and nuclear facilities that the NRC is to license and regulate. Further, it established the processes for issuing NRC licenses (including public hearings), inspecting facilities, promulgating regulations and imposing enforcement sanctions.

According to Sections 103, 183, 186 and 187, the NRC has the authority: to issue, amend or revoke authorizations and to set conditions.

For nuclear facilities and activities, a prior authorization shall be in force. Section 101 "License Required" of the Act "It shall be unlawful, (…) for any person within the United States to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import, or export any utilization or production facility except under and in accordance with a license issued by the Commission pursuant to section 103 or section 104". However, the Act does not give the NRC authority over military uses of radioactive materials, except for limited circumstances.

5.2. TYPES OF AUTHORIZATIONS

The IRRS team noted that the NRC is authorized to license and to regulate nuclear facilities (e.g., commercial nuclear power reactors, research reactors, uranium enrichment facilities, fuel fabrication facilities, spent nuclear fuel storage facilities, high-level radioactive waste disposal facilities) and nuclear materials (radioactive source material, special nuclear material and byproduct material).

NRC regulations establish the process of applying, for example, for a license, amending a license after it is issued, extending a power reactor license (10CFR Part 54) and decommissioning for a nuclear power reactor (10CFR 50.82). Each NRC license is issued for a specific period of time; for example, reactor operating licenses are issued for a period of 40 years and may be renewed for a period of up to 20 years. The issuance and amendment of reactor operating licenses is governed by NRC regulations in 10 CFR Part 50; the renewal of reactor operating licenses is governed by 10 CFR Part 54. More recently, NRC has promulgated regulations in 10 CFR Part 52 that apply to the issuance of Early Site Permits, Design Certifications, and Combined Operating Licenses (COLs). Some Early Site Permits and Design Certifications have already been granted following this process.

5.3. REQUIREMENTS FOR AUTHORIZATION

Prior to the granting of an authorization (a license), the applicant is required to submit a detailed demonstration of safety. A final safety analysis report (FSAR) must be included in each application for a license to operate a nuclear reactor facility. The FSAR describes the facility, presents the design bases and

the limits on plant operation, and provides a safety analysis of the structures, systems and components and of the facility as a whole. Detailed requirements relating to FSAR content are established in 10 CFR 50.34(b). The applicant's FSAR is the principal document upon which the NRC bases its safety evaluation supporting the issuance of a facility operating license. The updated FSAR (updated FSAR or UFSAR) incorporates changes made in accordance with 10 CFR 50.71(e). The UFSAR serves as a major source of information on the current plant design and supporting analyses, and is considered part of the current licensing basis.

The licensing basis for a plant is comprised of selected information exchanged between a licensee and the NRC relating to design features, equipment descriptions, operating practices, site characteristics, programmes and procedures, and other factors that describe a plant's design, construction, maintenance, and operation. Licensing basis information is contained in a variety of document types (e.g., final safety analysis report, license amendments, etc.). NRC regulations related to license renewal (10 CFR 54.3) define a facility's current licensing basis (CLB) as follows:

"The set of NRC requirements applicable to a specific plant and a licensee's written, commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports."

5.4. THE INITIAL LICENSE

The Act, (Sec. 182. License Applications) and NRC regulations require that nuclear power plant operating license applications include technical specifications (tech specs) relating to the amount, kind, and source of special nuclear material required, the place of usage, the facility's characteristics, and other information, as well as the basis for each tech specs proposed. When a reactor operating license is issued by the NRC, it typically contains tech specs that define mandatory operating limits and other requirements and actions that must be taken to ensure safe operation. Technical specifications content are specified in Section 10 CFR 50.36, which must include: (1) safety limits, limiting safety system settings and limiting control settings; (2) limiting conditions for operation; (3) surveillance requirements; (4) design features; and (5) administrative controls. The Act (Sec. 182 "License Applications") specifies that technical specifications are a part of the license, so, prior NRC approval is required to deviate from technical specifications requirements.

The IRRS team discussed and reviewed the license of one NPP was found to be consistent with NRC's regulatory approach.

5.5. LICENSE AMENDMENTS

The NRC has in place procedures for subsequent amendment, renewal, suspension or revocation of the initial authorization.

The requests for amendments are subjected to review prior to acceptance, in order to minimize expending significant NRC staff resources reviewing submittals that don't have adequate technical information. The Project Manager with the support of the technical branches carries out this review, usually within 25 working days after submittal of an application. A request will be accepted for review when it is

determined that the application contain sufficient information to allow a detailed technical review. If significant deficiencies are detected, additional information has to be provided or the request is returned to the applicant.

Deficiencies in submitting complete and accurate information concerning safety system design basis, safety margins, identification of the limiting situation or worst case analysis, failures to identify non compliance with the acceptance criteria or other relevant deficiencies can be treated as performance deficiencies and as findings in the Reactor Oversight Process, depending on the safety significance. Other relevant deficiencies that cannot be considered as performance deficiencies are communicated to the licensees to correct the situation as well as the licensees' internal process. However written procedures are not in place to make sure that the same criteria are consistently applied in all the cases. In addition, Title 10 of the CFR 50.9(a) requires that information provided to the NRC by a licensee shall be complete and accurate, consequently those failures may be considered violations and are subjected to enforcement actions, depending on the safety significance.

Approximately 600 applications for amendments are received per year and around 95% of the submissions are found to be acceptable for review without supplemental information. The extent of the review and the regulatory controls applied is commensurate with the relative risk associated to the proposed changes.

During the review of license amendment applications, the licensee may commit to implement actions considered by the NRC necessary to ensure that the proposal is acceptable. Those commitments are considered as part of the licensing basis. An audit on the compliance and the licensee management of the commitments is carried out by the NRC Project Manager on a three years basis. If significant deficiencies are detected in this audit, they have to be communicated to the Senior Resident Inspector for inclusion in his inspection report and treated as inspection findings in the Reactor Oversight Process.

All the amendment licensing process is carried out in a transparent manner. The documents provided by the licensee are available to the public and an opportunity for a hearing is provided for all license amendments. The normal process for the hearing is to publish a notice in the Federal Register. If the amendment does not involve consideration of significant hazards, the hearing may be held after the amendment is issued. At the end of the review process the NRC formally records and makes public the decision and the basis of the determination.

5.6. LICENSE RENEWAL

The Atomic Energy Act authorizes the NRC to issue licenses for power reactor to operate for 40 years and allows the license to be renewed. A 40 year term was selected on the basis of economic and antitrust considerations, not for technical limitations. In accordance with the NRC's regulation, a licensee may renew its operating license up to an additional 20 years and may apply for renewal as early as 20 years before expiration of the current license.

The NRC license renewal requirements are based on two key principles:

1) The regulatory process for currently operating plants is adequate to ensure that they will continue to maintain adequate levels of safety during the extended operation, with the exception of detrimental effect of aging on certain systems, structures and components, and a few other issues that may arise during the period of extended operation.
2) The plant's licensing basis is required to be maintained during the renewal term in the same manner and to the same extent as during the original licensing term.

The license renewal proceeds along two tracks, one for review of the safety issues (in accordance with the requirements of 10 CFR Part 54) and the other for the environmental issues (in accordance with 10 CFR Part 51). The extensive guidance prepared by the NRC, with stakeholder involvement, for implementing

the rules has greatly improved the efficiency and effectiveness of the process for an applicant to prepare the application and for the NRC staff to perform its review.

Public participation has extensively been involved in the license renewal process. A number of meetings are held in the vicinity of the plant to provide the public with information on the license renewal process, solicit input on the environmental review, and to provide the results of the NRC's inspections. A hearing process has been held to deal with the concerns by members of the public.

The team discussed extensively with the NRC staff on the aging management programmes and emphasized the need for a continuous learning and vigilant attitudes to capture the symptoms of changes that may appear in the plant structures, systems and components due to the aging effects and also to the ability of the licensee to detect and manage those situations in order to assure a safe operation during the entire life of the plant.

Also the aging effects on some non safety related structures, systems and components were addressed due to the importance of their safety function into the plant decommissioning phase. The IRRS team shared international experience where degradation of safety margins could lead to failure to maintain adequate control of stored radioactive materials as it is the case of the radioactive waste treatment systems. In addition, some attention should be paid to the maintenance and status conditions of non safety structures, systems, and components because signs of bad conditions on them can be an indication of poor aging managements that can affect safety. The need to reinforce the inspection programme when a plant enter in the extended operation period should be considered.

With the possibility of life extension of plants being considered beyond 60 years, consideration needs to be given to the performance of those systems required to provide an effective safety function during power operation but also in the decommissioning phase of the plant.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part-1 1 § 4.4 states that** *"The regulatory body shall established, either directly or through authorized parties, provisions for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and informing the decision making process."*
GP5	**Good Practices**: **The NRC licensing process, and in particular the license renewal process is carried out in a very transparent manner, providing opportunities for hearing and public involvement. A number of meetings are held in the vicinity of the plants to provide the public with information on the license renewal process, solicit input on the environmental review, and to provide the results of the NRC's inspections.**

5.7. TERMINATION OF LICENSE

NRC regulations (10CFR 50.75) establishes requirements for indicating how a licensee will provide reasonable assurance that funds will be available for the decommissioning process. During the operating licensing process, each power reactor applicant shall submit a decommissioning report. The report must contain a certification that financial assurance for decommissioning will be (for a license applicant), or has been (for a license holder), provided. The amount stated in the applicant's or licensee's certification may be based on a cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements must be submitted to NRC.

When a licensee has determined to permanently cease operations the licensee shall submit, to the NRC, a written certification of permanent cessation of operations. Once fuel has been permanently removed from the reactor vessel, the licensee shall submit a written certification of permanent fuel removal. Then operation of the reactor or emplacement or retention of fuel into the reactor vessel is no longer authorized.

Decommissioning will be completed within 60 years of permanent cessation of operations, although decommissioning beyond 60 years may be approved by the Commission.

Prior to or within 2 years following permanent cessation of operations, the licensee shall submit a post-shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The report must include a description of the planned decommissioning activities along with a schedule for their accomplishment, an estimate of expected costs, and a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements.

The IRRS team reviewed the process for License termination and discussed examples of its implementation with NRC staff. This included: license termination and licensing of a new licensee at an existing site; oversight of a licensee's financial viability; oversight of continued adequacy of decommissioning funds for each site; and adequacy of funding for the storage and transfer of spent fuel off site. No issues of significance were identified during the review.

5.8. EXEMPTIONS

The exemptions are legal reliefs to licensees from a requirement of the regulation. A licensee may request an exemption in the cases authorized by law. The application must demonstrate that the situation does not represent an undue risk and involves special circumstances as discussed in 10 CFR 50.12(a)(2). The review process for the exemptions is similar to the review process for the amendments, except that hearing opportunities are not considered.

5.9. RELIEF REQUEST

When a licensee finds that is not possible to meet the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, as required by 10 CFR 50.55a, there are provisions for requesting relief. The most common of relief concern the Code, Section XI, In-service Inspection (ISI) and In service Testing (IST).

5.10. ORDERS

The NRC may issue written orders to: (1) modify, suspend or revoke a license; (2) cease and desist from a given practice or activity; or (3) take such actions as may be proper. These orders may be immediately effective, but the licensee or any interested parties may ask for a hearing when received.

The team reviewed a Confirmatory Order to modify the license of a plant, issued after a previous contact with the licensee was established and it consented to the license modification and waived its right to a hearing in this order. The team also reviewed another Order issued to require a licensee to take some actions needed to ensure full compliance with the applicable Federal Emergency Management Agency (FEMA) regulation. In this case, as there was no previous licensee consent, the possibility of a hearing and of a request for the extension of time to accomplish the required actions was established in the Order.

Also, NRC regulation 10CFR Part 21 requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any licensed facility or activity who obtains information indicating: (a) that the facility, activity or basic component supplied to such facility or activity fails to comply with any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect.

Consequently, the NRC may also issue orders to unlicensed persons, including vendors, contractors, and their employees. The team reviewed a confirmatory order to a contractor related a violation to 10 CFR

50.7 “Employee Protection”. The NRC ordered this contractor to issue a written communication from contractor’s senior executive to its employees, involved in nuclear services, addressing a decision from U.S. Department Labor Administrative Review Board. Another was reviewed by the team where a confirmatory order was issued to an individual, prohibiting his involvement in NRC licensed activities because he deliberately provided inaccurate information (10CFR 50.5 “Deliberate misconduct”) causing the installation to be in violation of 10CFR 50.9 (Completeness and Accuracy of Information)”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part-1 1 § 2.13 states that** *“The regulatory body shall conferred with the legal authority to require an authorized party or an applicant... (a) all necessary information, including information from suppliers”*
GP6	**Good Practice: Vendors, contractors, or any individual providing services to the nuclear industry are required to inform on any failure of a facility or activity to comply with any applicable rule, regulation, order, or license, or if any basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to the NRC. The NRC has the authority for issuing orders to vendors and contractors to enforce this regulation.**

5.11. OPERATORS LICENSES

The NRC authorize according to 10 CFR Part 55 selected plant personnel who control the reactivity or power level of the reactor (called licensed operators), and senior operators who direct the activities of licensed operators but are also permitted to manipulate the controls. No other personnel are authorized or licensed by the NRC, but most key positions are subject to specific qualification, training and experience requirements, according to 10 CFR 50.120.

In both 10 CFR Part 55 and 10 CFR 50.120, The training programme must be derived from a systematic approach to training, as defined in 10 CFR 55.4, and has to provide qualified personnel to operate and maintain the facility in a safe manner in all mode of operation. The training programme must be periodically evaluated and revised as appropriated to reflect industry experience as well as changes to the facility, procedures, regulations and quality assurance requirements.

The candidates to be licensed operators or senior licensed operators in accordance with 10 CFR Part 55 have to be examined by the NRC before their licenses are granted. The exams include written, simulator and plant tests. The relevant matters on reactor physics, transient, accident analysis, radiation safety, operating and emergency procedures, and emergency planning are tested in the exams.

As a consequence of the training programme updating, the licensed operators and the senior licensed operator are trained in new scenarios, including beyond design basis events, during their retraining programmes. The team was informed that the initial training also cover those matters. However, they are not tested in the NRC examination programme.

The initial training of licensed operators and senior licensed operator to address beyond design basis are not tested in the NRC examination programme. This additional training was reported to be addressed in Licensee training prior to these personnel being authorized to operate the plant. However NRC does not verify itself that this training had been completed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part-1 1 § 4.30 states that** *“The regulatory body shall verify, by appropriated means, the competence of individuals having responsibilities for the safety of authorized facilities and activities”*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S4	**Suggestion: The NRC should develop means to verify that the new operators have received adequate training on management of severe accidents.**

6. REVIEW AND ASSESSMENT

6.1. ORGANIZATIONAL ASPECTS OF THE REVIEW AND ASSESSMENT PROCESSES

Discussion was focused to examine how a large regulatory body is coordinated in activities related to review and assessment, and how it is ensured that different parts of the NRC combine their expertise to issue authorizations in timely manner.

Internal organizational matters of the review are specified in office instructions (OI). OI LIC-101 License Amendment Review Procedures were reviewed more in detail during the IRRS mission. Any submission requiring licensing action is managed as a project under control of a project manager (PM), who is an appointed expert from the Division of Operating Reactor Licensing. PM coordinates the whole process of review and assessment and is responsible for high quality results to be achieved in timely manner. There are currently about 50 PMs appointed in the reactor licensing division. PMs in coordination with branch chiefs establish the review team across the divisions/branches.

Establishment of contacts with the licensee by means of NRC regional offices and PMs facilitates the review and assessment process. In case of a need it is possible to use services of NRC contractors or set up priorities based either on safety or economical implications of the submission. Adequate management of the process and sufficient resources available for the review and assessment is monitored through relevant performance indicators (related to number of actions completed in timely manner and improvement of the average age of actions) which include the quantitative targets.

There is no legally imposed time limit for finalizing the review and assessment. However, in accordance with internal rules the process normally should not exceed 1 year, for complex submissions up to 2 years. For “urgent” submissions such as relief from the Technical Specifications the schedule is coordinated with the licensee. The initial acceptance review (performed typically within a month according to OI LIC-109 Acceptance Review Procedures) ensures compliance with the basic conditions for detailed review. Thanks to well developed system of guidance documents the number of cases with non-accepted applications is very low. Usually in case of some NRC reservations the licensee himself decides to withdraw the submission. As demonstrated in the NRR Quarterly Performance Plan Report, all performance indicators relevant for reviews in timely manner are performed better than set up in the targets.

There is an electronic project management system in place monitoring the actual status of the projects. The system has been implemented since 3 years and is continuously improved. The system is an important management tool, providing for on-line checking the status of individual tasks and indicating risks of project implementation.

Although the whole process of review and assessment seems to be well controlled, there were several cases discussed during the mission where the expected duration of review was exceeded (like Duke Energy case presented in the Advance Reference Material, or other two specific cases discussed during the IRRS mission – see subsection 6.13). It was clarified that the reviews may take longer for a number of reasons including the complexity of the review, the safety significance of the proposal and the potential policy issues that they pose. These more challenging reviews are frequently discussed at higher levels of management. Observed exceptional delays associated with some major submissions were justified to be caused by time needed to resolve open issues rather than by limited NRC manpower.

6.2. TECHNICAL ASPECTS OF REVIEW AND ASSESSMENT AND UTILIZATION OF LESSONS LEARNED

Authorization submittals are reviewed and assessed by the NRC’s staff in accordance with clearly defined procedures. The NRC has developed Standard Review Plans (SRPs) for reviewing various types of

licensee submittals to ensure consistency of NRC staff reviews and to ensure the technical adequacy of the licensee's submittal. According to NRC regulations, the SRP was issued to establish criteria that the NRC staff use in evaluating whether an applicant/licensee meets the commission's regulations. The SRP contains guidance for NRC staff reviewers for performing safety reviews for applications to construct or operate nuclear power plants, or to obtain operating license amendments. SRPs address: (1) responsibilities of NRC staff reviewers; (2) matters that are reviewed; (3) the commission's regulations and acceptance criteria necessary for the review; (4) how the review is accomplished; (5) the conclusions that are appropriate; and (6) implementation requirements.

NUREG-0800, NUREG-1800, NUREG-1555, Supplement 1, NUREG-1700 and RS-001 were discussed in particular. SRPs are periodically updated (see Module 9 for more details). Additional technical information is available in topical reports (a report on Materials Reliability Program, MRP-169 was looked at as an example). Technical opinions are formed along the review process by individuals within the branches (each branch composed of 8-10 people), individual findings are reviewed and approved by the branch chief, who provides them to the PM for formulation of the decision. The PM also ensures the consistency of any information communicated to the licensee, such as requests for additional information. Routine submissions (like acceptance of a change in Technical Specifications) are approved at the branch level, while for complex submissions (such as license renewal) the authorization is signed in some cases by the office director.

As a part of review and assessment the NRC in complex cases performs independent audit calculations. Computer codes and plant models used for audit calculations may be different from those used by the licensees. More exceptionally the NRC performs or orders to perform confirmatory experiments, but due to their high cost collaboration with the industry or with other countries is often used.

The NRC makes use of the PRA as a basis for risk informed decision making and developed corresponding guidance for the licensees (Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis.”) and the NRC staff (Standard Review Plan NUREG-0800, Chapter 19, “Severe Accidents”). NRC’s PRA models are independent and plant specific and are developed by using NRC’s own PRA computer code SAPHIRE. The PRA models currently applied are Level-1 models for internal events (i.e., transients and LOCAs) occurring at full power operation. Some of the models also include a fire PRA. External events (e.g. earthquakes, external flooding etc.) and other operational modes (i.e., low power and shutdown operation) are not covered. The NRC did not develop Level-2 PRAs. However, NRC is currently working on an extension of its full power Level-1-models focussing on the implementation of (internal) fire and some external hazards such as earthquakes. In addition, the development of a pilot low power and shutdown PRA for BWR6 plants is ongoing. Limited Level-2-PRAs for an estimation of the large early release frequencies of different containment designs are currently under development as well.

High attention is paid to adequate qualification of staff involved in review and assessment. This is done first of all through the qualification program, which includes both general and position specific training (see Module 3 describing general framework for training). In addition, prior to review associated with a specific submission there is a practice that a senior staff or the branch chief shares with new individuals his views on scope and details from review of previous applications. These discussions are controlled by the NRC internal instruction LIC-101 and they are used as standard supervisory practice. Search for precedent licensing actions is also required by the LIC-101. The work planning sheets highlight not only the schedule but also key areas for the review. Senior staff members/mentors can also make peer review on case by case basis. Documentation of previous reviews is electronically searchable. Safety Evaluation Reports from previous cases provide quite detailed source of information. The licensees in their applications usually also refer to lessons learned from previous submissions.

Technical consistency between new and operating reactors is a very important issue at the NRC. When the Commission approved the formation of the Office of New Reactors, they directed the staff to ensure consistency between the offices. A joint office instruction formalizes the communication needed to ensure consistency. This office instruction is COM-114 (NRR)/COM-105 (NRO), "Protocol to Ensure Appropriate Technical, Regulatory and Policy Consistency between the Office of Nuclear Reactor Regulation and the Office of New Reactors." The necessity to utilize lessons learned from review and assessment of operating reactors for licensing of new plants is recognized by the staff, as well as the need of consistency. Communication has been established between the corresponding NRC divisions. Communication with the licensees also contributes to consistency between existing and new reactors, ACRS also addresses the issue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GSR Part 1, 4.48. *"The regulatory body shall record the results and decisions deriving from reviews and assessments, and shall take appropriate action (including enforcement action) as necessary. The results of reviews and assessments shall be used as feedback information for the regulatory process"*
GP7	**Good Practice: The process of sharing lessons learned between NRC offices dealing with operating and new reactors respectively is very well controlled, including establishment of formal links, and provides for systematic future utilization of broad experience gained from supervision of operating reactors.**
(1)	**BASIS:** GSR Part 1, 3.2, *„The features of the global safety regime include:… (e) Multilateral and bilateral cooperation that enhances safety by means of harmonized approaches as well as increased quality and effectiveness of safety reviews and inspections."* GS-G-1.2, art. 3.38 states that *„The regulatory body may decide to perform a limited number of audit calculations to check that the operator has justified a particular aspect of safety correctly, …"* GSR Part 4, 4.71. *"In addition, the regulatory body has to carry out a separate independent verification to satisfy itself that the safety assessment is acceptable and to determine whether it provides an adequate demonstration of whether the legal and regulatory requirements are met."*
GP8	**Good Practice: NRC maintains and utilizes internal capability for performing independent audit calculations by means of deterministic and probabilistic computer codes including development of such codes, and shares the computer codes and relevant experience with other regulatory bodies worldwide.**
(1)	**BASIS:** GSR Part 1, 4.48. *"The regulatory body shall record the results and decisions deriving from reviews and assessments, …. The results of reviews and assessments shall be used as feedback information for the regulatory process."*
GP9	**Good Practice: NRC as a standard practice identifies relevant precedent licensing actions and use them for new submittals. This practice significantly increases the efficiency of the review process by reducing expended resources.**
(1)	**BASIS:** GSR Part 1, 4.26. *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system."*
GP10	**Good Practice: NRC has developed and continuously updates a system of both procedural and technical guidance documents for review and assessment which are**

shared and made available to regulatory bodies worldwide.

6.3. COMMUNICATION WITH THE LICENSEES AND THEIR CONTRACTORS

Due to large number of operating reactors the NRC has in its pipeline correspondingly high but relatively stable number of ongoing licensing actions, typically varying between 600 and 800. In addition to major submittals, such as license renewal or power uprate, the submittals include more routine ones, such as modifications of the technical specifications, relief from the codes and standards, updating of the plant maintenance or piping inspection programme using risk informed approach, and approval of the reload analysis.

Detailed guidance documents available for the licensee (as described in subsection 6.2) significantly facilitate understanding of the regulatory requirements for format, quality and standards for submittals, as demonstrated by low number of non-accepted submittals (about 5 %). Poor quality submittals do not seem to be an issue and if they would appear they either would not be accepted or would be denied. Regular contacts are arranged between a licensing manager of the operator and NRC project manager. PM is assigned to manage all submittals from a given NPP. PM serves as a single contact point for the NPP, communicates directly with the plant and is aware of all potential submissions from that plant. In addition there are provisions to hold meetings (normally open for public) with the licensee prior to his submittal. Such meetings are occasional, case specific. The public is typically represented by the industry rather than by general public.

Even if a licensee/applicant submits a report prepared by a contractor the licensee/applicant is still responsible for the contents of the report. In practice, when a licensee submits a contractor's report, they will typically have the contractor involved in any discussions with the NRC related to the report.

6.4. COOPERATION OF NRC WITH THEIR CONTRACTORS AND OTHER EXTERNAL BODIES

Internal NRC resources are large and they are extensively used for review and assessment. Nevertheless there are provisions for using external contractors in case of lacking internal resources or expertise. Use of external contractors is subject to the decision by the technical staff. There are adequate provisions in place to finance contractors' work. In the area of operating reactors the number of contractors needed for adequate performance of review and assessment is quite limited. Contractors were selected based on their expertise in specific areas (e.g. fire protection, severe accident mitigation, finite element structural analyses). Compliance with 'no conflict of interest' rules was strictly verified. In terms of amount of work the contribution of contractors is however relatively small, less than ~ 10 %. A 'Technical Monitor' is assigned from the NRC staff to communicate with and to control the contractors. For the contractors the same rules apply as for the NRC itself (the audit calculations were discussed in particular). Even if work is performed by the contractor the NRC takes full responsibility for his results.

For operating reactors there is the Advisory Committee on Reactor Safeguards (ACRS) established as the only advisory body. ACRS are also involved in review and assessment of complex submissions, such as application for license renewal, or of fire protection issues. ACRS can also contract consultants to support their evaluations. (See section 3.4 providing further details on the role of ACRS)

The role of cooperation of the NRC with INPO in the area of review and assessment was discussed, in order to ensure that potential conflict of interest is prevented. It was clarified that there is no INPO involvement in review and assessment associated with licensing actions. The NRC has access to INPO reports and NRC cooperation with INPO is limited to sharing information related to operational

experience feedback. Regional NRC inspectors are informed of INPO findings and corrective actions. Another area for cooperation is utilization of INPO training programmes.

There are provisions for involvement of the public in review and assessment. Any information submitted to the NRC shall be publicly available, except proprietary and security sensitive information. Public meeting schedule is available on US NRC web page. Any license amendment submission requiring licensing action is announced in the Federal Register. Afterwards it is left to public to demonstrate their interest in the information. Actual interest of public significantly differs for different NPPs. Involvement of the public is more actively organized in connection with review of Environmental Report (ER), where public meetings are legally required.

6.5. UPDATING OF GUIDANCE DOCUMENTS RELATED TO REVIEW AND ASSESSMENT

The issue addressed in the discussion was how advances in knowledge and assessment methods are reflected in updating the regulations and guides, in particular (but not limited to) of the Standard Review Plans. There are various initiators for the update, e.g. reflection of changes in the regulations, licensee's proposal, or administrative reasons. Recent update in the area of fire protection, which introduced a risk informed approach as an alternative method (as compared to previous purely deterministic approach) was presented as an example. However, in the opinion of the IRRS mission these partial updates do not reflect comprehensively enough recent developments in methods of safety assessment.

IAEA Safety Requirements GSR Part 4 document was referred to as an international standard reflecting development and good practices in the area of safety assessment. Although some requirements of GSR Part 4 are reflected in the existing NRC guidelines and practices, others (e.g. consideration of new scientific and technological development, deterministic analysis of severe accidents, use of validated computer codes, sufficiently detailed documentation of safety assessment) seem not be comprehensively covered.

It was identified that GSR Part 4 should be used as additional source of information for future updates of NRC guidance documents in the area of review and assessment together with general use of IAEA Safety Standards for other areas, as already reflected in the management directive recently drafted.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1, Requirement 14: *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.* *3.2. The features of the global safety regime include: …. (c) Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices;* Further on, GS-G-1.2, art. 3.29 states that *,The regulatory body should require at all times reasonably practicable improvements in the safety of facilities and to this end should periodically review its regulations and guides against scientific and technological advances. "*
S5	**Suggestion: Future updates of the NRC's Standard Review Plans should take into account scientific and technological developments in the area of safety assessment as reflected in the relevant IAEA safety standards.**

6.6. APPROVAL OF COMPUTER CODES AND USE OF BEST PRACTICES FOR SAFETY ANALYSIS

Use of high quality validated computer codes is a precondition for adequate safety analysis. The issue of quality of computer codes used by the licensees or their contractors was also discussed. Regarding the validation of computer codes/models, the industry is responsible for demonstrating the adequacy. In some instances collaborative agreements are entered by the NRC, industry, and other countries to more effectively utilize the resources. When these collaborative agreements involve the NRC and the industry, they are structured to ensure that there is no conflict of interest.

No formalized procedure for certifying the codes is in place, however, the adequacy of the submittal is always evaluated. The review of submittal could include a review of the code, independent calculations with another computer code, or independent bounding calculations. The actual approach for performing the review is determined by the reviewer and the supervisor. The approach taken considers e.g. the significance of the proposal, the reasonableness of the results, and the margins in the analysis. For the deterministic analysis of loss of coolant accidents (LOCA) the NRC in accordance with regulations accepts only use of computer codes which are evaluated and approved by the NRC. Evaluation of other thermal-hydraulic codes is not legally required. However, even though not required by regulation, other thermal hydraulic codes used for transient analyses are also normally approved on a generic basis and limiting conditions for the code's application are specified in the NRC evaluation. A code may also be approved on a plant specific basis as part of a particular license amendment. In either case, the adequacy of a code for a specific application is always confirmed each time the code is used in a licensing action. Non thermal hydraulic codes are normally evaluated as a part of particular licensing action requests. Validity of the approval for analysis codes is not time limited so that use of obsolete evaluation models developed long time ago is not excluded from submissions to the NRC. The IRRS team did not find any reason to apply unique review and approval practice for the LOCA codes as compared with other computer codes.

The issue of unlimited approval of use of codes is closely related to the principle that all NRC approvals are generally valid for the life of the NPP. If the NRC concludes that something is acceptable, it is not legally possible to require a licensee to change even if better methods are available, unless the NRC subsequently demonstrates that there is a significant safety issue associated with that approval. More specifically, if a prior analysis relied on an old computer model and the results of the model show that regulatory limits are met, it is not possible to require the licensee to update their model simply because more advanced models are available. This process is controlled by regulations 10 CFR 50.109. Nevertheless the IRRS team is of opinion that this approach is not in full compliance with the IAEA Safety Standard GSR Part 1, art. 4.45 (6) and 4.45 (15).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GSR Part 1, 4.29 states that *"…The regulatory body stall be able to modify authorizations for safety related purposes. "* GSR Part 1, 4.45 (6) and 4.45 (15) require that (e.g. during assessment associated with license amendment) *"in the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as: …(6) Best practices; …(15) Relevant research and development plans or programmes relating to demonstration of safety; etc."*. Further on, GS-G-1.2, art. 3.17 states that *„…These safety objectives (see footnote 1) and regulatory requirements will themselves be founded on current knowledge as represented by technological developments in all pertinent fields."* GSR Part 4, 4.14. states that *"The calculational methods and computer codes that are used to carry out the safety analysis have to be verified, tested and benchmarked as appropriate to*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	build confidence in their use and their suitability for the intended application."
S6	**Suggestion: NRC should consider limiting its approval of codes submitted by vendors to a specific period of time to ensure the codes are periodically evaluated and updated, as necessary, to reflect lessons learned and the latest knowledge.**

6.7. RADIOLOGICAL ACCEPTANCE CRITERIA AND USE OF ALARA

Another issue related to review and assessment is associated with determination and use of legally established acceptance criteria, in particular of the radiological acceptance criterion for design basis accidents, i.e. 250 mSv effective dose (in accordance with the 10 CFR 50.67). This value is considerably higher than equivalent numbers currently used in many countries, even taking into account large conservatism embedded in demonstration of compliance with the criterion. It may be also recognized that some over-conservative assumptions (like molten core in case of design basis LOCA) can be beneficial for one component of safety (robustness of the containment) but at the same time it may be underestimating potential contribution of other component (ECCS). NRC regulates certain aspects of plant design/operation (e.g., routine emissions) using a combination of limits and ALARA. For design basis accidents, the principal focus is with respect to limits; however, NRC's backfit rule (50.109) establishes an ALARA-like process (cost-benefit analysis) for design modifications. IRRS Team believes that more attention should be paid to the ALARA principle both in setting up the radiological acceptance criteria as well as in assessment acceptability of the results which seems to be exclusively based on not exceeding the upper dose limit.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: GSR Part 1, 4.43 states that "*The regulatory body shall assess all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions … to determine whether radiation risks are as low as reasonably achievable.*" Further on, GS-G-1.2, art. 3.25 states that „*The safety objectives and regulatory requirements should cover, among other things: … —Dose limits and dose constraints (both occupational and public), amount of discharges to the environment and ALARA considerations*".
S7	**Suggestion: NRC should consider proper ways aimed at more direct implementation of ALARA principle in setting up the radiological acceptance criteria for design basis accidents as well as in assessment of acceptability of the results of relevant safety analysis.**

6.8. PROVISIONS FOR INDEPENDENT SAFETY ASSESSMENT BY THE LICENSEE

The IRRS mission requested whether adequate provisions are in place for independent verification of safety by the licensee as an important component of his prime responsibility for safety (IAEA Safety Requirements GSR Part 4).

The current US legislation does not explicitly impose such obligation on the operator and subsequently it is not verified regularly by NRC regulatory activities. The issue of independent verification of the design is addressed through the 18 criteria of 10 CFR 50 Appendix B, in particular Criteria III, Design Control and Criteria 18, Audits. Provisions of these Criteria require performance of design reviews "by individuals or groups other than those who performed the original design, but who may be from the same organization."

Depending on safety significance of the issue the licensee arranges for independent safety assessment. Two such cases were presented to the IRRS mission: a containment damage issue associated with the

steam generator replacement at the Crystal River Unit 3, and corrosion of containment liner at Oyster Creek. In these cases the licensee contracted independent assessment to a qualified organization, and the assessment was subsequently reviewed by the NRC.

The IRRS team considered important that independent verification of safety assessment by the licensees is a regular practice and its appropriate conduct is confirmed as part of the NRC review. The NRC should assess the consistency of the practice required by the 10 CFR 50, Appendix B with the above stated IAEA Requirements. This assessment should also address the scope and level of details required in the licensing amendment documentation, including updated FSAR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GSR Part 4, Requirement 21*"The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body."*
S8	**Suggestion: NRC should assess whether the current regulations adequately provide for an independent verification of the safety assessment under the responsibility of the licensee before its use or submittal to the regulatory body and whether this verification is adequately confirmed by the NRC.**

6.9. ENSURING CONSISTENCY OF REVIEW AND ASSESSMENT FOR VARIOUS DOCUMENTS

In connection with submissions for the license renewal for operating reactors, the NRC has to review two different licensing documents: Environmental Report (ER) (developed in accordance with the Environmental Policy Act), and Updated FSAR (in accordance with the Atomic Energy Act). In general, these documents may contain the same or similar information, in particular in the area of radiological impact of NPP operation on the environment. The issue was raised how to prevent inconsistent or conflicting information in two mentioned documents. However, it was clarified in the discussion that such inconsistency is not at present a real issue for the following reasons:

- Although reviews of two documents are managed by two different PMs, they are normally selected from the same branch and therefore with very good conditions for mutual sharing their views and findings,
- There are detailed guidance documents available for the technical review, NUREG-1555 with its supplement 1 for environmental report, and NUREG-0800 for FSAR,
- NUREG-1555, Supplement 1 requires the ER to address radiological effects of severe accidents (since effects of a license renewal on consequences of design basis accidents were stated to be small and therefore not required to be analysed), and on the other hand severe accidents are not covered by the FSAR.

The bases for limitation of information provided in above mentioned licensing documents were not completely clarified during the IRRS mission. It is therefore advisable to have the issue of consistency in mind if in the future scope of information included in licensing documents will be reconsidered.

The issue of consistency could in principle be also relevant for similar submittals from different NPPs, which are normally reviewed under control of different PMs. It is however believed that the current NRC practice referring to the results from precedent submittals for subsequent reviews is adequate to prevent potential inconsistencies.

6.10. INTERRELATION BETWEEN REVIEW AND ASSESSMENT AND INSPECTIONS

Review and assessment and inspections are interrelated activities that are important for effectiveness and consistency of the NRC regulatory role. Inspections in particular are aimed at verifying the compliance with the NPP design bases or monitoring implementation of agreed actions. On the other hand the results of inspections can initiate in depth review and assessment of identified issues.

During the discussions a number of examples were presented demonstrating the NRC's intent to overcome potential impact of organizational separation of assessment and inspection activities. Periodical meetings are held between headquarters' staff and the inspectors from regions in order to share views and discuss lessons learned. The exchange of information between assessors and inspectors works both directions. For example, compliance with the repair assessment criteria for steam generators or any item of the Technical Specifications is verified by the inspections. Examples were provided of inspection procedures for license renewal inspection and post-approval site inspection (see also subsection 6.13). Another example discussed during the mission was inspection guidance on Component Design Bases Inspection and other related guidance, which include also verification of calculations associated with the modifications of a component. Inspections also verify whether implementation of reviewed changes is performed only after approval by the NRC. In certain cases inspectors participate in the review, and reviewers accompany regional inspector during their inspections. Frequency of site visits by the reviewers varies depending on the issue.

Based on the IRRS discussion it can be concluded that adequate provisions are in place for utilization of assessment and inspection activities in an integrated manner (see also Module 7 of this report for further details).

6.11. PERFORMANCE OF REVIEW AND ASSESSMENT ON REGULAR BASIS

Guidance for periodic safety assessment for operating NPPs is provided in the IAEA Safety Guide NS-G-2.10. A number of IAEA Member States have chosen to use this approach that emphasises the responsibility of the licensee to carry out the assessment. The NRC participated in the Periodic Safety Review (PSR) safety guide development and recognizes the worth of the PSR but an alternative approach has been chosen referring to paragraph 2.7 of the IAEA guide that states "it is recognized that some States prefer alternative arrangements to PSRs. A systematic safety assessment programme dealing with safety issues significant events and changes in safety standards and practices as they arise is one example. This safety guide is not intended to discourage such alternative arrangements". The NRC considers it meets the intent of the PSR safety factors through a comprehensive set of regulations, inspections and safety review programmes. For the IRRS mission, the NRC compared all 14 PSR safety factors including plant design; actual conditions of systems, structures and components; equipment qualification; ageing; deterministic safety analyses; probabilistic safety assessment; hazard analysis; safety performance; use of experience from other plants and research findings; organization and administration; procedures; human factors; emergency planning; radiological impact on the environment to corresponding elements of the US programme in detail. The NRC concludes that its extensive and continuous oversight efforts including the onsite resident inspector program, generic issue identification, systematic evaluation process and licensee responsibilities under 10CFR 50, Appendix B, ensures a level of safety assessment comparable to the PSR process throughout the life of the NPPs and affords adequate protection to the public. Although according to the U.S. Atomic Energy Act the NRC is not required to continuously improve the level of adequate protection in accordance with current safety standards because the Act itself is silent on the concept of continuous improvement, it is believed by the NRC that the US approach to safety provides opportunities for the licensing basis to evolve over time to reflect updated standards and operating experience.

Concerning technical issues, there is an interaction between the NRC, INPO and the different owner groups to provide a coordinated approach. In addition to the NRC, INPO regularly evaluates operation performance through biannual independent assessments. NRC staff routinely review these reports as an

independent check to ensure that NRC processes are capturing similar performance insights. In a meeting with the IRRS team the NRC explained that enhancements to safety are made through rulemaking (Station Blackout, Anticipated Transient without Scram, Maintenance Rule), as well as major safety upgrades at the NPPs that were accomplished in the past. The NRC presented a list of specific examples, that included replacement of steam generators and reactor vessel heads, implementation of a digital feedwater control system, additional emergency diesel generators and upgraded DC systems.

The IRRS team shared with the NRC staff the experience of other countries in dealing with the license renewal process together with a PSR of the plant in order to identify examples of added value of the PSR and the benefits to the licensee of performing a PSR.

First of all, PSR is clearly the responsibility of the licensee. A PSR should provide the licensees understanding of whether adequate safety margins have been maintained, whether the safety margins have been verified with best available methods, and whether the management processes with relevance for safety have been kept current. In addition a PSR has been found valuable for training the young generation to understand and take into account the relevant safety issues.

As already stated the NRC has in place a number of programmes (the analysis of the operating experience, the Reactor Oversight Process, the generic upgrades and regulatory changes, the use of risk informed regulation and the license renewal rule) that are intended to ensure that the goals of the periodic safety review are met and that provide adequate protection to the health and safety of the public, as required by the Atomic Energy Act. Even though, in order to obtain a better insight on the differences and the benefits of the two approaches, further attention should be given to this subject. As an area for improvement, the NRC in its self-assessment identified the need to review the findings from other PSRs more systematically to verify that international experience is fully evaluated for potential applicability to U.S. licensees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GSR Part 1, 4.45. *"In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as: ….(16) Feedback of operating experience nationally and internationally, and especially of relevant operating experience from similar facilities and activities;* GSR Part 1, 4.46. *"For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner…. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach."* Further on, GS-G-1.2, art. 2.19 states that *„While the need for reassessment may arise in a number of ways (see para. 2.25), systematic safety reassessments, termed periodic safety reviews (PSRs), should be carried out by the operator at intervals to review the cumulative effects of ageing of the facility and of modifications, and the implications of operating experience and technical developments."*
S9	**Suggestion: NRC should incorporate lessons learned from Periodic Safety Reviews performed in other countries as an input to the NRC's assessment processes.**

6.12. FEEDBACK OF OPERATING EXPERIENCE

The NRC has developed and implemented a dedicated comprehensive operating experience feedback programme with the purpose to collect, evaluate, communicate, and apply operating experience by taking regulatory actions to help prevent safety-significant events and inform NRC decision making. The NRC

shares the lessons learned from the operating experience internally, with external stakeholders (including INPO), and with the international community.

The programme is coordinated by the Operational Experience Branch, which consists of its clearinghouse team and analysis team. 25 technical review groups are established using technical staff from various parts of the NRC. The clearinghouse makes initial screening of the events, but each event is subsequently reviewed at least by one of the technical review groups. The collection of the events is done via licensees' reports, inspection findings, and morning phone calls from regions and international reports (e.g. INES, IRS). There are about 500 reportable events per year from US NPPs which are screened based on risk significance and qualitative criteria such as potential failure modes not previously considered, or heightened public or governmental interest. For the screened-in events (about 4%) an in-depth investigation including trend and potential CCF analysis is performed, in particular with regard to potential generic implications. In this regard close links were established to the Office of Nuclear Regulatory Research which runs the Accident Sequence Precursor programme and the Generic Issues programme. As a result of event analysis, regulatory actions (e.g. initiation of reactive inspection or issuance of a generic communication) are taken if deemed necessary. Annual reports to the Congress on abnormal occurrences are provided to inform the Congress and the public on reactor events of importance.

All the information concerning operational experience feedback is stored (including events previously screened out) in a comprehensive database which can be used easily via an internal, centralized and well organized website. Due to the large number of operating reactors in the US the database provides unique opportunity for sharing experiences with interested parties both nationally and internationally.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GSR Part 1, 4.45. states that *"In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as: …(16) Feedback of operating experience nationally and internationally, and especially of relevant operating experience from similar facilities and activities;".*
GP11	**Good Practice: NRC has developed and implemented a robust operational experience feedback programme, including also guidance for safety enhancement and corrective actions recommended on the basis of lessons learned. The programme and a unique database are available for sharing experiences with all interested parties both nationally and internationally.**

6.13. IN-DEPTH REVIEW OF SELECTED CASES

Two specific cases illustrating the process and outcomes of the review and assessment were discussed by IRRS mission more in detail.

The first specific example was review and assessment performed in connection with 7 % power uprate (PU) of Millstone Power station; submitted to the NRC for the review in July 2007. Such scope of PU belongs to the so called stretch PU, larger uprates are called extended PU. Submittal by the licensee consisted of summary cover letter and 7 attachments with safety justification of the uprate, including supplemental Environmental Report.

PUs are dealt with by the NRC using the license amendment procedure. RS-001 document is used as technical guidance for the review. Different aspects of PU were assessed in the submittal with reference to applicable regulations, checking compliance with relevant General Design Criteria, etc. In the submission the licensee had to assess about 80 technical areas. Although the rules (acceptance criteria in particular) remain nearly the same as in original licensing, use of advanced methodologies is in general acceptable, except some special cases like determination of the source term.

A large number of NRC specialists (30-40 specialists is an estimate) were involved in the review. This resulted from the fact that 18 NRC technical branches should be involved with several specialists from each of the branches. About 35 requests for additional information were formulated during the review. For stretch PU the internally specified time limit for the review is 9 months from acceptance of submission, for extended PU it is 12 months from acceptance of the submission. If the submission would be combined with significant plant modifications, time for review may be extended. In the given case, the 9 months limit was exceeded (in fact the review took 10 months from NRC acceptance of the submission) because of the licensee's late responses to NRC questions.

The second case was demonstration of the process and the results of a specific review and assessment connected with an operating license renewal, as already described in general terms in subsection 5.7. Specific example discussed during the IRRS mission was license renewal for the Indian Point Energy Center PWR, submitted to the NRC in April 2007.

There is large volume of guidance documents available for the licensees. These documents include industry guidelines on the matter (endorsed by the NRC) and periodically updated Generic Aging Lessons Learned (GALL) report (NUREG-1801) with compilation of the relevant research results and operating experience. The guidance documents specify about 40-50 aging management programmes to be implemented. Lessons learned described in the documents are considered as expectations of the NRC either to be followed or to demonstrate acceptability of exceptions. A submission to the NRC should declare compliance with the guidance documents. Costs of NRC licensing actions are charged to the applicant.

License renewal is based on purely deterministic approach. The NRC review is performed using the relevant Standard Review Plan (NUREG-1800), based on GALL report. The GALL report is periodically updated with the reasons for the update explained in the Technical Basis for Revision. Guidance documents include also technical acceptance criteria (crack size, number of cycles, etc.). Focus of the review is on the safety related long life passive components, since the NRC has determined that active components are adequately covered by existing requirements including the Maintenance Rule (10 CFR 50.65). Industry document defines also the standard format of the submissions.

As described in subsection 5.7 the review of license renewal submittal consists of two parts: first part is review of aging of the components, second part is review of ER, which demonstrates the environmental impact of NPP life extension. Review is controlled by two PMs, respectively. Both of them are selected from the same branch in order to facilitate communication.

In the first part of the submittal compliance with the expectations both at the system level and at the component level should be demonstrated. Part of the submittal also refers to the corresponding update of FSAR. Part of the review of the submittal is on-site audit of information in the license renewal application and site specific operating experience related to aging. Screening methodology and aging management audits took about 3 weeks, with about 10 people present on site each week. Results of the review and assessment were documented in a Safety Evaluation Report, which is subsequently also reviewed by ACRS. Before taking the final decision the SER is provided to the applicant for factual verification with iterations until all open issues are resolved. In parallel an inspection report is developed. Usually there are no implications of the license renewal to plant backfitting; such backfitting should be dealt with as a separate issue.

In the second part of the review the ER is addressed. Supplement 1 of NUREG 1555 is a guidance document relevant for the license renewal. NUREG 1437 is used as a Generic Environmental Impact Statement; product of ER review is a supplement to generic statement.

There are already a large number of license renewals (59) issued by the NRC, 21 applications are currently under review. Standard schedule for licence renewal is 22 months, but actual duration depends mainly on public hearing process. After consideration of all stakeholder inputs the license renewal is

issued by the NRC provided the licensee demonstrated that the regulations were met. In case of opposing public opinion the case proceeds to the court (Atomic Safety and Licensing Board), which gives recommendations to the NRC on final decision. The review of the specific example of the license renewal discussed during the IRRS mission was not yet finished.

The issue of long-term operation and aging management of NPPs was also addressed in one of policy issue discussions. During this discussion the NRC expressed their readiness to participate in the development of the IAEA International Generic Aging Lessons Learned Report. Although further progress in understanding aging processes and their monitoring is needed and reflecting in current research plans, an adequate control of NPP long term operation is considered feasible.

It can be concluded that both specific cases of NRC's review and assessment demonstrate both organizationally and technically very well prepared and managed process. NRC willingness and practical steps towards broad sharing the lessons learned internationally are very much welcome.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: :** GSR Part 1, Requirement 15: *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.."*
GP12	**Good Practice: NRC collects and documents unique generic lessons learned in US from aging management, and is committed to continue to share them with nuclear community through the IAEA and other international channels as essential contribution to maintaining safety during long term operation of NPPs.**

7. INSPECTION

7.1. INSPECTION PROGRAM

NRC's inspection programme is an essential part of the ROP (Reactor Oversight Process). The ROP was developed late 1990's and implemented in early 2000. Reasons for the development of the ROP were the subjectivity of the previous NRC's approach to oversee and assess licensees via for example Systematic Assessment of Licensee Performance (SALP) and inspections on programmatic areas. With a more mature nuclear industry and better utilisation of operating experience, ROP was developed as a more objective tool for NRC to verify that licensees and plants are in compliance with regulatory requirements.

ROP was developed using a risk informed approach to determine areas to be inspected and areas to be followed with performance indicators. The inspections are focused on three key areas: reactor safety, radiation safety, and safeguards. These areas are divided into seven cornerstones, each of which contains inspections to ensure that objectives are being met. Satisfactory licensee performance in the cornerstones is credited with providing reasonable assurance that the reactor is being maintained and operated safely.

Baseline inspections are common to all plants and performed by on site resident inspectors and regional inspectors. The inspection programme will also review the "cross-cutting issues" of human performance, the "safety-conscious work environment," and how the utilities find and fix problems, areas that affect all cornerstones. Supplemental inspections beyond the baseline will be performed at plants with performance below established thresholds, as assessed through information gained from performance indicators and inspections. Additional (reactive) inspections may also be performed in response to a specific event or problem which may arise at a plant. To determine the safety significance of inspections findings, NRC has developed a Significance Determination Process (SDP).

Each calendar quarter, the resident inspectors and the inspection staff in the regional office will review the performance of nuclear power plants based on performance indicators and inspection findings. Every six months, this review will involve a more detailed review including other inputs such as, allegations, operating experience and insights from licensing project managers, for planning of inspections for the following 12-month period, and document this in an assessment letter These annual performance reports will be available to the public on the agency's web site, and the NRC staff will generally hold public meetings with utilities to discuss the previous year's performance at each plant.

The achievement of goals and the implementation of the inspection programme are annually assessed by NRC. This self-assessment includes feedback from inspectors, licensees and the public, as well as, industry working groups. Several new developments and improvements to ROP have resulted from this assessment process. Inspection areas can be created, dropped or adjusted based on self-assessment and results of the ROP.

NRC's inspection programme is described in more detail in NRC's public website and in the Inspection Manual Chapter 2515 and its appendices. IRRS team concludes that NRC's inspection programme to oversee the safety of operating reactors has well defined goals, logical structure and it is well documented and implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: G-S-R-1 states in para 4.50 that *The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	be inspected, in accordance with a graded approach.
GP13	**Good Practice: Inspection programme has clear goals and a logical structure to verify that plants are operated in compliance with the NRC regulations and licence conditions. For more information see following websites:** http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html http://www.nrc.gov/reactors/operating/oversight/program-documents.html#inspection
(1)	**BASIS**: GS-G-1.3 states in para 4.37 that *In order to inform the public of the safety of nuclear installations and of the effectiveness of the regulatory body, findings of inspections and regulatory decisions may be made publicly available. The extent to which such information is made publicly available will depend on the legal provisions in the State concerned.*
GP14	**Good Practice: Inspection procedures, plant specific inspection reports and assessment results are publicly available. For more information see following websites:** http://www.nrc.gov/reactors/operating/oversight/program-documents.html#inspection http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/listofrpts_body.html http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html#plantassess http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/listofasmrpt.html

7.2. INSPECTION AREAS

Inspection areas in the cornerstones cover initiating events, mitigating systems, barrier integrity, emergency preparedness, public radiation safety, occupational radiation safety, and physical protection. In addition to these, baseline inspection programme has separate inspections on licensee's problem identification and resolution (PI&R). The goal of PI&R inspections includes assessing how licensee's self assessment programme is working, and whether safety significant items are timely identified and corrected in all cornerstones.

As described in Inspection Manual Chapter 2515 the programme is designed to be indicative instead of diagnostic. The premise of NRC's inspection programme is that deficiencies in licensee's organisation (resources, responsibilities and authorisations), management system, knowhow and safety culture, manifests themselves in the outcomes of licensee's performance. Therefore, baseline inspection programme does not include specific inspections on these areas. However, NRC has trained inspectors to identify safety culture components and aspects in licensee's performance. These components and aspects are defined in Inspection Manual Chapter 0310 and are related, among other things, to conservative decision making, adequate resources, work control and practices, corrective action program, response to operating experience, conduct of self-assessment, open environment to raise safety concerns etc. IRRS team found the guidance and process very valuable to NRC.

Inspectors have to assess the presence of these cross cutting components in their inspections and oversight on the licensee. When safety significant findings are made, safety culture components or aspects related to the findings are documented in the inspection report. When plant performance assessment is done every six months, these findings are collected and collectively assessed. This process provides tools for NRC to assess the safety culture of the licensee and evaluate licensee's self-assessment on safety culture. In addition to process described above, NRC has established several other processes to provide indications on safety culture, such as the allegations, petitions and discrimination processes.

The Institute of Nuclear Power Plant Operations (INPO) has a role in the area of safety culture and training of personnel. Although the NRC maintains their independence (MOU between NRC and INPO can be found in ADAMS ML060060035) the NRC may be less intrusive if licensee's demonstrate that they are properly discharging their safety obligations through INPO activities. As an example, in the area of safety culture, INPO has provided guidance for all licensees, licensees perform benchmarking self-assessments every two years, and the INPO audits licensees to ensure performance and results are in line with this guidance. Another example is the accreditation process for non-authorized staff, were INPO provides accreditation of training programmes for plant personnel performing maintenance on plants. Given these INPO programmes are in place and are functioning properly, as well as, the risk informed nature of the NRC ROP process, the NRC has decreased its inspection and oversight activities in programmatic areas such as training programmes for plant maintenance personnel. However, if performance issues are identified NRC would increase oversight in these areas.

One specific area the IRRS team concluded that may not be adequately addressed in the inspection programme is provisions for severe accidents. Licensees have established severe accident management guidelines to provide adequate measures to cope with severe accidents. However, it is not clear how the performance of the licensee along these guidelines is verified in the current inspection areas.

IRRS team noticed also that NRC staff seems to play a significant role in response to plant upsets and unusual occurrences as part of their inspection activities. NRC staff responds to events and provides real time communication to senior management at the region. However, it is not clear whether this oversight could impact the roles and responsibilities of licensee staff in response to events.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: G-S-R-1 states in para 4.53 that *In conducting inspections, the regulatory body shall consider a number of aspects, including:* ▪ *Structures, systems, components and materials important to safety;* ▪ *Management systems;* ▪ *Operational activities and procedures;* ▪ *Records of operational activities and results of monitoring;* ▪ *Liaison with contractors and other service providers;* ▪ *Competence of staff;* ▪ *Safety culture;* *Liaison with the relevant organization for joint inspections, where necessary.*
GP15	**Good Practice: NRC has provided training and procedures to their inspectors to observe safety culture factors in licensee's performance. These observations are collectively evaluated according to an assessment process every six months.** **For more information see IMC 0305 and IMC 0310**
(1)	**BASIS**: GS-G-1.3 in para 3.14 states that *Inspections by the regulatory body should be concentrated on areas of safety significance. These are those SSCs and activities affecting safety or processes important to safety which are identified as such in the safety documentation submitted by the operator or in the findings of the regulatory body's review and assessment, or which are stipulated in the conditions attached to the licence.*
S10	**Suggestion: NRC should ensure that Severe Accident Management (SAM) is properly addressed in the Reactor Oversight Process (ROP)**
(1)	**BASIS**: G-S-R-1 states in para 4.57 that 4.57. *The authorized party shall be held accountable for remedying noncompliances, for performing a thorough investigation in accordance with an*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	agreed timetable and for taking all the measures that are necessary to prevent recurrence of the non-compliances.
S11	**Suggestion: NRC should review its inspection event response guidance and interact with licensees with an objective of reconfirming that the role of the NRC is understood and does not unduly influence the actions taken by the licensee.**

7.3. UTILISATION OF INSPECTION RESULTS AND INSPECTION EXPERIENCE

The inspection programme relies mostly on detailed observation of the resident inspectors on site and regional specialist inspectors. Resident inspectors observe licensee's activities and plant status, discuss with them on a daily basis and inform licensee on findings of safety significance. There is daily information flow from inspectors to the region accompanied by site specific project manager from HQ. In addition, safety coordination meetings are held frequently between regions and HQ staff to discuss and review all observations across the region.

The value and the responsibility to share inspections results timely is recognised by inspectors and the management throughout the NRC. Continuous exchange of information between the sites, regions and HQs staff provides an effective forum to identify generic issues and pass the information agency wide. Operating experience group participates in the daily information exchanges and passes relevant information to appropriate technical review groups. This enables NRC to utilise findings also in other regulatory processes such as License Renewal, Generic Aging Lessons Learned and Rulemaking.

Correct focus of inspections and interpretation of the inspection findings as well as effective use of resources is supported by region and HQ as well as support organisations. Site inspectors are supported by Regional specialists and experts from HQ. Some of the inspections are performed by multidisciplinary teams which supports mutual learning from each other and provides opportunities for effective interactions between resident inspectors and experts. Regional inspectors have access to support organizations, such as National Laboratories, for more in depth review of issues. Site, region and HQ staff work in a coordinated fashion and exchange information on a frequent basis. For example, project managers from HQ participate in licensee's performance assessment by providing insights from review and assessment activities related to for example license amendments. These insights are utilised on planning and sampling of the forthcoming inspections.

There are several forums for inspectors to share inspection experience between their peers. These include inspector newsletters that are published quarterly. Inspector seminars are organised every six months at each region and operating experience data that is shared on a daily basis. These together with inspector training and qualification, enables inspection programme and inspectors to work consistently agency wide.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-G-1.3 states in para 4.8 that *Arrangements should be made to ensure that all relevant staff of the regulatory body can fully contribute to the planning of inspections and in particular, if the offices of the regulatory body are distributed over a wide area, that resident inspectors are involved in the planning process. This will ensure the best use of the skills and knowledge of its staff.*
GP16	**Good Practice: There are effective ways to support inspection activities and share inspection findings within the region and HQ. This enables that generic inspection findings can be identified and adequately addressed with the licensees and also taken into**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	account in different regulatory processes.
(1)	**BASIS:** GS-G-1.3 states in para 4.8 that *Arrangements should be made to ensure that all relevant staff of the regulatory body can fully contribute to the planning of inspections and in particular, if the offices of the regulatory body are distributed over a wide area, that resident inspectors are involved in the planning process. This will ensure the best use of the skills and knowledge of its staff.*
GP17	**Good Practice: NRC has established several ways for inspectors to share experience and compare practices. This enables development of inspection practices and promotes consistent way of working of the inspectors and implementation of the inspection programme.**

7.4. INSPECTOR TRAINING AND QUALIFICATION

To ensure consistent implementation of the inspection programme and enable identification of significant safety issues by the NRC, a lot of emphasis is put on the training and qualification of inspectors. The competence of inspectors is achieved by a thorough, versatile and task specific training programmes. Training programmes are tailored depending on individual's background and prior experience as well as on planned tasks and duties as an inspector. Completed training is documented in detail in individual's qualification journal. There is more information on the inspector qualification in Inspection Manual Chapter 1245 "Qualification Programme for Operating Reactor Programmes" and its appendixes.

Implementation of the training programme is followed closely by individual's supervisor. Supervisor verifies with discussions that individual has adopted the essential parts of the topic and knows how to react in different situations and where to find additional information on the topic. Finally, the competence of an inspector is verified by a qualification board. The board discusses different scenarios with the individual and assesses if the individual would react and conduct according to expectations and values of the NRC.

Competence and human resources management of NRC is addressed in general in module 3.

7.5. USE OF RISK INSIGHTS IN THE INSPECTION PROGRAMME

As described in IMC 2515 and the background documentation for the ROP, risk insights are strongly utilised in NRC's inspection programme. Inspection areas within the programme are risk informed and performance based. The significance determination of the inspection findings is based on risk as far as applicable. In addition, inspectors use risk tools to provide insights when samples are selected for inspections. For example, resident inspectors have risk tools (including SAPHIRE models in some cases), figures of plant specific risk profiles and information on the risk significance of systems, structures and components. There also is a constant dialogue between resident inspectors and regional risk experts. This enables inspectors to evaluate risks related to licensee's actions, component unavailabilities and also to focus inspection activities on risk significant systems, structures and components and licensee activities.

However, it needs to be highlighted that tools available and utilised by the NRC inspectors are not comprehensive with regards to different hazards (external events) and plant states (low power and shutdown states). To ensure that inspection programme focuses on most risk significant areas in all plant states and that correct risk significance is assigned to inspection findings, risk tools and applications based on those tools should be as complete as possible or the limitations should be identified and compensated by other means. As risks do change over time and more information on different risks becomes available also risk tools and programmes based on those tools should be re-evaluated and updated as necessary. NRC has recently started activities to improve the completeness of its risk tools.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: G-S-R-1 states in requirement 29 that *Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.*
GP18	**Good Practice: Resident inspectors have risk tools (including SAPHIRE models) available to focus their inspections on risk significant items and to perform risk calculations to evaluate risk significance of component unavailabilities.**

7.6. VENDOR INSPECTIONS

By regulation, licensee must evaluate vendor's quality assurance programmes. The licensee may delegate to others, such as contractors or consultants, the work of oversight, but they still retain the safety responsibility to ensure that vendors supply items or services of adequate quality. Under 10 CFR Part 21 vendors must report to NRC and to Licensees any potential defects in items or services supplied to licensees that may create a substantial safety hazard or fails to comply with any regulation, order or license. Vendors must maintain procurement records. Vendors must also permit the NRC to inspect records, facilities and activities of items or services. Vendors are subject to the NRC enforcement process.

The NRC performs inspections based on vendor's performance, operating experience from plants, allegations and part of routine activities. NRC has vendor branches for NRR and NRO. NRR branch is responsible for vendor inspections of operating reactors. Vendor inspection process is documented and procedures as well as results of the vendor inspections are available on NRC's website. IMC manual chapter 2700 is the top tier document for vendor inspections. Since it has been updated in October 1990, NRC may want to evaluate the validity of the procedure to reflect current vendor inspection process.

NRC qualifies vendor inspectors with a well documented and organized training programmes, which takes approximately two years to complete. A qualified resident inspector could accomplish this training in about six months as there are several overlapping components of these training programmes.

Nuclear procurement issues committee (NUPIC) is an organization created by USA licensees to discharge their oversight obligations. NUPIC audits vendors and suppliers on behalf of all licensees, that provide components or services and also maintains approved suppliers list. NUPIC has access to trained personnel available from each licensee's organization to audit the vendors and suppliers. More information on NUPIC can be found from their website (www.nupic.com). The NRC has close interaction with NUPIC to ensure the audits meet the NRC regulations and requirements.

8. ENFORCEMENT

With the development and implementation of the ROP in early 2000, the NRC moved from a punitive oriented enforcement system to a safety oriented approach. Openness and predictability of this new approach have supported the licensee prime responsibility for safety and led to several safety enhancements under this oversight framework.

NRC can take appropriate enforcement actions in situations where an immediate health, safety, or security concern has been identified. However, the NRC expects that the licensees initiate appropriate corrective actions, on their own, even if not required to do so by a specific regulation. Safety or security concerns have to be terminated first, investigation and enforcement actions are considered later.

NRC's enforcement actions to address violations can be treated by the ROP or traditional enforcement methods. A violation is any observed non-compliance with regulations. All processes begin with the identification of an inspection or investigation finding or alleged violation.

The ROP is a risk informed process based on performance indicators and inspections. In this process significance determination process (SDP) is used to evaluate violations associated with most inspection findings at reactors. The SDP designates the finding's relative safety significance and assigns a colour (red, yellow, white, or green) to the finding associated with a violation. The results of the SDP are publicly available and the consequent negative publicity on the licensee resulting from greater than green is an effective enforcement tool.

In its enforcement programme based on ROP, NRC applies resources to risk significant issues in a consistent and credible manner: priority of work is put on items that are most significant to safety. The openness and the transparency of the ROP-based enforcement process promotes licensee's continuous improvement. In addition, programme encourages the licensees to self identify and correct; however NRC has access to licensee information to ensure adequate oversight. As a general practice, self-identification and self-initiated corrective actions lead to avoidance of a civil penalty.

The traditional process is applied to violations involving wrongdoing, wilfulness, or discriminations, or affecting the NRC's ability to oversee licensed activities. Discriminations within the mandate of the NRC are typically cases where an employee is prevented from raising her or his concern on safety or security issue. In the traditional process the violations are not evaluated by the SDP, but assigning a Severity Level (I, II, III, or IV) to designate the violation's relative severity.

It is possible to enter and transfer from the ROP to the traditional process and vice versa. In addition the NRC has been proactive in implementing an Alternate Dispute Resolution (ADR) process based on the Administrative Dispute Resolution Act of 1996, which provides an impartial mediator to reach resolution of issues that, once agreed upon, lead to enforceable licensing actions. (For more information see the Alternate Dispute Resolution process under the enforcement programme at www.nrc.gov).

By following a documented process with management review, NRC discretion can be used to elevate or reduce enforcement actions.

Regardless of the process used (ROP or traditional enforcement), the Enforcement Policy provides the means and guidance for the NRC to evaluate violations and take appropriate action commensurate with the seriousness of the violation. The NRC Enforcement Policy describes the policy and procedures that the NRC and its staff intend to follow in initiating and reviewing enforcement actions in response to violations of NRC requirements. The general policy and procedures are available on the NRC public Web site and the NRC's Agency wide Documents Access and Management System.

NRC staff has adjusted the enforcement policy and programme to reflect a mature industry. NRC has several methods of enforcement, graduated and logically lay out. Processes include a significance

determination process for cited and non-cited violations (cited violations require a specific response from the licensee to be put on the public record, non-cited can be dealt with in the licensee's corrective action programme) and the ability to escalate actions. The programme is well resourced with competent and qualified staff and it is effectively implemented. Enforcement is well integrated to the inspection programme but still separated from inspection activities allowing inspection staff to continue with their oversight. Based on the statistics, enforcement response time is commensurate with the risk and complexity of the issue. In addition, the NRC has a separate office of investigations (OI) which conducts investigations of alleged wrong doing at facilities licensed by the NRC to determine wilfulness or deliberate actions. OI is staffed by criminal investigators with Federal law enforcement backgrounds and makes referrals of substantiated criminal cases to the U.S. Department of Justice.

Of note is the NRC allegation programme which is managed through the office of enforcement. This programme reinforces the freedom of employees in the nuclear industry to raise safety concerns without the fear of retaliation. The allegation process is a well documented and implemented programme at the NRC. The programme oversight is coordinated with baseline and regional inspections and lessons learned and trends of results are used to continuously improve. Safety conscious work environment and problem identification and resolution programme inspections verify that employees are encouraged to raise safety concerns promptly with their employers without fear of retaliation, concerns are promptly addressed and feedback is provided. The enforcement programme allows the NRC to proactively address safety culture issues through a "chilling effect letter". This programme is well coordinated with the licensee's safety culture assessment processes. (For more information see the Allegation Process at www.nrc.gov)

The process allows the licensee to prioritize the corrective actions within their problem identification and corrective action systems because this has led to better management of licensee resources. For example, when findings are made that require corrective actions to improve licensee's programmes and processes, NRC does not generally specify a period of time for taking corrective actions. NRC's expectation is that licensee sets adequate timeline and priority to perform necessary corrective actions to avoid repetition. NRC has the possibility to follow licensee's actions via baseline inspections on corrective actions programme and with the NRC's assessment process. In practice all regulatory concerns are dealt with expeditiously. Enforcement activities are reviewed by NRC management and appropriate oversight is exercised to ensure enforcement is consistent and commensurate with risk.

9. REGULATIONS AND GUIDES

9.1. LEGISLATION AND REGULATIONS

The US legislation and regulations system on nuclear and radiation safety is structured as a three level framework: the nuclear safety related Acts, the implementing Federal Regulations, and the supporting Regulatory Guides. Industry consensus standards related to the nuclear and radiation safety can also be made as part of the regulations by endorsing them in the Federal Regulations or Regulatory Guides or by including them into the licensing basis of a facility.

The US Congress has established the basis for regulations in the Atomic Energy Act from 1954 and in its later amendments. This Act authorizes NRC to issue Federal Regulations.

The hierarchy and structure of the US nuclear and radiation safety regulations and guides is generally consistent with international practices.

9.2. EXISTING REGULATIONS AND GUIDES

The fundamental laws governing regulation of civilian uses of nuclear materials and facilities are Atomic Energy Act of 1954 and the Energy Reorganization Act of 1974. The Atomic Energy Act establishes the licensing process for nuclear related facilities and activities, and the regulatory apparatus to oversee compliance with the regulations and license conditions. The Energy Reorganization Act of 1974 (ERA) established the NRC and assigned it the chief safety regulatory responsibility for civilian uses of radioactive material.

Since its establishment in 1974, NRC has issued a wide range of Federal Regulations, which set specific standards and requirements for protection of the public health and safety. These regulations are mandatory and can be applied in adjudicatory decisions that help in interpretation of general terms and requirements in the Acts. NRC's regulations are included in Chapter I of Title 10, "Energy," of the Code of Federal Regulations (CFR) and can be found on the NRC website http://www.nrc.gov/reading-rm/doc-collections/cfr/. These regulations are binding on all persons and organizations that are regulated by NRC that process nuclear materials or operate nuclear facilities.

To support the consistent application of Federal Regulations, NRC has developed a large amount of Regulatory Guides. These guides are non-mandatory guidelines and information documents. The issuance of the non-mandatory guidance is authorized by Atomic Energy Act of 1954 as amended, and 10 CFR Part 1, "Statement of Organization and General Information," which gives the NRC the authority to publish additional information to support agency activities. The guides describe acceptable methods of implementing NRC regulations, techniques used by NRC staff in evaluating specific problems or postulated accidents, and information needed by the NRC staff in its review of applications for permits and licenses. In some cases, licensees may incorporate the non-mandatory guidance into a facility's operating license; when that occurs, the guidance becomes mandatory for that specific facility. Most of the non-mandatory guidance documents provide detailed methods for a licensee to demonstrate compliance with a specific portion of the regulations. If the licensee opts to demonstrate compliance in an alternate manner, NRC's licensing review may take longer, and the licensee may be required to submit sufficient evidence to demonstrate that the alternative method fully meets the intent of the regulations.

In addition to the regulations and guidance directed to the applicants, licensee, and other stakeholders, the NRC has also developed internal guidance for its own staff, with the objective to enhance effectiveness, efficiency, and consistency of NRC's technical reviews. Among this guidance are Standard Review Plans for reviewing safety analysis reports and licensee submittals as well as management directives and internal office instructions (procedures). This internal guidance is also made available to applicants and licensees who can benefit from it when preparing submittals for NRC review.

Some parts of the regulations are very prescriptive, but they do not negatively impact safety. For instance, 10 CFR Part 20.1901 and 20.1902 regulates very precisely the standard radiation symbol and the words associated. 10 CFR Part 2.802 dealing with "Petition for rulemaking" gives email address, phone numbers and mail address where petitions can be transmitted. 10 CFR Part 50.54 fixes the minimum requirements per shift for one-site staffing of nuclear units by operators and senior operators. 10 CFR Part 20.1003 and 20.1004 is providing with the quality factors and absorbed dose equivalences per type of radiation and organ dose weighting factors.

The IRRS mission concluded that the regulations and guides specify in a clear and transparent manner the principles, requirements and associated criteria for safety upon which the regulatory judgments, decisions and actions are based.

9.3. PROCESS FOR DEVELOPMENT OF REGULATIONS AND GUIDES

NRC develops Federal Regulations through a process known as "rulemaking." The Rulemaking process ensures that the intent of a rule is fully understood by all stakeholders and its impact is adequately evaluated before the rule is enacted. NRC has made publicly available on its website the procedures for developing new regulations. The procedures are explained in Management Directive 6.3, "The Rulemaking Process", NUREG/BR-0053 "United States Nuclear Regulatory Commission Regulations Handbook", and for nuclear facilities licensed under 10 CFR Part 50, Nuclear Reactor Regulation's Office Instruction LIC-300, "Rulemaking Procedure".

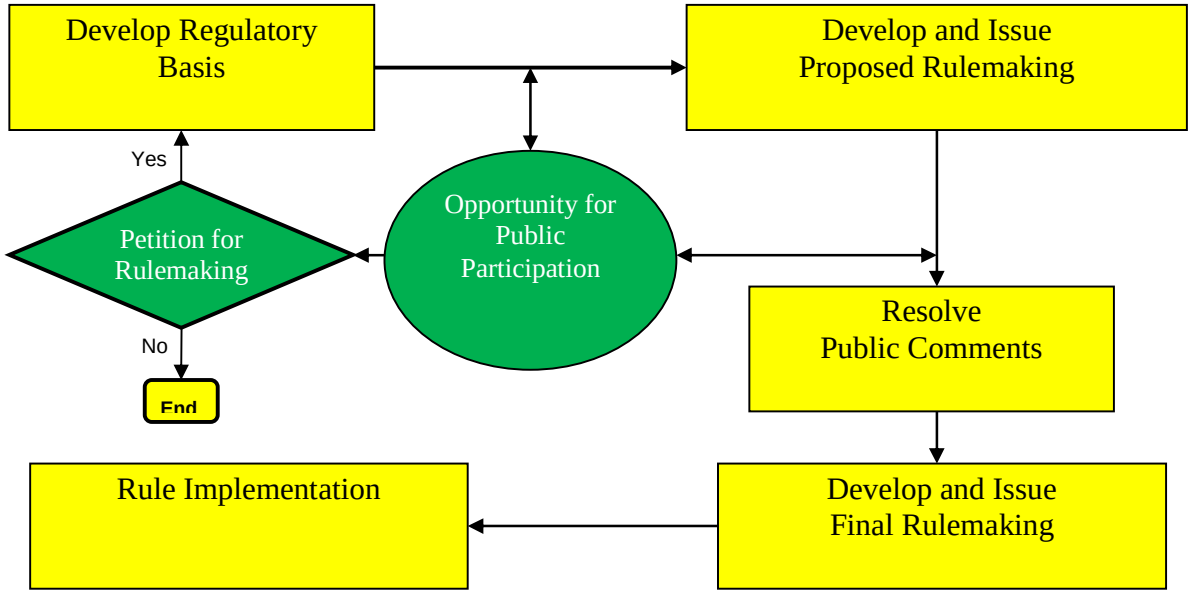
The initiative for rulemaking can come from many different sources: The U.S. Congress can direct changes, industry or members of the public can petition the NRC for changes, or the agency itself may identify from its ongoing activities a need for a conforming, corrective, or other type of action. Priority for completion of new or revised regulations depends on the applicable statutory requirements, contributions to safety (level of risk) or security, Commission direction, or the role of the revision in improving effectiveness and efficiency of NRC or licensee activities.

Coordination and consistency inside NRC is ensured in particular by:

- the composition of the working group formed for a specific rulemaking action (lead Office, Office of the General Council, Division of Administrative Services, Office of Information Services, other Offices, as appropriate);
- the Rulemaking Coordinating Committee (RCC). The Office of Administration chairs the committee, which consists of representatives from the primary offices involved in rulemaking. The focus of the committee is to ensure consistency in methods used to develop and promulgate rules;
- a steering group, which may be established for certain significant rulemaking actions, to help guide the staff and resolve significant questions during the rulemaking process.

Before initiating a rulemaking action and after developing a technical basis to support the rulemaking issue, NRC prepares a proposed rulemaking package that includes a regulatory analysis and an environmental assessment to support the proposed regulation.

The rulemaking process includes, at different stages of the process, participation of stakeholders such as the general public, licensees, and other Government agencies. The NRC uses a public website http://www.regulations.gov , to provide an opportunity for members of the public to provide views on the rulemaking process, and to access and comment on NRC rulemaking actions. This internet website contains proposed rulemakings that have been published in the Federal Register, petitions for rulemaking, the agenda of regulations under agency development, draft and final regulations and regulatory guides and other types of documents related to rulemaking proceedings. The CFR is edited annually to incorporate the regulations effective as of its date of revision. The CFR, used in conjunction with the daily Federal Register, provides the definitive version of the NRC's regulations.



Overview of NRC rulemaking process

When addressing complex or controversial regulatory issues, NRC may seek public involvement during the development of the technical basis for regulatory action before any decision is made to initiate rulemaking. Complex rulemakings or rulemakings that affect a large number or a disparate group of stakeholders may warrant the formulation of a formal communications plan. NRC may organize workshops in parallel of the rulemaking process in order to get insights from the public.

All rulemaking documents, as well as all comments received on the proposed rule are made publicly available on the NRC public website. Similar comments are grouped together and resolved by NRC staff. The NRC staff response indicates whether the comments were persuasive and, if so, what changes were made to the proposed regulations. If the comments were not persuasive, the NRC's response provides a logical discussion of why the comments were not included in the final rule. These responses are part of the final rule package accessible on NRC website.

Guidance documents are subject to a process similar to rulemaking. The draft document Management Directive 6.6 "Development and Revision of Regulatory Guides", provides guidance to NRC staff on how to prepare regulatory guides, and is currently scheduled to be issued in the near future.

The average numbers of 10 CFR amendments for last years are given in the following table.

	2006	2007	2008	2009	2010 (up to October)
Final rules amendments applied to all entities, including power plant licensees, regulated by NRC	8	11	20	7	8
Final rules amendments applied to existing	2	5	10	5	1

power plant licensees (backfit)					

NRC does not currently have a general policy to periodically review and revise the Federal Regulations and Regulatory Guides. However, NRC takes initiatives to make revisions if new information is identified, or repeating safety and security relevant experience occurs, or when technology has advanced. Furthermore, in 2006 NRC initiated an effort to review, prioritize, and revise all Regulatory Guides. The NRC is continuing this effort to ensure that appropriate guidance is updated, and anticipates completion of this process by the end of 2012. Concerning power reactors, NRC has developed more than 200 Regulatory Guides. To date, one third of these guides has been created or updated since 2007. At the date of the mission, more than 20 Regulatory Guides concerning power reactors were under the public comments process.

The IRRS mission considers that the way NRC notifies interested parties and the public of the principles and associated criteria for safety established in its regulations and guides and involves consultation with interested parties in the development of the regulations and guides, is a good practice and demonstrates the transparency of NRC work.

Although the IRRS team found that the regulations and guides were revised over time to reflect operating experience and technological advances, there is no general NRC implementing procedure to guide the periodic systematic review of its regulations and guide, based on operating experience feedback and the development of international safety standards.

9.4. RULES ON BACKFITTING

As defined in 10 CFR Part 50.109, backfitting means a modification of or addition to systems, structures, components, or the design of a facility; or a design approval or manufacturing license for a facility; or procedures or organization required to design, construct or operate a facility. Any of these may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position.

The backfit rule was amended in the aftermath of the 1979 TMI accident due, in part, to the issuance of several new regulatory requirements that lacked sufficient analysis of the impact of the implementation of those requirements had on nuclear power plant licensees, or a clear understanding of the safety benefit of those requirements. Based on that experience the Commission established a rule that states: “the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in … that there is a substantial increase in the overall protection of the public health and safety or the common defence and security to be derived from the backfit and that the direct and indirect cost of implementation for that facility are justified in view of this increased protection”.

However, such an analysis is not required if NRC finds and declares that:

- a modification is necessary to bring a facility into compliance with a license or NRC regulations and orders; or
- regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defence and security; or
- the regulatory action involves defining or redefining what level of protection to the public health and safety or common defence and security should be regarded as adequate.

The IRRS mission considers that the complexity of the analysis the NRC is required to perform, to support a backfit determination, and the large amount of NRC staff effort needed to resolve stakeholder comments on this analysis, particularly with to the estimated values and impacts expressed in monetary

terms may make it difficult for the NRC to issue regulations and guidance that aim to make non substantial safety enhancement at the operating nuclear power plants.

The IRRS team recognizes that NRC has issued some new requirements to enhance safety under the backfit rule over the years. However, an observation was made during the mission that the licensee actions to upgrade the quality and reliability of the operating facilities and to strive for their safety enhancement appears to be less than in many other countries where aging facilities are in operation. Although some plants have taken voluntary proactive measures to improve safety such as replacement of buried pipe work, installing new diesel generators, and modernizing the I&C and main control rooms, some other plants may not upgrade the quality and reliability of their equipment as long as they can demonstrate that a plant is in compliance with the regulations.

9.5. CONSENSUS STANDARDS

Consensus standards are frequently incorporated by reference in the regulations and guidance documents. A consensus standard is defined as a technical standard developed and or adopted by a domestic or international voluntary consensus body. Management Directive 6.5, "NRC Participation in the Development and Use of Consensus Standards", recommends the use of consensus standards and encourages NRC staff to participate in the development of both national and international consensus standards to support the NRC's mission and to encourage the industry to develop codes, standards, and guides that can be endorsed by the NRC and implemented by the industry. The endorsement of consensus standards reduces the need for the development of NRC regulations, and this reduces the cost to both industry and the Government. Participation in the development of consensus standards also allows the NRC to interact with licensees and industry representatives in an open manner, which helps facilitate better understanding and knowledge transfer within the nuclear area.

9.6. RELATION TO THE IAEA SAFETY STANDARDS

The IRRS team observed increasing interest on the part of the NRC to consider IAEA Safety Standards when the regulations are being developed.

The IRRS mission was provided examples of drafts taking into account the IAEA standards, e.g. draft Regulatory Guide DG-8034 "Occupational Radiation Dose Assessment in Light – Water Reactor Power Plants Design Stage Person – Sievert (Man-Rem) Estimates". There are also on-going reviews of the IAEA safety standards on digital I&C with respect to their potential use in NRC Regulatory Guides preparation.

Another example, International Radiological Protection Commission (ICPR) published its recommendation in Publication 60 in 1990 and in Publication 103 in 2007. In addition, IAEA published its Basic Safety Standards on Radiation Protection and Safety of Radiation Sources in 1996 and is revising its basic safety standards according to ICRP Publication 103.

The IRRS team suggests that NRC consider performing a systematic study on the potential value of harmonizing its Federal Regulations and Regulatory Guides with the IAEA Safety Standards. Furthermore, the IRRS team suggests that NRC should continue its process of revising its regulation 10 CFR 20, Standards for Protection against Radiation, and other guidelines related to radiation protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R part 1, Requirement 32 states that *The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which it regulatory judgments, decisions and actions are based.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS**: **GS-R part 1 Requirement 33 states that** *Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.*
(3)	**BASIS: GS-R part 1, Requirement 34 states that** *The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.*
S12	**Suggestion: The NRC should prioritize the development and issuance of a formal procedure for development and revision of Regulatory Guides.**
S13	**Suggestion: The NRC should consider making an implementing procedure to guide the periodic systematic review for its regulations and guides based on operating experience feedback and the development of international safety standards.**
(1)	**BASIS: GS-G-1.4 para 2.14 states that** *It should be recognized that a system of regulations is no substitute for good engineering and good management practices. Unduly detailed formal regulatory requirements can inhibit engineering innovation and good management initiatives, and may even be counterproductive if they have the effect of relieving or tending to relieve the operator of the responsibility for safety. Only a serious concern for safety on the part of all those concerned, not limited to the obligation to meet regulatory requirements, will engender a true safety culture and bring about lasting resolutions of safety issues.*
S14	**Suggestion:** The **NRC should consider possible measures to ensure that all licensees are more proactive in upgrading the systems, structures and components of their facilities with the objective to improve safety margins. (See also S1)**
GP19	**Good Practice: The NRC has developed a systematic and completed set of regulations and guides, and developed practicable and useful working documents, such as standard review plan, reactor oversight process, and related procedures and programmes. This is a good way and useful not only for standardization of use of regulations but also for knowledge management.**
GP20	**Good Practice: The rulemaking process is very well-documented, comprehensive for the different stakeholders, with clear organisation and responsibilities for each actors, overall coordination, consultation of interested parties and regulatory analysis taking into account impact on the licensees, the public and the NRC.**

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. BASIC RESPONSIBILITIES

The arrangements for emergency response actions both within and outside nuclear power plants are dealt with through the regulatory process, which is shared by the two federal agencies the NRC and the Federal Emergency Management Agency (FEMA), which is part of the U.S. Department of Homeland Security (DHS). The NRC is responsible for regulating the licensees' emergency planning, while FEMA has responsibility for offsite planning.

At the federal level the NRC has the responsibility to provide all necessary information about its licensees needed and requested by the federal government and agencies to fulfil their statutory functions. The FEMA is the responsible federal agency for emergency management addressing all hazards. The national coordinating authority for emergencies was established by Presidential Executive Order 12148, which, in 1979, soon after the nuclear accident at Three Mile Island, assigned to the new FEMA the principal role in coordinating off-site emergency planning at nuclear power plants. Soon thereafter, the NRC and FEMA entered into a memorandum of understanding (MoU) about their respective roles. Nearly 30 years of practice have demonstrated the sufficiency of the current legal bases of coordination and resolution of differences. The agencies that are involved in radiological preparedness are part of the Federal Radiological Preparedness Coordinating Committee and their representatives meet quarterly or more frequently to discuss problems and concerns and to develop strategies for success. Not only meetings among the Federal agencies but also between Federal agencies, States, and local communities take place to promote cooperation.

The National Response Framework as an overarching document outlines the response of the Federal Government to a variety of events. The plan incorporates best practices and procedures from incident management disciplines, e.g. homeland security, emergency management, law enforcement, fire fighting, public works, public health, responder and recovery worker health and safety, emergency medical services, and the private sector, and integrates them into a unified structure. It forms the basis of how the Federal government coordinates with State, local, and Tribal Governments and the private sector during incidents.

The Nuclear/Radiological Incident Annex to the National Response Framework describes the NRC's responsibilities. The NRC is responsible for coordination of on-site response for radiological events occurring at NRC-licensed facilities and for radioactive materials either licensed by the NRC or under the NRC's Agreement States Programme. As coordinating agency, the NRC has technical leadership for the Federal Government's response to the event. If the severity of an event rises to the level of General Emergency, or is terrorist-related, DHS will take on the role of coordinating the overall Federal response to the event, while the NRC will retain a technical leadership role. Other Federal agencies that may respond to an event at an NRC licensed facility, or involving NRC-licensed material, include FEMA, the Department of Energy, the Environment Protection Agency (EPA), the Department of Agriculture, the Department of Health and Human Services, the National Oceanographic and Atmospheric Administration, and the Department of State.

10 CFR 50.47, "Emergency Plans," and Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 are the principal pieces of regulations used by the NRC to regulate licensees emergency preparedness and response. They contain the standards and requirements and are incorporated into the facility's license by 10 CFR 50.54,"Condition of License." In addition, 10 CFR 50.47, as supported by Appendix E to 10 CFR Part 50 requirements list the minimum requirements for emergency plans for use in attaining an acceptable state of emergency preparedness.

Meeting the regulations ensures that there is an adequate level of preparedness both in the onsite as well as offsite emergency preparedness.

The important documents, which define criteria for emergency planning and for protective measures, and are aimed at State/local level, are:

- 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" (issued November 1980), and its Supplement 3, Proposed Revision 1, "Guidance for Protective Action Recommendations for General Emergencies",
- "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" (EPA-400-92-001), which lists criteria for evacuation and/or shelter-in-place, depending on the projected doses and the duration of the release,

The local or State authority has the ultimate authority to implement protective action decisions, which means also the authority over protective action decision making.

The NRC evaluates the adequacy of the licensee's emergency plan, and FEMA evaluates the adequacy of the State and local (offsite) emergency plans and reports their findings to the NRC.

At the local level, responders such as fire, police, and medical have defined duties and responsibilities under the NRF and the REP. The local authority, e.g. Mayor or Governor, also has defined responsibilities under both plans. The Governor in most States has the authority to order protective actions. State and local officials must be involved in offsite emergency response. From the beginning, as sought for under the Executive Order, State and local governments have played an important role in emergency planning. The respective State, Federal, and local roles in existing plans are regularly exercised and judged under federal standards. However, emergency planning at nuclear power plants does not require the participation of State and local governments, and the Federal Government does not have legal authority to force State and local governments to participate in emergency planning. If a State or local government chooses not to participate in the offsite emergency plan, then the licensee must submit its own emergency plan that provides reasonable assurance that adequate protective measures can and will be taken in an emergency.

Under NRC regulations in 10 CFR 50.47(a)(1), except as provided in paragraph (d) of this section, no initial operating license for a nuclear power reactor will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed nuclear power reactor operating license. The NRC will base its finding on a review of the FEMA findings and determinations as to whether State and local emergency plans are adequate and whether or not there is reasonable assurance that they can be implemented, and on the NRC's assessment as to whether or not the applicant's onsite emergency plans are adequate and whether or not there is reasonable assurance that they can be implemented. A FEMA finding will primarily be based on a review of the plans. Any other information already available to FEMA may be considered in assessing whether there is reasonable assurance that the plans can be implemented.

The emergency plan is reviewed periodically by NRC emergency preparedness inspectors, NRC resident inspectors, and during the full-participation exercises that occur every other year.

The NRC inspectors evaluate the licensee performance in the exercises, as well as inspect the licensee EP programme.

10.2. FUNCTIONAL REQUIREMENTS

Establishing Emergency Management and Operations

Among the functional requirements, IAEA safety standard GS-R-2 sets a strong requirement for the establishment of emergency management and operations. The country shall make arrangements to coordinate the emergency responses of the entire off-site response organization with the on-site response to include a command and control system for the local and national response to any nuclear or radiological emergency.

In the USA, there is a sophisticated system to guarantee that the required arrangements are in place and they function properly. In this regard the responsibilities of the licensees (providing the on-site response), the NRC (regulating the licensees), the local authorities (responsible for the protection of the local population) and the Federal Emergency Management Agency (coordinating the off-site emergency response) are clearly defined in documents and frequently tested by exercises. This system has evolved during the past five decades and has been assimilated with the country's political and administrative structure (with special regards to the relative independence of the States and the self-governance of the local communities). A special feature of the emergency management is the doctrine of 'tiered response' which emphasizes that response to an emergency should be handled at the lowest jurisdictional level capable of handling the work. There are detailed emergency plans and procedures on different levels of the whole national emergency response system, which – in line with the recommendations of the IAEA standards – fully adopt the 'all-hazard' approach and guarantee the optimal use of the available resources of the country. The concept is described in the National Response Framework (NRF) documents. More specifically, the details of the NRC response in a nuclear power plant can be found in the NRC Incident Response Plan (NUREG-0728, Rev. 5).

The responsible off-site official in the case of a major nuclear emergency is assumed by the governor or mayor or designee of the respective State or county. The NRC regulates the emergency preparedness through the requirements which need to be met by the licensee that adequate capabilities, including manpower, resources and expertise, are ensured to the, responsible off-site official, that he or she gets appropriate advice (consultancy) to be able to provide for an effective decision making about protective actions. However, there are extensive resources at the federal level, which can be activated to support the emergency management (mitigation and recovery) actions at the request of the State/local authorities and fully respecting their independence and sovereignty over their territory. It has to be noted with the exception of the NRC involvement, that the first phase of the nuclear emergency (urgent protective actions) is managed at the State/local level, and most of GS-R-2 requirements are met by this level.

The management structure of the nuclear emergency response is exemplary and can be used as a reference for other national systems with similar administrative structure. This special structure, however, can be a limiting factor when trying to copy the US emergency management system to other countries. Part of this structure, which is of major interest for other countries, is the organization at State/local level.

Identifying, Notifying and Activating

The ability of a licensee to correctly evaluate and classify an emergency condition that could lead to a radiological release offsite is an integral part of the NRC's overall evaluation of the emergency preparedness programme. The NRC evaluates the licensee's ability to correctly classify an event and make the appropriate notifications offsite.

The NRC is committed to maintain communication and share information with external stakeholders during normal operations or while responding to an incident. The federal agencies or departments routinely notified are DHS, FEMA, the Department of Energy, Environmental Protection Agency, the Department of Agriculture, the Department of Health and Human Services, and the Department of Transportation for transportation incidents, as well as cooperating agencies, i.e. the Department of

Commerce, the Department of Defense, the Department of Housing and Urban Development, the Department of Interior, the Department of Justice, the Department of Labor, the Department of State, the Department of Veterans Affairs, the General Services Administration and Red Cross. Other external stakeholders are State, Tribal, and local agencies. A liaison team in the NRC's Operations Center communicates with counterparts in State and congressional offices, as well as Canada and Mexico if necessary, during an emergency. Public Affairs staff communicates with its counterparts in other federal agencies, the nuclear power plant, the public and the media through telephone calls, e-mails and press releases posted to the NRC's Website.

Taking Mitigatory Action

Limitation of threat escalation and returning facility to a safe and stable state is provided by application of abnormal and emergency operating procedures for the design basis accidents and with the severe accident management guidelines for the beyond design basis accidents. Provision of technical assistance to the operational staff in the nuclear power plant is from the utility and the rest of the industry, while teams for mitigating the consequences of an emergency (damage control, fire fighting) are required by the provisions of 10 CFR 50.47, (b), (1) and (2), as well as App. E, IV.A.6, and elaborated further in the NUREG-0654.

Applicable provisions of GS-R-2 in 4.33-34 and 4.39 and 4.40 are met by the extensive set of measures for choosing and implementing the appropriate mitigatory actions.

Taking Urgent Protective Action

This requirement of the GS-R-2 focuses on the priorities of radiation emergency preparedness and response. During response life-saving, preventing the occurrence of severe deterministic effects and reasonably reducing the risk of stochastic effects are the priorities. The main requirements for preparedness are associated with the facilitation of these response priorities, requiring that:

- The country adopts national intervention levels for taking urgent protective actions in accordance with the relevant international standards;
- Arrangements are in place for effectively making and implementing decisions on urgent protective actions to be taken off the site;
- Arrangements are in place to ensure the safety of all persons on the site in the event of a nuclear or radiological emergency.

Based on the interviews and the reviewed documents the response objectives in the US are fully in accordance with the requirements of GS-R-2. These protective actions are regularly exercised and evaluated during the emergency drills in the facilities regulated by the NRC.

Regarding the national intervention levels the US uses Protective Action Guides (PAGs) that are published by the Environmental Protection Agency, based on a consensus with other Federal agencies involved in the national emergency preparedness. The application of these PAGs is tested and evaluated during emergency exercises.

The focus of these emergency drills and exercises is typically on short-term response to emergency conditions, including interdiction of food and recommending use of stored feed to livestock. Other Federal agencies, as prescribed in the NRF, take the lead for long-term protective actions (such as impounding crops and other food-chain protections), for evacuations (a U.S. State responsibility), and for environmental cleanup. The Protective Action Manual, EPA 400, is a multi-agency guidance document that addresses short, intermediate, and longer term actions. Decision making is a key issue in case of introducing urgent protective actions. These actions directly affect people's life and property, therefore the mandate of deciding in these issues is given to the (elected) political leadership. It is exercised in line

with the formerly mentioned ‘tiered response’ doctrine (response to an emergency should be handled at the lowest jurisdictional level capable of handling the work).

The arrangements for the protection of the on-site personnel are in place and the safety standards are in compliance with the international standards (e.g. 250 mSv guidance value for volunteering emergency workers in life-saving action).

The PAGs do not always agree with the recommended generic intervention levels but, in general, there is a sufficient level of compliance, in the sense that the PAGs are somewhat more conservative than the IAEA recommended values. (E.g. evacuation is considered justified according to the IAEA standards at 50 mSv avertable dose, whereas this protective action is considered justified in the US if the projected dose exceeds 10 mSv.)

Providing Information and Issuing Instructions and Warnings to the Public

In 10 CFR 50.47(b) (7), the NRC states, “Information is made available to the public on a periodic basis on how they will be notified and what their initial actions should be in an emergency, the principal points of contact with the news media for dissemination of information during an emergency are established in advance, and procedures for coordinated dissemination of information to the public are established.”

Licensees annually provide the population within 10 miles of a plant with pamphlets, calendars, and other sources of information on what to do during an emergency response to an incident. A study was made which analyzed the actual understanding of population of the information received and the received feedback was used to improve the process. It was entitled “Follow-up Survey on Information Effectiveness of Licensees’ Communications”. Also transient and special population receives instructions about appropriate actions to take in case of an emergency.

Protecting Emergency Workers

GS-R-2 sets requirements for the protection of the emergency workers. According to this requirement sufficient arrangements must be in place to provide protection for a) emergency workers in threat category I, II or III or within the precautionary action zone or the urgent protective action planning zone and b) radiation specialists, radiation protection officers, emergency team of radiological assessors and medical personnel who may respond to radiation emergencies.

The primary responsibility for the proper response on the site rests with the licensee, in line with the general regulatory concepts. Paragraph (11) of 10 CFR 50.47 requests that: “means for controlling radiological exposures, in an emergency, are established for emergency workers. The means for controlling radiological exposures shall include exposure guidelines consistent with EPA Emergency Worker and Lifesaving Activity Protective Action Guides”. Paragraph (12) of the same Section sets requirement for the safety of the medical responders: “Arrangements are made for medical services for contaminated injured individuals”. The fulfillment of these requirements is regularly checked by the NRC during the inspections, drills and exercises.

In general, the off-site incident commander is responsible for giving on-the-scene instructions to emergency workers. However, this person cannot act alone (not being fully competent in radiation protection issues), and may require expert advice by the radiation protection staff about the application of the emergency workers’ turn-back limits.

Assessing the Initial Phase

The NRC staff at the NRC’s Emergency Operations Center monitors the plant conditions from the licensee’s emergency response data system line, which feeds certain plant parameters by modem directly to the NRC. The NRC staff reviews the data and monitors the licensee’s decisions to ensure that it is taking the appropriate actions to protect public health and safety.

Both the licensee and NRC monitor and evaluate plant conditions to anticipate, and reduce the risk of possible radiological releases that may occur as a result of an accident or other incident at a nuclear power plant. The NRC evaluates the licensee's ability to correctly classify an event and make the appropriate notifications offsite. These are part of the risk-significant planning standards that the NRC has identified and as such are monitored closely.

Should there be a release, radiological assessments are performed by the licensee, the NRC, experts at a Federal Radiological Monitoring and Assessment Center established near the site of an accident, and some U.S. States. Different plume models may be used for diversity and assurance.

Besides original plant systems installed at their construction, the NRC required installation of additional systems as a set of lessons learned after the TMI-2 accident, among those were installation of post-accident radiation monitoring system, i.e. hi-range radiation monitors, which enable reliable measurements of high levels of radiation in the containment as well as through the stack (plant vent). All relevant plant parameters are compared with the Emergency Action Levels (EALs), which are used determining the appropriate emergency class.

The operational intervention levels contained in GS-R-2, do not exist. The NRC document (NUREG-0654/ FEMA-REP-1, Supplement 3) allows for classification of a general emergency based on measurements. How this should be made, i.e. how to directly relate measurements and classification has not been addressed in the document. It was assumed that dose rates were projected based on plant parameters (i.e. on a calculation by a plume release code). The IRRS team encourages developing initial operational intervention levels in line with the IAEA requirements and guidance, which would facilitate implementation of the last two boxes in the scheme in the aforementioned document, i.e. "continue assessment based on field monitoring", and "modify protective actions, as necessary".

Keeping the Public Informed

GS-R-2 requires that arrangements be made for providing useful, timely, truthful, and consistent information to the public, responding to incorrect information and rumors and responding to requests for information from the public and from news and information media.

10 CFR 50.47 defines the standards of planning also regarding the communications. According to paragraph (6), "provisions exist for prompt communications among principal response organizations to emergency personnel and to the public". Paragraph (7) requires that "information is made available to the public on a periodic basis on how they will be notified and what their initial actions should be in an emergency (e.g., listening to a local broadcast station and remaining indoors), the principal points of contact with the news media for dissemination of information during an emergency (including the physical location or locations) are established in advance, and procedures for coordinated dissemination of information to the public are established." The joint NRC-FEMA publication NUREG-0654/FEMA-REP-1 sets criteria for preparation and evaluation of radiological emergency response plans, including those components dealing with public communication (II. Planning Standards and Evaluation Criteria, F and G).

The Headquarters-level Office of Public Affairs staffs the agency's Operations Center during an event and is responsible for communicating the NRC executive team's actions to the media and public. Public Affairs also provide staff at the Incident Response Center in the appropriate region to communicate regional activities in connection with the emergency, as necessary. The NRC public affairs staff coordinates the release of information with public affairs staff at other federal agencies. Using prewritten disaster communication templates and following an extensive crisis communication response plan, the NRC intends to communicate effectively with key audiences during a crisis to provide accurate, timely, and reliable information. These communications should serve to do the following:

- Convey the status of the crisis and NRC actions to protect people and the environment;

- Reduce uncertainty and dispel rumors in order to minimize public panic;
- Underscore NRC professionalism and credibility and reassure employees, Congress, the public, and stakeholders that the situation is being handled appropriately.

Public information at the federal level is coordinated by the Department of Homeland Security (DHS) through the well-tested National Incident Crisis Communication Line, which involves public affairs personnel from all federal agencies. There is a similar line established for state communicators. DHS will initiate a virtual federal Joint Information Center almost immediately, while FEMA is responsible for establishing a JIC at the site of the emergency. The DHS crisis communication philosophy is that there will be many different messages from many different "messengers" and that all communicators will 'stay in their lane' and convey only information specific to their role in the crisis. Which agency will serve as the primary "voice" for the federal government as a whole in a significant crisis is at the discretion of the White House.

Taking Long Term Protective Actions

In case of long term protective actions the decision maker is still the State/local authority, which now receives support from his/hers services and in case of a widespread contamination also from the federal level, if requested. The only exemption being food, which is regulated at the federal level and the Food and Drug Administration (FDA) makes decisions about the safe food. For decisions about other actions, i.e. relocation, decontamination of roads, houses, facilities, environment, respective State/local authorities/services provide recommendations to the Governor/Mayor. The Governor/Mayor can receive appropriate support from federal resources including consultation with the NRC.

It is planned that in case of widespread contamination, the Federal Radiological Monitoring and Assessment Center (FRMAC) which is under DoE would be activated and deployed.

In case of an emergency with a radioactive release, extensive environmental radiation monitoring would be taking place. Field monitoring can be performed by the FRMAC, which travels to where the emergency has occurred. It was understood that other stakeholders, such as State laboratories, universities, State health and environmental authorities also do measurements, but the measurements are not fed into a single comprehensive database. However, sending the monitoring teams out and taking the measurements is coordinated in the respective emergency operations center(s), but the measurements themselves are not always consolidated to a common database.

The IRRS team considered a common database made available to all interested parties would be helpful to the radiological assessors and protective actions teams. It would also provide means for early identification of potential false data that might confuse the stakeholders.

Mitigating the Non-Radiological Consequences

Functioning of each federal organization is in principle independent and self-sufficient, thus each of them has its own rumour control, i.e. staff, dedicated to monitor the media and react to the false information disseminated by the media. Such function is activated also in the NRC.

There are legal documents in place, which provide compensation and help in the stage of response and recovery:

– Price-Anderson Act from 1957, providing compensation for damage due to nuclear emergencies,
– Stafford Act - providing compensation in case of any major emergency,
– Convention on Supplementary Compensation for Nuclear Damage.

Conducting Recovery Operations

Provisions that the operator shall establish criteria to be used for reentry of the facility to the normal mode resuming operation are contained in App. E, IV.H.

Conducting recovery operations is a demanding task after a nuclear disaster, which requires tremendous resources. In a more realistic case, when the authority is faced with the legacy of past activities, the main challenges, besides performing decontamination to bring the dose levels to the so called levels "acceptable for living on contaminated areas", are reassuring the population that risks are acceptable. The EPA guidelines are dealing with those levels, which say that the lifetime dose to the population after the event shall not exceed 5 rem (50 mSv).

10.3. REQUIREMENTS FOR INFRASTRUCTURE

Organization

The system of national (Federal), State, local community and facility level emergency response organisations involved in the emergency response is well established and fully functional. Due to different (historical, administrative, political and cultural) reasons the scheme of the coordination and cooperation between the different organizations is rather complex but well developed and regularly tested. There are several documents that describe the schemes of distribution of functions and responsibilities (e.g. NRF, NUREG-0728, U.S.NRC MD 8.2 etc.).

It is important to note that the increment of the complexity of a system unavoidably increases its vulnerability and the chances of failing will grow.

Logistical Support and Facilities

There are numerous facilities (many Emergency Operations Centers, which belong to the NRC, FEMA, federal/State/local authorities). Field monitoring capabilities are available at State level. At federal level teams can be brought to any location from the two centers of FRMAC.

The NUREG-0654/ FEMA-REP-1 requires in its chapter H. Facilities and Equipment among other, that a licensee has to establish and operate the following facilities: TSC, OSC an EOF, as well as installing on-site monitoring systems, having access to off-site monitoring systems, and having emergency equipment. Functioning of off-site facilities is overseen and evaluated by the FEMA.

At State/local level are Public Information Centers (PIC) to provide coordinated public information dissemination. The assembly/reception centers are established outside EPZ of each site to facilitate evacuation.

Communication means are excellent (telephone, radio, satellite, conference calls), as well as computational and web based means (hardware and software including codes).

For long term phase: Joint Field Operations Center is established in a suitable location bringing State/local and federal resources under the same roof. The location is decided ad hoc based on the actual circumstances. For deploying the resources land and air vehicles are used.

Training, Drills and Exercises

The exercise programme for the licensee shall include a description of specialized initial training and periodic retraining programmes to be provided to each of the following categories of emergency personnel:

i. Directors and/or coordinators of the plant emergency organization;

ii. Personnel responsible for accident assessment, including control room shift personnel;

iii. Radiological monitoring teams;

iv. Fire control teams (fire brigades);

v. Repair and damage control teams;

vi. First aid and rescue teams;

vii. Medical support personnel;

viii. Licensee's headquarters support personnel;

ix. Security personnel.

In addition, a radiological orientation training programme shall be made available to local services personnel; e.g., local emergency services/Civil Defense, local law enforcement personnel, local news media persons.

Appendix E to 10 CFR Part 50 requires that an exercise of the onsite emergency plan be conducted every 2 years. In addition, Appendix E also requires "provisions for a training programme for employees of the licensee, including those who are assigned specific authority and responsibility in the event of an emergency, and for other persons who are not employees of the licensee but whose assistance may be needed in the event of a radiological emergency." It also requires that offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the plan. These exercises can be combined into the same exercise.

The NRC also has a programme that uses performance indicators to monitor success rate and participation during drills and exercises conducted between the biennial evaluated exercises. If the level of success or participation drops below thresholds, a range of actions including additional inspections may be triggered.

For emergency exercises at a power plant, the exercise scenarios are developed by the licensee. Scenarios must be adequate to exercise all required portions of the emergency plan. Typically, a committee comprised of the licensee staff, local and State representatives and FEMA staff determine the objectives to be tested; for example, all objectives must be tested within the 6 year exercise cycle, and the distribution of objectives within the 6 year exercise cycle is the subject of discussion and negotiation. If a scenario proves not to be sufficiently challenging, the NRC may require the licensee to conduct a repeat exercise with a more challenging scenario.

The NRC participates in scheduled exercises at Headquarters, at the appropriate regional office, onsite, and at nearby but offsite centers. During full participation exercises, NRC inspectors are onsite to evaluate the licensee response to the exercise. The inspectors use NRC Inspection Procedure 71114.01. DHS FEMA evaluates the offsite entities' performance during these exercises. The FEMA exercise evaluation manual is used by FEMA. In addition, NRC resident inspectors can review off-year exercises (exercises in the year when there is no biennial evaluated exercise) and routine drills.

The Millstone EP Drill that coincided with the IRRS mission gave a unique opportunity to the Module 10 sub-group to observe how a facility exercise is conducted and evaluated by the NRC. The professionalism and high level competence of the staff was impressive and convincing.

It was noted with satisfaction that "IAEA call" and "IAEA second call" messages appeared among the exercise injects, indicating that the interest of the international community in case of an incident in a US reactor is rightfully assumed. However, the ENAC message that would provide the necessary technical information to the IAEA IEC was not put together and sent to Vienna. It is strongly recommended that this additional component should be made a regular element of the exercises. The IEC is a willing partner in such communication exercise.

The exercise programme is comprehensive, sound and it is in line with the requirements, which are meticulously tested to provide reasonable assurance that emergency preparedness meets the requirements. In order to perform analysis and evaluation how the requirements are met, the exercises contain elements of predictability. It is not said that course of scenarios are predictable, but the main steps and their timing

definitely are. It seems that exercise controllers developed such scenarios that does not allow for deviation from the planned course. This is, in principle, good, because such scenarios meet the objectives and keep all the participants busy. On the other hand, it is suggested to develop in addition some more challenging scenarios. The challenges can comprise safety/security interfaces and to develop and test other abilities, i.e. error recognition, intuition, patience, non-conventional communication skills, etc. The emergency exercise programme should remain predictable to ensure responders do follow agreed processes but also challenging to demonstrate their capability to respond to uncertainties which may not be fully pre planned, such as, human performance and safety/security interface issues. Some of the scenarios should also cover the late and recovery phase.

Quality Assurance Programme

Proper functioning of the NRC emergency preparedness capability is ensured by regular exercises, its evaluation and feedback process. Self-assessments are performed. Testing of equipment, technical means and communications is outsourced, but overseen by the NRC staff.

There is the Corrective Actions Programme in place, as well as the Responder Qualification Programme.

In the future the emergency quality assurance programme shall be integrated and become a part of an overarching NRC's management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: GS-R-2 para 4.54 states that *"For facilities in threat category I or II arrangements shall be made, before and during operations, to provide information on the response to a nuclear or radiological emergency to permanent, transient and special population groups or those responsible for them and to special facilities within the precautionary action zone and the urgent protective action planning zone. This shall include information on the nature of the hazard, on how people will be warned or notified and on the actions to be taken in the event of a nuclear or radiological emergency. The information shall be provided in the languages mainly spoken in these emergency zones and the effectiveness of this public information programme shall be periodically assessed."*
GP21	**Good Practice: NRC commissioned a detailed study to determine the effectiveness of the licensees public awareness programme to find out how the public understands the information on risks and actions to be taken in case of an emergency.**
(1)	**BASIS**: GS-R-2 para 3.8 states that *"The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. For a facility in threat category I, II or III "Appropriate emergency [preparedness and response] arrangements shall be established from the time that nuclear fuel [or significant amounts of radioactive or fissile material] is brought to the site, and complete emergency preparedness as described here shall be ensured before the commencement of operation." (Ref. [12], para. 2.36.) The regulatory body shall ensure that such emergency arrangements are integrated with those of other response organizations as appropriate before the commencement of operation. The regulatory body shall ensure that such emergency arrangements provide a reasonable assurance of an effective response, in compliance with these requirements, in the case of a nuclear or radiological emergency. The regulatory body shall require that the emergency arrangements "shall be tested in an exercise before the commencement of operation [of a new practice]. There shall thereafter at suitable intervals be exercises of the emergency [arrangements], some of which shall be witnessed by the regulatory body." (Ref. [12], para. 2.37.)"*
GP22	**Good Practice: The NRC introduced performance indicators for emergency preparedness, e.g. Drill/Exercise Performance; Emergency Response Organization Drill**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Participation; Alert and Notification System Reliability, which are evaluated every three months.
(1)	**BASIS**: GS-R-2 para 5.33 in conjunction states that *"Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals84, 85. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained86 (see paras 3.8, 3.16, 5.37 and 5.39 for further requirements in relation to exercises)."*
(2)	**BASIS:** GS-R-2 para 3.8 states that *"The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. For a facility in threat category I, II or III "Appropriate emergency [preparedness and response] arrangements shall be established from the time that nuclear fuel [or significant amounts of radioactive or fissile material] is brought to the site, and complete emergency preparedness as described here shall be ensured before the commencement of operation." (Ref. [12], para. 2.36.) The regulatory body shall ensure that such emergency arrangements are integrated with those of other response organizations as appropriate before the commencement of operation. The regulatory body shall ensure that such emergency arrangements provide a reasonable assurance of an effective response, in compliance with these requirements, in the case of a nuclear or radiological emergency. The regulatory body shall require that the emergency arrangements "shall be tested in an exercise before the commencement of operation [of a new practice]. There shall thereafter at suitable intervals be exercises of the emergency [arrangements], some of which shall be witnessed by the regulatory body." (Ref. [12], para. 2.37.)"*
GP23	**Good Practice: A sound and detailed on-site and off-site emergency exercise programme has been developed over the last thirty years, for a variety of scenarios with well balanced and comprehensive set of objectives, which are tested – based on previously defined evaluation criteria - by a series of exercises over a six year period.**
(1)	**BASIS**: GS-R-2 para 5.33 states that *"Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals84, 85. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained86 (see paras 3.8, 3.16, 5.37 and 5.39 for further requirements in relation to exercises)."*
(2)	**BASIS:** GS-R-2 para 4.30 states that *"The State shall make arrangements for promptly notifying and providing relevant information to, directly or through the IAEA, those States that may be affected by a transnational emergency. The State shall make arrangements for promptly responding to requests from other States or from the IAEA for information in respect of a transnational emergency, in particular with regard to minimizing any transnational consequences."*
S15	**Suggestion: The NRC procedures for the IAEA emergency notification (ENAC) should**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	be improved and the emergency exercise programme should include periodic testing of ENAC reporting to the IAEA.
(1)	**BASIS**: GS-R-2 para 4.71 states that *"For the precautionary action zone and the urgent protective action planning zone, arrangements shall be made for promptly assessing any radioactive contamination, releases of radioactive material and doses for the purpose of deciding on or adapting the urgent protective actions to be taken following a release of radioactive material. This capability shall include arrangements for promptly conducting environmental monitoring and monitoring for contamination on people (e.g. evacuees) within the emergency zones, including the availability of designated trained teams and instrumentation. In addition, arrangements shall be made for promptly assessing the results of environmental monitoring and monitoring for contamination on people in order to decide on or to adapt urgent protective actions to protect workers and the public, including the application of operational intervention levels (OILs) with arrangements to revise the OILs as appropriate to take into account the conditions prevailing during the emergency."*
S16	**Suggestion: The NRC should discuss with its Federal partners the consideration of a proposal for the development of initial operational intervention levels (OILs) in line with the GS-R-2 provisions.**
(1)	**BASIS**: GS-R-2 para 4.67 states that *"Radiation monitoring and environmental sampling and assessment shall be carried out in order to identify new hazards promptly and to refine the strategy for response."*
(2)	**BASIS**: GS-R-2 para 4.73 states that *"Arrangements shall be made to ensure that relevant information is recorded during an emergency and retained for use during the emergency, in evaluations conducted following the emergency and for the long term health monitoring and follow-up of the emergency workers and members of the public who may potentially be affected."*
S17	**Suggestion: The NRC should discuss with its Federal partners the consideration of a proposal for merging of all field measurements performed during an emergency by different stakeholders in a single database. This database should be made available online for decision making purposes.**
(1)	**BASIS**: GS-R-2 para 5.36 states that *"The performance of exercises at facilities in threat category I, II or III shall be evaluated against established response objectives that demonstrate that identification, notification, activation and other initial response actions can be performed in time to achieve the practical goals of emergency response (see para. 2.3)."*
S18	**Suggestion: The NRC should continue to explore options with the Federal and State partners in order to expand the scope of the emergency exercise programme by adding elements to demonstrate the capability to responds to unpredictable courses of events and to make the exercise programme more challenging to all the participants.**

11. INTERFACES WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

The responsibility of NRC is to protect the public and workers against the radiation hazards from industries using radioactive materials and to promote the common defense and security. This includes the regulation of safety and security at nuclear power plants. It has therefore always been responsible for regulating nuclear security. Ensuring adequate safety and security protection of the public are key strategic goals for its Strategic Plan for 2008 – 2013.

Following the events of 11 September 2001 NRC reviewed and analysed the adequacy of emergency response and security arrangements at the nuclear sites it regulated. As a result of this review NRC issued several Information Notices and Orders to operators of nuclear power plants. In March 2009 an amendment, ref 10CFR Part 73 titled 'Physical Protection of Plant and Materials' (final rule) was issued for implementation in March 2010. A key feature of the document was the requirement for a nuclear safety/security interface in 10 CFR 73.58. In addition NRC Regulatory Guide 5.74 titled "Managing the Safety/Security Interface' is also relevant.

IAEA Requirement GS - R - 1, Reg 12 states 'The government shall ensure that within the government and legal framework adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system for accounting for and control of nuclear material.' The requirement specifies four main responsibilities namely:

- Assessment of the configuration of facilities and activities for the optimization of safety with factors relating to nuclear security,
- Oversight and enforcement to maintain arrangements for safety and nuclear security,
- Liaison with Law enforcement,
- Integration of emergency response arrangements for safety related and nuclear security related incidents.

11.2. REGULATORY PROGRAMME

The new 10 CFR 73.58 requires licensees to

(1) Assess and manage the potential for adverse effects on safety and security, including the site emergency plan, before implementing changes to the plant configurations, facility conditions, or security, and

(2) Communicate any potential conflicts to appropriate licensee personnel and take compensatory and/or mitigative actions to maintain safety and security under applicable NRC regulations, requirements, and license conditions.

The scope of changes to be addressed and managed by the licensee must include planned and emergent activities, such as, but not limited to, physical modifications, procedural changes, changes to the operator actions or security assignments, maintenance activities, system reconfiguration, access modification, etc.

The new 10 CFR 73.55(c) (7) requires that licensees review and update existing procedures to satisfy the requirements which would include the interface between safety and security. Also, 10 CFR 73.55(m) requires licensees to ensure that the reviews and audits of its site physical protection programme include activities involving the interface between safety and security.

In order to facilitate the accomplishment of these regulations, the NRC developed the Regulatory Guide 5.74, "Managing the Safety/Security Interface". The guidance states that a licensee's management

controls and processes for interface between safety and security should ensure that the site's security organization is notified of potential changes to

(1) The characteristic of the site's physical layout

(2) The configuration of facilities

(3) Structures, systems, and components

(4) The site's operational procedures, and

(5) Day-to-day planned activities

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: INSAG 24, Point 28 states** *"The regulator must define the requirements to be satisfied by the operator for both safety and security"*
GP24	**Good Practice: The regulations and guides issued by the NRC to avoid the potential for adverse effects on safety from security and vice versa are comprehensive and provide an appropriate framework to assure that the licensees put in place an adequate management of the safety/security interface.**

11.3. NRC INSPECTION ON SAFETY/SECURITY INTERFACE

The Reactor Oversight Process includes both safety and security issues. To ensure that licensees are complying with the new regulation, the NRC has incorporated the evaluation of the licensee's interfaces between safety and security into its inspection procedures. The Resident Inspectors conduct inspections on a routine basis, and regional and Headquarter inspectors perform periodic security inspections. These inspections are intended to, in part, identify safety/security interfaces.

Discussions took place with a Resident Inspector on how the safety/security interface was inspected. Inspection of the safety/security interface was included as part of the Reactor Oversight Programme (ROP). Although no formal training courses are provided, individual study activity, instruction and written guidance was provided to staff on how to conduct the inspections. The inspections covered: observations; checks on people; plant; infrastructure; and observing meetings. Inspectors were also routinely briefed by NRC on security issues relevant to their inspections on site. Evidence was also provided where feedback from inspectors on the inspection programme had resulted in adjustments to improve its effectiveness.

Information was also provided to confirm that in areas where specialist security support was needed on Resident Inspector inspections NRC Regional Office support was provided. For the Force on Force inspections and drills specialist support was provided by NRC HQ staff. NRC staff also confirmed they routinely observed licensee briefings on safety/security actions and issues. In addition they also confirmed a full participation emergency response exercise involving safety/security interfaces was required to be carried out by each licensee every two years. These exercises included the support of other law enforcement agencies.

11.4. ORGANISATIONAL STRUCTURE IN NRC

The NRC has several internal processes that promote interfaces between nuclear safety and security inside the agency. Discussions took place with NRC staff on how nuclear security policy was implemented into the nuclear safety programme. Following the resolution of issues in response to the events of 11 September 2001 NRC took the decision to formally integrate the safety/security interface into their normal processes, through the safety/security advisory panel and working group. This resulted in an office instruction ref COM -111 being produced. Following their IRRS self assessment it has been further

updated ref COM -111, R.1 dated 27 September 2010 to reflect changes in a number of areas including organization, management and personnel responsibilities.

The team reviewed the latest document COM – 111, R1 to establish the liaison responsibilities of branches within the relevant regulatory offices. Discussion with a selection of staff confirmed there was clear evidence of pro-active engagement and effective management of the safety, security and emergency preparedness interface. The commitment of NRC management in promoting challenge within its organization on the safety/security interface together with the need for NRC to strive for a culture of continuous improvement in learning from events was clearly evident. In addition the team also recognized the commitment by NRC to ensure that security should be promoted as an important part of a licensee's safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 12** *"Within the governmental and legal framework adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security ..... of accounting for ; and control of nuclear material."*
GP25	**Good Practice: The procedures developed and implemented by NRC establish clear responsibility of assignments and communication channels to allow an effective management of its internal interfaces between safety, security and emergency preparedness.**

11.5. NRC OPERATIONAL EXPERIENCE PROCESS

NRC Operational Experience Branch staff routinely review event reports and circulate these to interested contact points based on their screening criterion on a daily basis. The scope of the screening carried out was discussed at some length to establish the breadth of potential issues considered as learning opportunities or potential challenges to safety at nuclear power plants. During these discussions it was clearly evident that the process was challenging and sought to consider a broad range of issues within and outside the nuclear industry. The IRRS team also recognized the professionalism, capability and skill of the NRC staff involved in capturing relevant operational experience information. The team recognized that the Operational Experience Branch collects relevant information from both the nuclear and non nuclear industry, but the team was not able to verify that its procedures reflect the collection of non-nuclear information. The NRC is in the process of making changes to the procedures and is including the assessment of non-nuclear information in the current update.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: INSAG 24, Rec 4** *"The responsibilities of operating bodies and state organisations are well defined in relation to both safety and security"*
(2)	**BASIS: INSAG 24, Para 65** *"Event concerning equipment failures, identifies anomalies, human errors and sabotage attempts must be recorded and evaluated appropriately"*
S19	**Suggestion**: **NRC's Operational Experience Branch procedures should be updated to include non nuclear information which should be collected to evaluate understanding to any impact to safety or security that may inform the safety/security interface.**

11.6. INTERACTION WITH INDUSTRY

The team explored the safety/security interface arrangements with industry and Industry associations such as NEI and INPO. Information was provided to confirm the role of the Nuclear Energy Institute NEI co-ordinating industry security matters through exchanges with NRC including monthly telephone

conferences, an annual conference, working groups and a database. The database also includes safety/security interface information. Although NEI clearly does co-ordinate industry matters on security it does not cover the safety/security interface.

Discussion with NRC staff also noted that although INPO did take a lead on nuclear safety matters for industry it did not cover the safety/security interface. The information gained from operating experience in nuclear power plants or other industries makes it possible to improve its safety/security interface. The team therefore did not consider the nuclear industry was sufficiently pro-active to ensure relevant safety/security interface issues were effectively considered, co-ordinated and actioned to ensure adequate protection of the public.

It is recognized that the exchange of information in the security domain is limited based on the sensitivity of such information. However, it is important to recognise that where safety/security interface shortfalls are identified controlled sharing of information is necessary for ensuring continuous improvement by industry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: INSAG 24, Rec 4** *"The State needs to make sure that the responsibilities of the operating organisation and .... are well defined in relation to both safety and security"*
S20	**Suggestion: NRC should take further action to encourage industry to take actions to ensure the effective co-ordination of the safety/security interface issues.**

11.7. SAFETY CULTURE

Consideration was also given by the team to the work being carried out by NRC on Safety Culture which included the contribution made by security in delivering safety. NRC had been active in this area since 1989 with the most recent Draft Safety Culture Policy Statement being placed in the Federal Register for comment in November 2009. The proposal clearly states that nuclear safety and security are clearly intertwined and that it is important to integrate the activities to ensure they do not adversely diminish safety or security.

11.8. NRC RESPONSE ARRANGEMENTS

The IRRS team also confirmed that NRC staff had recognized the need to work with other US Law Enforcement Agencies to ensure they understood the potential impacts of an offsite security force response to plant safety. The NRC staff had therefore been actively involved with other Law Enforcement Agencies in testing and exercising the adequacy of their safety/security interface arrangements.

11.9. CONFIGURATION OF FACILITIES AND ACTIVITIES

NRC confirmed that they had taken action post 11 September 2001 to ensure improvements in physical protection were made where appropriate. It had also been important to ensure additional security provisions did not compromise nuclear safety. The ROP had been used to validate the adequacy of the changes made on site.

The criterion for license modifications is covered under 10 CFR 50.90. The provision for minor changes is covered under 50.54(p) where NRC does not require to be informed of changes. However, NRC confirmed that they reviewed all security changes.

11.10. ASSESSMENT AGAINST INSAG – 24

Although the IAEA INSAG 24 document titled "The Interface between Safety and Security at Nuclear Plants" had not been included by NRC in their self assessment due to the recency of its issuance in

relation to the start of the IRRS mission, the IRRS team were provided with a review by NRC staff against those Recommendations in Chapter 8 relevant to NRC responsibilities. The team was also able to confirm NRC had carried out an assessment against INSAG -24. The team discussed the responses together with examples of how they considered NRC activities were consistent with the recommendations. Apart from the two suggestions raised in section 11.3, and 4 of this part of the report the IRRS team considered NRC had adequately demonstrated the relevant INSAG Recommendations had been met through: the actions they had taken in developing and issuing regulations; developing a safety and security culture policy; ensuring adequate communications; and preparing for and testing emergency preparedness.


IRRS
Integrated Regulatory Review Service
Mission to the United States
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1. Gustavo Caruso	Division of Nuclear Installation Safety	G.Caruso@iaea.org
2. Miroslav Svab	Division of Nuclear Installation Safety	M.Svab@iaea.org
3. Peter Zombori	Incident Emergency Centre	P.Zombori@iaea.org
4. Marlene Kobein-Apolloner	Division of Nuclear Installation Safety	M.Kobein@iaea.org
OFFICIAL USRNC LIAISON OFFICER:		
1. Bruce Boger	US Nuclear Regulatory Commission	Bruce.boger@nrc.gov

APPENDIX II – MISSION PROGRAMME

IRRS MISSION PROGRAMME		
Sunday, 17 October 2010		
IRRS Opening IRRS Review Team Meeting		
14:00 - 18:00	- Opening Remarks by the IRRS Team Leader (Mr. Laaksonen) - Self-introduction of all Attendees - Introductory words by Liaison Officer. - Presentation on the IRRS Methodology and Reporting (Mr. Caruso) - Presentation Mission conduct/review (Mr. Laaksonen) - First Impression from experts arising from the Advanced Reference Material (ARMS)	
Monday, 18 October 2010		
IRRS Entrance Meeting		
09:00 - 11:45	Opening Remarks by Chairman Jaczko Opening Remarks by the IRRS Team Leader Mr. Laaksonen Self-Introductory of the IRRS Review Team Counterpart Presentations: Overview of the USNRC's regulatory approach - Introduction of Modules	IRRS Review Team NRC Counterparts
13:00 - 16:30	Module Discussion/Interviews (Module 1, 5, 6, 7, 9 and 10)	IRRS Review Team NRC Counterparts
19:00 -	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer
Tuesday, 19 October 2010		
Daily Discussions / Interviews		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-12:00	Module Discussion/Interviews (Module 2, 5, 6, 7, and 9)	IRRS Review Team NRC Counterparts
13:00-16:00	Module Discussion/Interviews (Module 2, 6, 8, 9 and 12)	IRRS Review Team NRC Counterparts
13:00-17:30	Millstone Emergency Preparedness Drill	IRRS Emergency Review Team NRC Counterparts
16:00-17:30	White Paper Discussion: Approach to Safety	IRRS Review Team Senior NRC Staff
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer

IRRS MISSION PROGRAMME		
Wednesday, 20 October 2010		
Daily Discussions / Interviews (Travel to site visits)		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-12:00	Module Discussion/Interviews (Module 3, 6, 8, 9, 10 and 11)	IRRS Review Team NRC Counterparts
13:00-16:00	Module Discussion/Interviews (Module 11a Periodic Safety Review)	IRRS Review Team NRC Counterparts
14:30 -	Travel to Region 1 (King of Prussia, PA)	P. Tiippana K. LaFreniere G. Wack M. Svab NRC Counterpart
16:00-17:30	Policy Issue Discussion: Human Resources and Knowledge Management	IRRS Review Team NRC Counterparts
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer
Thursday, 21 October 2010		
Daily Discussions / Interviews follow up		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-12:00	Module Discussion/Interviews (Module 4, 5, 6, 9, 10 and 12)	IRRS Review Team NRC Counterparts
13:00-16:00	Module Discussion/Interviews (Module 11b Feedback of Operating Experience - Discussion)	IRRS Review Team NRC Counterparts
13:00 – 18:30	Site Visit to Limerick Generating Station	P. Tiippana K. LaFreniere G. Wack M. Svab NRC Counterpart
16:00-17:30	Policy Issue Discussion: Long-Term Operation and Aging Management	IRRS Review Team NRC Counterparts
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer
Friday, 22 October 2010		
Daily Discussions / Interviews and Site Visits		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-12:00	Module Discussion/Interviews (Module 1, 2, 3 and 4 follow up discussions)	IRRS Group Review NRC Counterparts
09:00 – 18:30	Site Visit	P. Tiippana

IRRS MISSION PROGRAMME		
	Meet with Resident Inspectors Plant Tour with RI Observe Inspection Meet with Site Management	K. LaFreniere G. Wack M. Svab NRC Counterpart
13:00-16:00	Policy Issue Discussion: Openness and Transparency	IRRS Review Team NRC Counterparts
16:00-17:30	Policy Issue Discussion: Long-Term Operation and Aging Management	IRRS Review Team NRC Counterparts
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer
Saturday, 23 October 2010		
Report Writing		
09:00 – 18:00	IRRS Review Team Meeting and Report writing	
Sunday, 24 October 2010		
Report Writing		
09:00 – 18:00	Report Writing	
Monday, 25 October 2010		
Daily Discussions		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-17:30	Follow up discussions/ Interviews with Counterparts	IRRS Group Review NRC Counterparts
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer
Tuesday, 26 October 2010		
Daily Discussions		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-17:30	Follow up discussions/ Interviews with Counterparts	IRRS Group Review NRC Counterparts
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer
Wednesday, 27 October 2010		
Review of Mission report and, mission report handover		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-12:00	Follow up discussions/ Interviews with Counterparts	IRRS Group Review NRC Counterparts
13:00-16:30	IRRS Review Team meeting on draft mission Report	IRRS Review Team
16:30-17:30	IRRS Review Team and NRC discussion on Draft Mission report	IRRS Review Team
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team

IRRS MISSION PROGRAMME		
		Liaison Officer
Thursday, 28 October 2010		
Plenary Session and Preparation for the exit meeting		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-12:00	IRRS Review Team and NRC discussion on Draft Mission report – comments by counterpart on IRRS report	IRRS Review Team NRC Counterparts
13:00-17:30	IRRS Review Team finalization of mission report	IRRS Review Team
17:30 – 19:00	Daily IRRS Review Team Meeting	IRRS Review Team Liaison Officer
Friday, 29 October 2010		
EXIT MEETING and PRESS CONFERENCE		
08:00-08:30	IRRS Team/NRC Status Meeting	IRRS TL, DTL and IAEA Coordinator NRC Senior Staff
09:00-12:00	IRRS Exit Meeting, followed by Press Conference	IRRS Review NRC Counterparts

APPENDIX III – SITE VISITS

SITE VISITS	
1.	Site visit to US NRC Region 1 Office at King of Prussia
2.	Site Visit to Limerick Generating Station
3.	Site Visit to Salem Station

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	USNRC Lead Counterpart	USNRC Assistant Lead Counterpart	USNRC Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**			
	Young-Soo Eun Erik Jende	Steve Burns	Jeri Buchholz, HR	Steve Crockett Michael Gartman
2.	**GLOBAL NUCLEAR SAFETY RÉGIME**			
	Young-Soo Eun Erik Jende	Tim McGinty	Karen Henderson Mike Cheok	Anneliese Simmons
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**			
	Young-Soo Eun Erik Jende	Tom Blount	Ed Williamson	Xiaosong Yin Beth Mizuno Mary Spencer
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**			
	Erik Jende	John Lubinski	Jeri Buchholz	Michael Gartman Pat Smith
5.	**AUTHORIZATION**			
	Colin Patchett Victor Manuel Gonzalez Isabel Mellado	Joe Giitter	Brian Holian	Sean Meighan
6.	**REVIEW AND ASSESSMENT**			
	Jozef Misak Ralph Schulz	Michele Evans	Mark Cunningham	Steve Laur Ken Karwoski
7.	**INSPECTION**			
	Petteri Tiippana Kenneth Lafreniere	Fred Brown	Dave Lew	MaryAnn Ashley Rich Barkley Cheryl Khan

	IRRS EXPERTS	USNRC Lead Counterpart	USNRC Assistant Lead Counterpart	USNRC Support Staff
8.	**ENFORCEMENT**			
	Petteri Tiippana Kenneth Lafreniere	Roy Zimmerman	Dave Lew	Bob Summers Rich Barkley Cheryl Khan
9.	**REGULATIONS AND GUIDES**			
	Liu Hua Guillaume Wack Miroslav Svab	Dave Skeen	Sher Bahadur	Tim Reed Mark Orr Kerby Scales
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**			
	Igor Grlicarev Peter Zombori	Chris Miller	Darrell Roberts	Patricia Milligan Lisa Gibney Ray Powell
11.	**INTERFACES WITH NUCLEAR SECURITY**			
	Colin Patchett Victor Manuel Gonzalez Isabel Mellado	Melanie Galloway	Rich Correia	Tim Harris Dennis Gordon Steve Laur
THEMATIC AREAS				
Periodic Safety Review				
Jozef Misak Ralph Schulz		Brian Holian	Louise Lund	Albert Wong
Feedback of Operating Experience				
Jozef Misak Ralph Schulz		Mike Cheok	Stu Richards	Rebecca Sigmon Jeff Dehn
POLICY ISSUE DISCUSSIONS				
Transparency and Openness				
IRRS Review Team		Beth Hayden	Ray Lorson	Scott Burnell
Long-Term Operation and Ageing Management of Nuclear Facilities				

	IRRS EXPERTS	USNRC Lead Counterpart	USNRC Assistant Lead Counterpart	USNRC Support Staff
IRRS Review Team		Sam Lee	Stu Richards	Stacie Sakai
Human Resources and Knowledge Management				
IRRS Review Team		Jeri Buchholz	Mary Givvines	Michael Gartman
WHITE PAPER: U.S. Approach to assuring safety				
IRRS Review Team		Bruce Boger		Trent Wertz

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**S1**	**Suggestion: In the absence of a direct legal statement about the prime responsibility for safety, the NRC should provide a consistent, clear message to the licensees that they have responsibility to take their own initiatives to improve safety whenever reasonably practicable.**
	GP1	**Good Practice: The NRC uses written Memoranda of Understanding with other agencies who have shared authority with the NRC.**
2. GLOBAL NUCLEAR SAFETY REGIME	**GP2**	**Good Practice: The NRC's information exchange programmes, and its active participation in the multilateral and bilateral cooperation programmes are providing a strong contribution to worldwide development of nuclear safety practices and to dissemination of knowledge to other countries.**
	S2	**Suggestion: The NRC should evaluate the added value to safety of harmonizing its regulations and guides with the IAEA safety standards and consider the possible means to take into account the IAEA Safety Standards in the regulations and regulatory guides.**
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**GP3**	**Good Practice: The proactive, systematic and integrated human capital planning of NRC supported by information technology tools.**
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**R1**	**Recommendation: The NRC should identify/confirm and describe its organizational wide core processes and support processes and include process inputs, flows and outputs (e.g., develop a process map) in order to confirm and document a fully integrated Management System.**
	R2	**Recommendation: The NRC should develop a methodology and implement a holistic Management System Review at planned intervals to ensure the continuing effectiveness of the management system.**
	S3	**Suggestion: The NRC should continue to develop its draft Management System Description Document and accommodate in this document the**

AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		results of the recommendations given above.
	GP4	**Good practice: The NRC´s Open Door Policy, Non Concurrence Process and Differing Professional Opinions Programme are good instruments for reinforcing a questioning attitude at all levels of the organization and thereby promoting safety culture. [See www.nrc.gov/about-nrc/values for more information].**
5. AUTHORIZATION	**GP5**	**Good Practices: The NRC licensing process, and in particular the license renewal process is carried out in a very transparent manner, providing opportunities for hearing and public involvement. A number of meetings are held in the vicinity of the plants to provide the public with information on the license renewal process, solicit input on the environmental review, and to provide the results of the NRC's inspections.**
	GP6	**Good Practice: Vendors, contractors, or any individual providing services to the nuclear industry are required to inform on any failure of a facility or activity to comply with any applicable rule, regulation, order, or license, or if any basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to the NRC. The NRC has the authority for issuing orders to vendors and contractors to enforce this regulation.**
	S4	**Suggestion: The NRC should develop means to verify that the new operators have received adequate training on management of severe accidents.**
6. REVIEW AND ASSESSMENT	**GP7**	**Good Practice: The process of sharing lessons learned between NRC offices dealing with operating and new reactors respectively is very well controlled, including establishment of formal links, and provides for systematic future utilization of broad experience gained from supervision of operating reactors.**
	GP8	**Good Practice: NRC maintains and utilizes internal capability for performing independent audit calculations by means of deterministic and probabilistic computer codes including development of such codes,**

AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		and shares the computer codes and relevant experience with other regulatory bodies worldwide.
	GP9	**Good Practice: NRC as a standard practice identifies relevant precedent licensing actions and use them for new submittals. This practice significantly increases the efficiency of the review process by reducing expended resources.**
	GP10	**Good Practice: NRC has developed and continuously updates a system of both procedural and technical guidance documents for review and assessment which are shared and made available to regulatory bodies worldwide.**
	S5	**Suggestion: Future updates of the NRC's Standard Review Plans should take into account scientific and technological developments in the area of safety assessment as reflected in the relevant IAEA safety standards.**
	S6	**Suggestion: NRC should consider limiting its approval of codes submitted by vendors to a specific period of time to ensure the codes are periodically evaluated and updated, as necessary, to reflect lessons learned and the latest knowledge.**
	S7	**Suggestion: NRC should consider proper ways aimed at more direct implementation of ALARA principle in setting up the radiological acceptance criteria for design basis accidents as well as in assessment of acceptability of the results of relevant safety analysis.**
	S8	**Suggestion: NRC should assess whether the current regulations adequately provide for an independent verification of the safety assessment under the responsibility of the licensee before its use or submittal to the regulatory body and whether this verification is adequately confirmed by the NRC.**
	S9	**Suggestion: NRC should incorporate lessons learned from Periodic Safety Reviews performed in other countries as an input to the NRC's assessment processes.**
	GP11	**Good Practice: NRC has developed and implemented a robust**

AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		operational experience feedback programme, including also guidance for safety enhancement and corrective actions recommended on the basis of lessons learned. The programme and a unique database are available for sharing experiences with all interested parties both nationally and internationally.
	GP12	**Good Practice: NRC collects and documents unique generic lessons learned in US from aging management, and is committed to continue to share them with nuclear community through the IAEA and other international channels as essential contribution to maintaining safety during long term operation of NPPs.**
7. INSPECTION	**GP13**	**Good Practice: Inspection programme has clear goals and a logical structure to verify that plants are operated in compliance with the NRC regulations and licence conditions. For more information see following websites:** **http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html** **http://www.nrc.gov/reactors/operating/oversight/program-documents.html#inspection**
	GP14	**Good Practice: Inspection procedures, plant specific inspection reports and assessment results are publicly available. For more information see following websites:** **http://www.nrc.gov/reactors/operating/oversight/program-documents.html#inspection** **http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/listofrpts_body.html** **http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html#plantassess** **http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/listofasmrpt.html**
	GP15	**Good Practice: NRC has provided training and procedures to their inspectors to observe safety culture factors in licensee's performance. These observations are collectively evaluated according to an assessment process every six months.**

AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		For more information see IMC 0305 and IMC 0310
	S10	**Suggestion: NRC should ensure that Severe Accident Management (SAM) is properly addressed in the Reactor Oversight Process (ROP)**
	S11	**Suggestion: NRC should review its inspection event response guidance and interact with licensees with an objective of reconfirming that the role of the NRC is understood and does not unduly influence the actions taken by the licensee.**
	GP16	**Good Practice: There are effective ways to support inspection activities and share inspection findings within the region and HQ. This enables that generic inspection findings can be identified and adequately addressed with the licensees and also taken into account in different regulatory processes.**
	GP17	**Good Practice: NRC has established several ways for inspectors to share experience and compare practices. This enables development of inspection practices and promotes consistent way of working of the inspectors and implementation of the inspection programme.**
	GP18	**Good Practice: Resident inspectors have risk tools (including SAPHIRE models) available to focus their inspections on risk significant items and to perform risk calculations to evaluate risk significance of component unavailabilities.**
8. ENFORCEMENT	**There were no recommendations, Suggestions or Good Practices in this section**	
9. REGULATIONS AND GUIDES	**S12**	**Suggestion: The NRC should prioritize the development and issuance of a formal procedure for development and revision of Regulatory Guides.**
	S13	**Suggestion: The NRC should consider making an implementing procedure to guide the periodic systematic review for its regulations and guides based on operating experience feedback and the development of international safety standards.**
	S14	**Suggestion: The NRC should consider possible measures to ensure that all licensees are more proactive in upgrading the systems, structures and**

AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		components of their facilities with the objective to improve safety margins. (See also S1)
	GP19	Good Practice: The NRC has developed a systematic and completed set of regulations and guides, and developed practicable and useful working documents, such as standard review plan, reactor oversight process, and related procedures and programmes. This is a good way and useful not only for standardization of use of regulations but also for knowledge management.
	GP20	Good Practice: The rulemaking process is very well-documented, comprehensive for the different stakeholders, with clear organisation and responsibilities for each actors, overall coordination, consultation of interested parties and regulatory analysis taking into account impact on the licensees, the public and the NRC.
10. EMERGENCY PREPAREDNESS AND RESPONSE	GP21	Good Practice: NRC commissioned a detailed study to determine the effectiveness of the licensees public awareness programme to find out how the public understands the information on risks and actions to be taken in case of an emergency.
	GP22	Good Practice: The NRC introduced performance indicators for emergency preparedness, e.g. Drill/Exercise Performance; Emergency Response Organization Drill Participation; Alert and Notification System Reliability, which are evaluated every three months.
	GP23	Good Practice: A sound and detailed on-site and off-site emergency exercise programme has been developed over the last thirty years, for a variety of scenarios with well balanced and comprehensive set of objectives, which are tested – based on previously defined evaluation criteria - by a series of exercises over a six year period.
	S15	Suggestion: The NRC procedures for the IAEA emergency notification (ENAC) should be improved and the emergency exercise programme should include periodic testing of ENAC reporting to the IAEA.
	S16	Suggestion: The NRC should discuss with its Federal partners the consideration of a proposal for the development of initial operational

AREAS	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		intervention levels (OILs) in line with the GS-R-2 provisions.
	S17	**Suggestion: The NRC should discuss with its Federal partners the consideration of a proposal for merging of all field measurements performed during an emergency by different stakeholders in a single database. This database should be made available online for decision making purposes.**
	S18	**Suggestion: The NRC should continue to explore options with the Federal and State partners in order to expand the scope of the emergency exercise programme by adding elements to demonstrate the capability to responds to unpredictable courses of events and to make the exercise programme more challenging to all the participants.**
11. INTERFACES WITH NUCLEAR SECURITY	**GP24**	**Good Practice: The regulations and guides issued by the NRC to avoid the potential for adverse effects on safety from security and vice versa are comprehensive and provide an appropriate framework to assure that the licensees put in place an adequate management of the safety/security interface.**
	GP25	**Good Practice: The procedures developed and implemented by NRC establish clear responsibility of assignments and communication channels to allow an effective management of its internal interfaces between safety, security and emergency preparedness.**
	S19	**Suggestion: NRC's Operational Experience Branch procedures should be updated to include non nuclear information which should be collected to evaluate understanding to any impact to safety or security that may inform the safety/security interface.**
	S20	**Suggestion: NRC should take further action to encourage industry to take actions to ensure the effective co-ordination of the safety/security interface issues.**

APPENDIX VI – USNRC REFERENCE MATERIAL USED FOR THE REVIEW

[1] IRRS Questions and Answers:

- *Module 1: Responsibilities and Functions of the Government*
- *Module 2: Global Nuclear Safety Regime*
- *Module 3: Responsibilities and functions of the Regulatory Body*
- *Module 4: Management System of the Regulatory Body*
- *Module 5: Authorization*
- *Module 6: Review and Assessment*
- *Module 7: Inspection*
- *Module 8: Enforcement*
- *Module 9: Regulations and Guides*
- *Module 10: Emergency Preparedness and Response*
- *Module 11a: Periodic Safety Review*
- *Module 11b: Feedback of Operating Experience*
- *Module 12: Interfaces with Nuclear Security*

[2] References to Modules

Module 1: Responsibilities and Functions of the Government

1. *Title 5 of the Code of Federal Regulations*
- *CFR 5801, "Supplemental Standards of Ethical Conduct for Employees of the Nuclear Regulatory Commission"*
2. *Title 10 of the Code of Federal Regulations*
- *10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"*
- *10 CFR Part 9, "Public Records," Subpart C, "Government in the Sunshine Act Regulations"*
- *10 CFR Part 20, "Standards for Protection against Radiation," Subpart E, "Radiological Criteria for License Termination"*
- *10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"*
- *10 CFR 50.75, "Reporting and Recordkeeping for Decommissioning Planning"*
- *10 CFR 50.80, "Transfer of Licenses"*
- *10 CFR 50.82, "Termination of License"*
- *10 CFR 50.83, "Release of Part of a Power Reactor Facility or Site for Unrestricted Use"*
- *10 CFR 50.109, "Backfitting"*
- *10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"*
- *10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste"*
- *10 CFR 70.38, "Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas"*
- *10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-level Radioactive Waste, and Reactor-related Greater than Class C Waste"*
- *10 CFR 72.74, "Reports of Accidental Criticality or Loss of Special Nuclear Material"*
- *10 CFR 73, "Physical Protection of Plants and Materials"*
- *10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements"*
3. *U.S. Constitution*
- *Article 1, Section 7 - Revenue Bills, Legislative Process, Presidential Veto*
- *Article 6 - Debts, Supremacy, Oaths*
4. *NRC's Governing Legislation - Summary*
5. *Atomic Energy Act of 1954, as Amended (Public Law 83-703) (NUREG-0980, Volume 1, No. 8, Item 1)*
- *Chapter 2, Sec. 11. Definitions.*

- *Chapter 3, Sec. 29. Advisory Committee on Reactor Safeguards.*
- *Chapter 6, Special Nuclear Material.*
- *Chapter 7, Source Material.*
- *Chapter 8, Byproduct Material.*
- *Chapter 10, Atomic Energy Licenses.*
- *Chapter 10, Sec. 103. Commercial Licenses.*
- *Chapter 11, Sec. 121. Effect of International Arrangements.*
- *Chapter 11, Sec. 122. Policies Contained In International Arrangements.*
- *Chapter 11, Sec. 123. Cooperation with Other Nations.*
- *Chapter 14, Sec. 161. General Provisions.*
- *Chapter 14, Sec. 170. Indemnification and Limitation of Liability (Price-Anderson Act).*
- *Chapter 16, Judicial Review and Administrative Procedure.*
- *Chapter 16, Sec. 184. Inalienability of Licenses.*
- *Chapter 16, Sec. 186. Revocation.*
- *Chapter 16, Sec. 189. Hearings and Judicial Review.*
- *Chapter 18, Sec. 222. Violations of Specific Sections.*
- *Chapter 18, Sec. 223. Violation of Sections Generally.*
- *Chapter 18, Sec. 234. Civil Monetary Penalties for Violations of Licensing Requirements.*
- *Chapter 28, Sec. 1801. Uranium Enrichment Decontamination and Decommissioning Fund*

6. *Energy Reorganization Act of 1974, as Amended(Public Law 93-438) (NUREG-0980, Volume 1, No. 8, Item 2)*
- *Title II, Sec. 202. Licensing and Related Regulatory Functions Respecting Selected Administration Facilities.*
- *Title II, Sec. 205. Office of Nuclear Regulatory Research.*

7. *Reorganization Plan of 1980 and Other Documents Pertaining to NRC Jurisdiction (5 U.S.C. App I) (NUREG-0980, Volume 1, No. 8, Item 3*
- *Reorganization Plan No. 3 of 1970 (5 U.S.C. App I, Title III) (Item 3-B)*

8. *The Low-Level Radioactive Waste Policy Amendments Act of 1985 (Title I), as Amended (Public Law 99-240) (NUREG-0980, Volume 2, No. 8, Part I, Item 2-B)*
9. *The Nuclear Waste Policy Act of 1982, as Amended (Public Law 97-425) (NUREG-0980, Volume 2, No. 8, Part I, Item 3-A)*
10. *Hazardous Materials Transportation Uniform Safety Act of 1990, as Amended (Public Law 101-615) (NUREG-0980, Volume 2, No. 8, Part I, Item 5-A)*
11. *Title V of the Independent Offices Appropriations Act of 1952 (Public Law 82-137) (NUREG-0980, Volume 2, No. 8, Part I, Item 6-A)*
12. *Administrative Law Statues (NUREG-0980, Volume 2, No. 8, Part I, Item 7)*
- *Administrative Procedures (Administrative Procedure Act) (Item 7-A)*
- *Public Information; Agency Rules, Opinions, Orders, Records, and Proceedings (Freedom of Information Act) (Item 7-A, Section 552)*
- *Judicial Review (Item 7-E)*
- *Congressional Review Act (Item 7-F)*

13. *NRC Appropriation Acts (NUREG-0980, Volume 2, No. 8, Part I, Item 8)*
- *Energy and Water Development Appropriations Act of 2006 (Public Law 109-103) (NUREG-0980, Volume 2, No. 8, Part I, Item 8)*

14. *Environmental Policy Act of 1969, as Amended (Public Law 91-190) (NUREG-0980, Volume 2, No. 8, Part I, Item 13-C)*
15. *NRC Management Directives*
- *MD 6.3, "The Rulemaking Process" June 2, 2005*
- *MD 8.4, "Management of Facility-specific Backfitting and Information Collection" October 28, 2004*
- *MD 9.3, " Organization and Function, Advisory Committee on Reactor Safeguards"*

- *MD 11.7, "NRC Procedures for Placement and Monitoring of Work With the U.S. Department of Energy (DOE)" March 2, 2007*
- *MD 11.8, "NRC Procedures for Placement and Monitoring of Work With Federal Agencies Other Than the U.S. Department of Energy (DOE)" March 2, 2007*

16. *Public Involvement in the Nuclear Regulatory Process (NUREG/BR-0215, Revision 2, October 2004)*
17. *NRC Regulatory Agenda: Semiannual Report (NUREG-0936)*
18. *Reactor Oversight Process (NUREG-1649, Revision 4, December 2006)*
19. *NRC's Organizational Values*
20. *Office of Nuclear Reactor Regulation Office Instructions*

- *COM-203, "Informal Interfacing and Exchange of Information with Licensees and Applicants," Revision 2, April 9, 2009*

21. *Performance Budget/Congressional Budget Justification (NUREG-1100)*
22. *Commission Policy Statements*
23. *NRC Strategic Plan (NUREG-1614)*

- *Volume 2, Part 1 - FYs 2000-2005*
- *Volume 2, Part 2 - FYs 2000-2005*
- *Volume 3, FYs 2004-2009*
- *Volume 4, FYs 2008-2013*

24. *Executive Order 12148--Federal Emergency Management*
25. *Memorandum of Understanding (MOU) between the Environmental Protection Agency and the Nuclear Regulatory Commission, "Consultation and Finality on Decommissioning and Decontamination of Contaminated Sites," September 30, 2002.*
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- *Chapter 6, Engineered Safety Features*
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- *Chapter 10, Steam and Power Conversion System*
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- *Chapter 12, Radiation Protection*
- *Chapter 13, Conduct of Operations*
- *Chapter 14, Initial Test Program and ITAAC-Design Certification*
- *Chapter 15, Transient and Accident Analysis*
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Module 7: Inspection

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- *10 CFR Part 20, "Standards for Protection Against Radiation"*
- *10 CFR Part 21, "Reporting of Defects and Noncompliance"*
- *10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"*
- *10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing*

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- *10 CFR 50.34, "Contents of Applications; Technical Information"*
- *10 CFR 50.35, "Issuance of Construction Permits"*
- *10 CFR 50.54, "Conditions of Licenses"*
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- *10 CFR 50.57, "Issuance of Operating License"*
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- *10 CFR 2.201, "Notice of Violation"*
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- *10 CFR 2.204, "Demand for Information"*
- *10 CFR 2.205, "Civil Penalties"*

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- *Chapter 14, Sec. 161, General Provisions*
- *Chapter 16, Sec. 186. Revocation*
- *Chapter 18, Sec. 223. Violation of Sections Generally*
- *Chapter 18, Sec. 232. Injunction Proceedings.*
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3. *Enforcement Program Annual Report*
- *Calendar Year 2009*
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- *IP 95001, "Inspection For One Or Two White Inputs In A Strategic Performance Area", November 9, 2009*
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- *10 CFR 2.203, Subpart B, "Settlement and Compromise"*
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- *10 CFR 2.206,Subpart B, "Requests for Action under this Part"*
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- *10 CFR 2.801, Subpart H, "Initiation of Rulemaking"*
- *10 CFR 2.802, Subpart H, "Petition for Rulemaking"*
- *10 CFR 2.803, Subpart H, "Determination of Petition"*
- *10 CFR 2.804, Subpart H, "Notice of Proposed Rulemaking"*
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- *10 CFR 2.809, Subpart H, "Participation by the Advisory Committee on Reactor Safeguards"*
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- *10 CFR Part 51, "Environmental Protect Regulations for Domestic Licensing and Related Regulatory Functions"*
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- *10 CFR Part 71, "Packaging and Transportation of Radioactive Material"*
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- *Chapter 2, Sites Characteristics and Site Parameters*
- *Chapter 3, Design of Structures, Components, Equipment, and Systems*
- *Chapter 4, Reactor*
- *Chapter 5, Reactor Coolant System and Connected Systems*
- *Chapter 6, Engineered Safety Features*
- *Chapter 7, Instrumentation and Controls*
- *Chapter 8, Electric Power*
- *Chapter 9, Auxiliary Systems*
- *Chapter 10, Steam and Power Conversion System*
- *Chapter 11, Radioactive Waste Management*
- *Chapter 12, Radiation Protection*
- *Chapter 13, Conduct of Operations*
- *Chapter 14, Initial Test Program and ITAAC-Design Certification*
- *Chapter 15, Transient and Accident Analysis*
- *Chapter 16, Technical Specifications*
- *Chapter 17, Quality Assurance*
- *Chapter 18, Human Factors Engineering*
- *Chapter 19, Severe Accidents*
- *Appendices*
- *NUREG 1575, Revision 1, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)" Initial Report, August 2000*
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- *Chapter 6 through References*
- *Appendices A-H*
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16. *Office of FSME – Policy and Procedures*
- *FSME P&P 6-10, "FSME Procedures for Preparation and Review of Rulemaking Packages," Revision 1, May 2009*

Module 10: Emergency Preparedness and Response

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- *10 CFR 50, Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities"*
- *10 CFR 50.34, "Contents of Applications; Technical Information"*
- *10 CFR 50.47, "Emergency Plans"*
- *10 CFR 50.70, "Inspections"*
- *10 CFR 52.12, "Scope of Subpart"*
- *10 CFR 52.13, "Relationship to Other Subparts"*
- *10 CFR 53.15, "Filing for Applications"*

- *10 CFR 52.16, "Contents of Application; General Information"*
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- *10 CFR 52.18, "Standards for Review of Applications"*
- *10 CFR 52.21, "Administrative Review of Applications; Hearings"*
- *10 CFR 52.23, "Referral to the Advisory Committee on Reactor Safeguards (ACRS)*
- *10 CFR 52.24, "Issuance of Early Site Permit"*
- *10 CFR 52.25, "Extent of Activities Permitted"*
- *10 CFR 52.26, "Duration of Permit"*
- *10 CFR 52.27, "Limited Work Authorization after Issuance of Early Site Permit"*
- *10 CFR 52.28, "Transfer of Early Site Permit"*
- *10 CFR 52.29, "Application for Renewal"*
- *10 CFR 52.31, "Criteria for Renewal"*
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- *10 CFR 52.35, "Use of Site for Other Purposes"*
- *10 CFR 52.39, "Finality of Early Site Permit Determinations"*

2. *Title 44 of the Code of Federal Regulations*
- *44 CFR 351.10, Subpart B - Federal Radiological Preparedness Coordinating Committee and Regional Assistance Committees, "Establishment of Committees"*
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3. *Title 49 of the Code of Federal Regulations*
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- *IP 71114, "Reactor Safety Emergency Preparedness," June 29, 2006*
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- *Table I, "Five Categories of Nuclear and Radiation Related Threats for the Purposes of the Requirements"*

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Module 11a: Periodic Safety Review

1. *Title 10 of the Code of Federal Regulations*

- *10 CFR 50, "Domestic Licensing of Production and Utilization Facilities"*
- *10 CRF 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants"*

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- *NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," U. S. Regulatory Commission, Rockville, MD, January 1997*
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- *NUREG-1649, "Reactor Oversight Process," Revision 4, December 2006*
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- *Volume 1, Revision 1 (September 2005)*
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- *Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants (NUREG-75/014), Appendices VII – X*

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- *IMC 0308 Attachment 1, "Technical Basis for Performance Indicators" (November 2007)*
- *IMC 0308 Attachment 2, "Technical Basis for Inspection Program" (October 2006)*
- *IMC 0308 Attachment 3, "Significance Determination Process Basis Document" (October 2006)*

- *IMC 0308 Attachment 3, Appendix A, "Technical Basis for At Power Significance Determination Process" (November 2007)*
- *IMC 0308 Attachment 3, Appendix B, "Technical Basis for Emergency Preparedness Significance Determination Process" (July 2005)*
- *IMC 0308 Attachment 3, Appendix C, "Technical Basis for Occupational Radiation Safety Significance Determination Process" (July 2005)*
- *IMC 0308 Attachment 3, Appendix D, "Technical Basis for Public Radiation Safety Significance Determination Process" (June 2004)*
- *IMC 0308 Attachment 3, Appendix F, "Technical Basis for Fire Protection Significance Determination Process (IIIMC 0609, Appendix F) At Power Operations" (February 2005)*
- *IMC 0308 Attachment 3, Appendix G, "Technical Basis for Shutdown Operations Significance Determination Process" (February 2005)*
- *IMC 0308 Attachment 3, Appendix H, "Technical Basis for Containment Integrity Significance Determination Process" (May 2004)*
- *IMC 0308 Attachment 3, Appendix I, "Technical Basis for Operator Requalification Human Performance Significance Determination Process" (July 2005)*
- *IMC 0308 Attachment 3, Appendix J, "Technical Basis for Steam Generator Tube Integrity Findings Significance Determination Process" (May 2004)*
- *IMC 0308 Attachment 3, Appendix K, "Technical Basis for Maintenance Risk Assessment and Risk Management SDP" (May 2005)*
- *IMC 0308 Attachment 4, "Technical Basis for Assessment" (July 2005)*
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Module 11b: Feedback of Operating Experience

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- *LIC-401, "NRR Reactor Operating Experience Program"*

2. *NRC Management Directives*

- *MD 5.12, "International Nuclear Event Scale Participation" March 13, 2002*
- *MD 6.5, "NRC Participation in the Development and Use of Consensus Standards"*
- *MD 8.3, "NRC Incident Investigation Program," March 27, 2001*
- *MD 8.7, "Reactor Operating Experience Program"*

3. *NUREG-Series Publications Web site*

- *NUREG 0090, Volume 31, "Report to Congress on Abnormal Occurrences – Fiscal Year 2008"*
- *NUREG-0090, Volume 31 (PDF - 231 KB)*
- *Appendices A–F (PDF - 221 KB)*
- *NUREG 1022, "Event Reporting Guidelines" Event Reporting Guidelines: 10 CFR 50.72 and 50.73*
- *Revision 1*
- *Revision 2*
- *NUREG 1649, Revision 4, "Reactor Oversight Process"*

4. *SECY 09-0054, "Reactor Oversight Process Self-assessment for Calendar Year 2009"*
5. *Inspection procedure*

- *IP 71152, "Problem Identification and Resolution"*

6. *Reactor Operating Experience Task Force Report*
7. *NRC Inspection Manual (IMC)*

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8. *Title 10 of the Code of Federal Regulations*

- *10 CFR Part 20, "Standards for Protection Against Radiation"*
- *10 CFR Part 21, "Reporting of Defects and Noncompliance"*
- *10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors"*
- *10 CFR 50.73, "Licensee Event Report System"*

9. *Generic Communications*

- *Generic Letter 82-04, Use of INPO SEE-IN Program*

Module 12: Interfaces with Nuclear Security

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- *IMC 0308, "Reactor Oversight Process (ROP) Basis Document," November 18, 2007*
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7. *NRC Inspection Procedures (IPs)*
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9. *NRC Regulatory Issue Summaries (RIS)*
- *RIS 2006-12, "Endorsement of Nuclear Energy Institute Guidance, "Enhancement to Emergency Preparedness Programs for Hostile Actions," July 19, 2006*
- *RIS 2006-12, Attachment, White Paper, "Enhancement to Emergency Preparedness Programs for Hostile Actions," Revised November 18, 2005*
- *RIS 2008-08, "Endorsement of Revision 1 to Nuclear Energy Institute Guidance Document NEI 06-04, "Conducting a Hostile Action-Based Emergency Response Drill," March 19, 2008*
- *RIS 2008-08, Enclosure, NEI 06-04, Revision 1, "Conducting a Hostile Action-Based Emergency Response Drill," October 30, 2007*
10. *Memorandum from Executive Director for Operations to the Advisory Committee on Reactor Safeguards regarding the draft Regulatory Guide DG-5021, "Managing the Safety/Security Interface," March 25, 2009*
11. *NRC Regulatory Guide 5.74, "Managing the Safety/Security Interface" June 2009*
12. *Proposed Rule, "Enhancements to Emergency Preparedness Regulations," March 12, 2008 (74 FR 23254)*
13. *Commission Papers (SECY) and Staff Requirement Memoranda (SRM)*
- *SECY-99-007, "Recommendations for Reactor Oversight Process Improvements," January 8, 1999*
- *SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-up to SECY-99-007)," March 22, 1999*
- *SRM-SECY-00-049, "Results of the Revised Reactor Oversight Process Pilot Program," March 28, 2000*
- *SECY-09-0075, "Safety Culture Policy Statement," May 18, 2009*

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.1** - Organization and Staffing of the Regulatory Body for Nuclear Facilities
4.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.2** - Review and Assessment of Nuclear Facilities by the Regulatory Body
5.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.3** - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
6.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** - Documentation for Use in Regulatory Nuclear
7.	**IAEA SAFETY STANDARDS SERIES No. GS-R-2** - Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements
8.	**IAEA SAFETY STANDARDS SERIES No. GS-R-3** - The Management System for Facilities and Activities
9.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.1** - Application of the Management System for Facilities and Activities
10.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.3** - The Management System for the Processing, Handling and Storage of Radioactive Waste
11.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.4** - The Management System for the Disposal of Radioactive Waste
12.	**IAEA SAFETY STANDARDS SERIES No. GS-G-4.1** - Format and Content of the Safety Analysis Report For Nuclear Power Plants Safety Guide
13.	**IAEA SAFETY STANDARDS SERIES No. NS-G-2.9** - Commissioning for Nuclear Power Plants Safety Guide
14.	**IAEA SAFETY STANDARDS SERIES No. NS-G-2.10** - Periodic Safety Review of Nuclear Power Plants Safety Guide
15.	**IAEA SAFETY STANDARDS SERIES No. NS-G-211** - A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide

APPENDIX VIII – ORGANIZATIONAL CHART USRNC