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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

JAPAN

Tokyo, Japan

25 to 30 June 2007

DIVISION OF NUCLEAR INSTALLATION SAFETY
DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE

IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the

regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- a balance between technical and policy discussions among senior regulators;
- sharing of regulatory experiences;
- harmonization of the regulatory approaches among Member States; and
- mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than eighty Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

REPORT

INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

REPORT TO
THE GOVERNMENT OF JAPAN

Tokyo, Japan
25 to 30 June 2007

REPORT

INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)

REPORT TO THE GOVERNMENT OF JAPAN

Tokyo, Japan
25 to 30 June 2007

Mission date: 25 to 30 June 2007
Regulatory body: Nuclear and Industrial Safety Agency (NISA)
Location: NISA Headquarters, Tokyo, Japan
Regulated facilities and practices: Nuclear power plants
Organized by: IAEA

IAEA Review Team

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FOREWORD

by Mohamed ElBaradei
Director General

The General Conference Resolution of September 2006 related to the measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "Recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS."

At my opening speech of the fiftieth regular session of the General Conference in 2006, I stated that: "The Agency's safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators."

5 March 2007 | Vienna, Austria
IAEA Board of Governors

Introductory Statement to the Board of Governors

by IAEA Director General Dr. Mohamed ElBaradei
Integrated Regulatory Review Service

"The newly established Integrated Regulatory Review Service (IRRS) is intended to help Member States enhance their legislative and regulatory infrastructures, and to harmonize regulatory approaches in all areas of safety. It will also be one of the most effective feedback tools on the application of Agency standards. The first full scope IRRS was conducted last year in France."

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 authorities of Japan, an international team of experts visited the Nuclear and Industrial Safety Agency (NISA), the regulatory authority for nuclear safety, in June 2007 to conduct an Integrated Regulatory Review Service (IRRS) mission.

In order to ensure an efficient mission, a preparatory mission for the IRRS was carried out in February 2007. The objective was to determine the issues to be discussed in the main IRRS mission. In particular, the consistency and completeness of Japan's self-assessment was reviewed and a number of technical and policy issues to be reviewed by the main mission were identified.

The purpose of the IRRS was to facilitate regulatory improvements in Japan and throughout the world from the knowledge gained and experiences shared by NISA and the reviewers through the evaluation of the effectiveness of Japan's regulatory authority, its regulatory framework and its regulatory activities. The IRRS request included nuclear safety of nuclear power plants excluding radiation protection aspects. NISA requested that this mission also covers NISA's public information practices.

The IRRS Review Team consisted of experts – senior regulators – from Member States, staff from the IAEA and an IAEA administrative assistant.

The IRRS team carried out a review of the following relevant areas: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; and the management system of the regulatory body.

The mission included a series of interviews and discussions with key personnel at NISA and at other organizations, and observation of an inspection at a nuclear power plant. NISA supplied a package of documentation and self-assessment in advance of the mission and the team presented its findings based on the IAEA safety standards. Additionally, the IRRS team, together with NISA staff, discussed policy issues relating to the regulation of nuclear safety. The results of the discussions will serve as a useful basis for the evolution of future IRRS missions and will assist with continuous improvement in the regulation of nuclear safety.

The IRRS Review Team noted the open, transparent and learning attitude of NISA staff throughout this mission, and it was evident that significant effort had been put into the preparation of the mission. During the review the administrative and logistical support was excellent and the team was extended full cooperation in technical discussions with NISA personnel.

The IRRS Review Team appreciates and acknowledges NISA's participation in international cooperation activities and encourages NISA to continue its active role in the exchange of experience and expertise among regulators.

The IRRS team wants to highlight three major findings:

1) Japan has a comprehensive national legal and governmental framework for nuclear safety in place; the current regulatory framework was recently amended and is continuing to evolve;
2) NISA as the regulatory body plays a major role for directing and coordinating the evolution of the regulatory framework;
3) Challenges have already been addressed to improve the relations among NISA, the nuclear industry and stakeholders in order to come with a better understanding and cooperation. Further work is underway.

The IRRS Review Team identified good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to further strengthen the effectiveness of regulatory oversight. These recommendations and suggestions will support NISA in improving its regulatory performance and some of them are related to areas in which NISA have already implemented a programme for change.

The most relevant good practices identified are:

- NISA's relationship management programme is well-structured and comprehensive;
- The regulations and standards to be applied for licensing and approval applications have been clearly stated;
- The operating experience for major events has been thoroughly investigated and appropriate countermeasures have been enforced on the licensees.

The IRRS Review Team believes that consideration of the following recommendations and suggestions should be given high priority either because they were identified in several areas of review or because the experts considered that they will contribute significantly to the enhancement of the overall performance of the regulatory system:

- The role of NISA as the regulatory body and that of NSC, especially in preparing safety guides, should be clarified;
- NISA should continue to develop its efforts to address the impacts of human and organizational factors on safety in operation;
- NISA should develop a strategic human resources management plan to face future challenges;
- NISA should continue to foster relations with industry that are frank and open yet formal and based on mutual understanding and respect; and
- NISA should continue the development of its comprehensive management system.

The IRRS Review Team findings are summarized in Appendix V.

I. INTRODUCTION

At the request of the Japanese Government Authorities, an IAEA team consisting of ten experts from nine Member States, two staff members from the IAEA and an IAEA administrative assistant visited the Nuclear and Industrial Safety Agency (NISA) in June 2007 to conduct an Integrated Regulatory Review Service (IRRS). In February 2007 a preparatory mission had been carried out at NISA headquarters, Tokyo, to determine the issues to be discussed at the main IRRS meeting, in order to ensure the mission would be carried out efficiently. In particular, the consistency and completeness of Japan's self-assessment was reviewed, in order to assess if compliance with the IAEA safety standards (technical issues and policy issues) had been adequately evaluated. In addition, new technical and policy issues to be reviewed at the main mission were identified.

The purpose of the mission was to conduct a review of the entire Japanese regulatory framework and the regulatory activities relating to nuclear power reactors to review the effectiveness of NISA and to exchange information and experience in the regulation of the areas considered by IRRS. The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; and the management system of the regulatory body.

In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of nuclear safety. Regulatory technical and policy issues were identified after reviewing a broad spectrum of information including insights resulting from the conclusions of the review meetings of the Convention on Nuclear Safety, international conferences and forums and previous IAEA safety review services.

The mission was conducted from 25 - 30 June 2007. Before and during the mission, NISA and NSC made available a collection of reference material for the team to review. This material consisted of a large number of legal, regulatory and internal documents, in particular the report on self-assessment including the IAEA questionnaire. During the mission the team performed a systematic review of all topics using the report on self-assessment, the reference material and related presentations, interviews with NISA and NSC staff and direct observation of their working practices during an inspections carried out by NISA.

IRRS activities took place mainly at the NISA headquarters. Visits and discussions were held at Kashiwazaki Kariwa Nucleare power station, NSC, JNES, JANTI, ANRE and representatives of the nuclear industry (see Appendix III).

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct an IRRS mission to review the Japanese legal and governmental infrastructure for nuclear safety, and the effectiveness of the Japanese regulatory body (NISA) and to exchange information and experience among NISA and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The key objectives of this mission were to enhance nuclear safety by:

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

The scope requested by Japan for this IRRS mission was:

- Safety of nuclear power plants (BWR and PWR).

III. BASIS FOR THE REVIEW

A) PREPARATORY MISSON

At the request of the Japanese Government Authorities, an IAEA team of five experts consisting of three external experts and two staff members from the IAEA visited the Nuclear and Industrial Safety Agency (NISA) in February 2007 to conduct a preparatory mission for the Integrated Regulatory Review Service (IRRS). In May 2006, an information meeting was conducted at NISA headquarters, Tokyo, to discuss the objective and purpose of the review, as well as its scope in connection with all aspects covered by the Japanese regulatory authority.

The objective of the preparatory mission was to determine the issues to be discussed in the main IRRS meeting, to ensure that the mission would be carried out efficiently. In particular, the consistency and completeness of Japan's self-assessment was reviewed, to assess if compliance with the IAEA safety standards (technical and policy issues) was adequately evaluated. In addition, new technical and policy issues to be reviewed during the main mission were identified.

The preparatory work for the preparatory mission was carried out by the IRRS IAEA Team Coordinator Gustavo Caruso, NSNI/IAEA, and by the IRRS Deputy Team Coordinator, Adriana Nicic, NSNI/IAEA.

During the preparatory phase, a number of documents of the advance reference material (ARM) that had been received electronically from NISA were distributed to the experts. These documents underwent a preliminary review, which was conducted in a systematic way, based on the IRRS modules and using the appropriate review criteria (IAEA safety standards); the results of this review were used as an input for the IRRS preparatory mission.

The main documents provided by NISA and NSC as part of the ARM and which were reviewed by the experts in preparation for the preparatory mission are included in Appendix VI. The most relevant IAEA safety standards used as review criteria are GS-R-1, Safety Requirements on Legal and Governmental Infrastructure, and GS-R-3, Safety Requirements on The Management System for Facilities and Activities.

The preparatory mission consisted of a systematic review of all eight IRRS modules identified in the mission's scope, with the objectives of:

- Identifying main issues to be focused on by the main mission;
- Providing NISA with initial feedback on the information provided in the ARM;
- Clarifying the answers provided to the IRRS questionnaires, which are based on the requirements of GS-R-1 and GS-R-3; and
- Identifying additional information and material to be prepared for the main mission.

The conduct of the preparatory mission included:

- An entrance meeting, including plenary presentations;
- A review of the IRRS modules through presentations and discussions, including question and answer sessions; and
- An exit meeting, including plenary presentations.

The entrance meeting was held on Monday, 5th February 2007, with the participation of senior management of NISA, NSC and JNES. Opening remarks were made by Mr. Kenkichi Hirose, Director General of NISA, Mr. Andre-Claude Lacoste, President of the French Regulatory Authority (ASN) and Mr. Gustavo Caruso, Head, Regulatory Activities Section, Division of Nuclear Installation Safety, Department of Nuclear Safety and Security, IAEA. In addition, the

plenary session included presentations made by Mr. Hirose – Roles and Responsibilities of NISA, Mr. Katayama – Roles and Responsibilities of Nuclear Safety Commission (NSC), Mr. Nariai – Roles and responsibilities of JNES and Mr. Hiraoka – Outline of the Japanese Regulatory System. (The programme of the preparatory mission is provided in Appendix X)

The review of the IRRS modules was conducted in parallel sessions by the two IRRS sub-teams, led by the Team Leader, Mr. Lacoste (modules 1, 2, 3, and 8) and the Deputy Team Leader, Mr. Laaksonen (modules 4, 5, 6 and 7). The Japanese counterparts were organized in 8 teams, one for each IRRS module. Each session contained presentations by Japanese counterparts, addressing the outline of the regulatory system for a specific module, the results of the self-assessment (responses to IRRS questionnaires and the self-assessment report) and key topics, based on documents such as materials for the Policy Dialogues. Sufficient time for discussions and questions and answers was planned for each session. The information collected and discussed each day by each sub-team was reviewed by all IRRS team members, and main issues were identified and discussed daily with NISA representatives. These issues formed the basis for the conclusions presented at the exit meeting.

The exit meeting was held on Thursday, 8th February 2007, with NISA authorities, in particular Mr. Hirose, Director General of NISA, Mr. Soda, Commissioner of NSC and senior managers, department heads, division heads, section heads, and technical and support staff from NSC and JNES. The plenary session also included presentations of the main conclusions of the review; these presentations were made by the IRRS Team Leader and the Deputy Team Leader.

The preparatory mission included also a discussion between the IRRS IAEA Team Coordinator and NISA representatives on the logistics and preparation for the main mission.

For the whole duration of the preparatory mission, an open, frank and constructive atmosphere was created and maintained by the Japanese counterparts. Active participation by technical and managerial experts, knowledgeable in the review topics, was observed in all review sessions; this facilitated and significantly contributed to an effective and efficient manner of transferring information between the host country and the IRRS team members. The presentations prepared by NISA, NSC and JNES were clear, of high quality, provided the team with adequate understanding of the Japanese regulatory system and represented a good introduction to the organization of NISA and the challenges it faces. The discussions were well supported by professional teams from the host country, who were available to answer to IRRS team questions. It should also be mentioned that all activities of the preparatory mission were also supported by high-level translation services provided by the host country.

Upon completion of the presentations and discussions of all review modules, the IRRS team analysed the collection of available information, and prepared the conclusions of the preparatory mission in the form of a list of policy and technical aspects. Most of these topics are relevant to several IRRS modules; Appendix XI contains this list, with references to the appropriate IRRS modules. These elements were taken into account by NISA, NSC and JNES in preparation for the main IRRS mission**.** For each of the issues identified, some additional information, such as presentations, examples of regulatory outputs, objective evidence of regulatory actions, documents submitted by applicants or licensees, and regulatory documents, needed to be prepared by the Japanese counterparts, as appropriate. Appendix XII contains more details about the requested information. The information already presented during the preparatory mission was not to be duplicated in the additional presentations and materials to be prepared for the main mission.

During the main mission, in order to reach the most reliable and significant conclusion possible, it needed to be ensured that the reviewers would have ‘sufficient contact with reality’. This means that meetings with relevant organizations were to be held to confirm what had been presented and to ensure an adequate coverage of organizational interfaces and the proper discharge of regulatory roles and responsibilities. Such organizations would include local inspector offices, ANRE, METI,

operators, local governments, and NGOs. Further discussion between NISA and the IRRS team led to agreement on the list.

The IRRS team members who participated in the preparatory mission were required to ensure that all the information already presented during this mission would be adequately transferred and explained to the new IRRS team members (who were to participate in the main mission) by the IAEA Secretariat.

It was discussed and agreed with the host country that the IRRS mission would take place 25th to 30th June 2007, and that the IRRS team would have 10 experts in addition to the IAEA staff.

A draft agenda for the IRRS mission was developed; this is provided in Appendix II.

B) MAIN MISSION PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the mission was carried out by the IRRS IAEA Team Coordinator, Gustavo Caruso, NSNI/IAEA, and by the IRRS Deputy Team Coordinator, Adriana Nicic, NSNI/IAEA. This work was based on the results of the preparatory mission (see Section A) where the additional material to be prepared by NISA and NSC (Appendix XII) and the list of issues for the Policy Dialogues (Appendix XI) were identified. Taking into account the scope as indicated above, it was agreed that the IAEA Review Team would comprise ten external experts from nine Member States (see Appendix I). The distribution of working areas and the assignment of NISA were conducted according to Appendix IV.

During the preparatory period all documents of the advance reference material (ARM) were sent electronically by NISA to the IAEA, which then distributed the ARM to the experts. All details and organizational aspects were defined with the nominated NISA Counterparts – Liaison Officer Mr. Tomoho Yamada and Deputy Liaison Officer Masahiro Yagi.

A significant amount of work was carried out by the reviewers and by the IAEA staff before the review in order to prepare the initial impressions about the ARM, to review the answers to the questionnaire sent to NISA, to prepare for the interviews and direct observations on site and to identify additional relevant material necessary to review during the mission.

C) REFERENCES FOR THE REVIEW

The main reference documents provided by NISA and NSC for the review mission are listed in Appendix VI. The most relevant IAEA safety standards and other reference documents used for the review are listed in Appendix VII.

D) CONDUCT OF THE REVIEW

An entrance team meeting was conducted on 24th June 2007 at the Grand Prince Hotel Akasaka by the IRRS Team Leader, the IRRS IAEA Team Coordinator and the IRRS Deputy Team Coordinator to discuss the specifics of the mission, to clarify the basis for the review, background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. The Liaison Officer and the Deputy Liaison Officer were present in this meeting. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 25th June 2007, with the participation of NISA, NSC and JNES senior management. Opening remarks were made by Mr. Kenkichi Hirose, Director General of NISA, and Mr. Andre-Claude Lacoste, IRRS Team Leader. Mr. Gustavo Caruso, IRRS IAEA Team Coordinator, presented the results of the preparatory mission to Japan which had been held in February 2007. Mr. Kunihisa Soda, Commissioner of the Nuclear Safety Commission, and Mr. Hideki Nariai, President of Japan Nuclear Energy Safety Organization (JNES) also participated in the entrance meeting.

During the mission, a systematic review was conducted for all the review areas with the objective of providing NISA with recommendations and suggestions as well as of identifying good practices. The review was conducted through meetings, interviews and discussions with NISA, NSC and JNES personnel, visits to relevant organizations, assessment of the ARM, and direct observations regarding the national practices and activities, particularly in the context of an inspection.

The team performed its activities based on the mission programme given in Appendix II.

The exit meeting was held on Saturday, 30th June 2007, with the NISA authorities: Mr. Kenkichi Hirose, Director General of NISA, Mr. Kunihisa Soda, Commissioner of NSC, Mr. Hideki Nariai, President of JNES attended the meeting as well as department heads, division heads, section heads, technical staff and support staff. The main conclusions were presented by Mr. Andre-Claude Lacoste, IRRS Team Leader, and closing remarks were made by Mr. Philippe Jamet, Director, Division of Nuclear Installation Safety, Department of Nuclear Safety and Security, IAEA. The draft technical notes were handed over to NISA at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

This chapter includes discussions on the following Policy Dialogues:

- Policy Dialogue 1, Institutional Matters at NISA, NSC, METI, ANRE and NISA/JNES

A legislative framework for nuclear safety is in place in Japan. Requirements for authorization and control of nuclear power plants are set out mainly in the *Atomic Energy Basic Law (1955)*, the *Law on Regulations of Nuclear Sources Material Nuclear Fuel Material and Nuclear Reactors (1957)*, and the *Electricity Utilities Industry Law (1964).*

In recent years the legislation in Japan has been amended and updated. Governmental responsibilities for nuclear safety have been reorganized, with the aim of strengthening the legal and governmental framework in response to incidents that have occurred and to prevent recurrence.

The practice by the Japanese government of continuously improving the legal and governmental framework for nuclear safety in the light of experience is highly commendable.

The current national legislation establishes several governmental entities such as Atomic Energy Commission (AEC), Nuclear Safety Commission (NSC), Ministry of Economy, Trade and Industry (METI), Agency for Natural Resources and Energy (ANRE), Nuclear and Industrial Safety Agency (NISA) and Japan Nuclear Energy Safety Organization (JNES). The law goes into detail with regard to organizational arrangements which may cause complexity and the responsibilities for nuclear safety among these entities, although defined in the relevant laws, seem intertwined.

NISA was established by law in 2001 as a special agency attached to ANRE within METI. METI and ANRE are also engaged in setting energy policy and promoting nuclear energy. NISA is delegated responsibility from the Minister of METI as the regulatory body, and carries out its assigned responsibilities. In case of conflict between safety and promotion, the Minister will put priority on safety, as required by law. METI established its National Strategic Plan based on such priority. NISA is effectively independent from ANRE, in correspondence with the requirements of GS-R-1. This situation could be reflected in the legislation more clearly in future.

The Nuclear Safety Commission (NSC) is an important organization. The NSC plays both a supervisory role and an advisory role. NSC provides recommendations in the name of the Prime Minister to the competent minister (the Minister of METI), which is required by law to consider them. NSC is empowered by law to require reports from NISA and performs double-check reviews of NISA's work on issuing licences. In the double-check process, NSC produces regulatory guides and NISA utilizes them as criteria for issuing a licence.

The role of NISA as the regulatory body and that of NSC, especially in preparing safety guides should be clarified.

Inspection activities, which are an important part of the functions and responsibilities of the regulatory body, have been partly assigned to JNES by law. For policy reasons NISA sources these functions solely to JNES, while in return JNES works almost exclusively for NISA.

Consequently NISA has to manage the interface with JNES with regard to its inspection activity.

Conclusion

Japan has a comprehensive national legal and governmental framework for nuclear safety in place. This framework includes several entities, principally NSC, NISA and JNES, involved in regulatory activities for nuclear safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para. 2.4 states that *"Legislation shall be promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transport safety. This legislation:*

(1) shall set out objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future;

(2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation;

(3) shall establish authorization and other processes (such as notification and exemption), with account taken of the potential magnitude and nature of the hazard associated with the facility or activity, and shall specify the steps of the processes;

(4) shall establish a regulatory body with the authority outlined in para. 2.6;

G1 **Good Practice:** Japan is continuously making efforts to update and improve its legislative and governmental framework with the aim of strengthening arrangements for nuclear safety in the light of incidents which have occurred and to prevent recurrence.

(1) **BASIS:** GS-R-1 para. 2.2 states that *"There are certain prerequisites for the safety of facilities and activities. These give rise to the following requirements for the legislative and governmental mechanisms of States:*

(1) A legislative and statutory framework shall be established to regulate the safety of facilities and activities.

(2) A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.

(3) Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides.

(4) The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities.

(5) No other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety.

(6) Adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste.

(7) Adequate infrastructural arrangements shall be made for the safe transport of radioactive material.

(8) An effective system of governmental emergency response and intervention capabilities shall be established and emergency preparedness shall be ensured.

(9) Adequate infrastructural arrangements shall be made for physical protection, where these influence safety.
(10) Adequate financial indemnification arrangements shall be made for third parties in the event of a nuclear or radiation accident in view of the damage and injury which may arise from an accident.
(11) The technological infrastructure necessary for ensuring the safety of facilities and activities shall be provided, where this is not provided by other organizations."

(2) **BASIS:** GS-R-1 para. 2.4 states that *"If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and co-ordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator. The main functions of review and assessment and inspection and enforcement shall be organized in such a way as to achieve consistency and to enable the necessary feedback and exchange of information. In addition, the authorities responsible for the different disciplines concerned in the regulatory process, such as those responsible for nuclear, radiation, radioactive waste and transport safety, shall be effectively co-ordinated."*

(3) **BASIS:** GS-R-1 para. 2.6 states that *"The regulatory body shall have the authority:*
(1) to develop safety principles and criteria;
(2) to establish regulations and issue guidance;
(3) to require any operator to conduct a safety assessment;
(4) to require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;
(5) to issue, amend, suspend or revoke authorizations and to set conditions;
(6) to require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;
(7) to enter a site or facility at any time to carry out an inspection;
(8) to enforce regulatory requirements;
(9) to communicate directly with governmental authorities at higher levels when such communication is considered to be necessary for exercising effectively the functions of the body;
(10) to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate;
(11) to communicate independently its regulatory requirements, decisions and opinions and their basis to the public;
(12) to make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate;
(13) to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods; and
(14) to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information."

R1 **Recommendation:** The role of NISA as the regulatory body and that of NSC, especially in producing safety guides, should be clarified.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S1	**Suggestion:** NISA is effectively independent from ANRE, in correspondence with the GS-R-1. This situation could be reflected in the legislation more clearly in future.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

This chapter includes discussions on the following Policy Dialogues:

- Policy Dialogue 7, Transparency and Openness

The IAEA Review Team understands that NSC plays a key role in setting policy in nuclear safety. NISA has described in its basic policy its organizational target of 'Safety assurance of citizens and preservation of environment'. NISA has also described a code of conduct based on the following four principles:

- Strong sense of mission;
- Scientific and rational judgements;
- Neutrality and justice;
- Transparency in our operations.

NISA has described its decision making process and public communication as being based on scientific and rational judgement, while less account is taken of issues related to management of safety and human performance.

Regulatory requirements and guidance are available from various sources. Under the *Law on the Regulations of Nuclear Sources, Material, Nuclear Fuel and Reactors*, NSC has published some sixty guides on various aspects of nuclear safety. The *Electricity Utilities Law* sets out technical criteria for approval of NPP construction, various pre-service inspections, the operational safety programme and in-service periodic inspection. Academic bodies produce subordinate technical standards which NISA endorses. In addition, NISA has produced a review guide for the operational safety programme.

The *Law on the Regulations of Nuclear Sources, Material, Nuclear Fuel and Reactors* requires a licence to be granted for the establishment of a reactor. NISA assesses submissions by the applicant as required by the legislation. NSC also carries out an independent assessment of applications for licences and provides an opinion which the 'competent minister' (the Minister of METI) is required by law to consider.

Following a decision by the Minister of METI on a licence to establish a reactor, NISA performs assessments of the construction plan. NISA headquarters and JNES inspectors perform periodic inspections as defined in regulations, while NISA resident inspectors carry out operational safety inspections and investigations. In this scheme of inspections, following the guidance given above, considerable emphasis is placed on technical criteria with correspondingly less emphasis on the provision of guidance to the operating organization on developing and submitting comprehensive operational safety programmes and addressing all elements relevant to safety in operation, including human and organizational factors.

As part of its management policy, NISA established two key activities relating to 'relationship management' and 'knowledge sharing' and has created the Nuclear Safety Public Relations and Training Division. 'Relationship management' is focused on managing the interfaces with NISA's external stakeholders including licensees, the public, local communities, the media, other government departments and international organizations to further improve the effectiveness and transparency of the nuclear regulatory regime and to build public confidence and trust. 'Knowledge sharing' is focused on sharing information within the organization in order to improve the quality and effectiveness of NISA activities.

'Relationship management' has introduced new initiatives such as enhanced participative public hearings and dialogues, the use of newsletters and email newsletters (with approximately 1000 subscribers) and providing information through CATV (NISA-TV).

A number of initiatives have been introduced to improve information exchange and discussion between NISA and licensees at all levels. NISA's main objective for relationship management activities with licensees was stated as "*Ensure sufficient opportunities for opinion exchanges in various fora, of which transparency is a prerequisite, so that licensees understand NISA's regulatory positions, and also so that NISA recognizes their views against them*." Initiatives include the introduction of a 'pocket handbook' with 10 rules for inspectors to promote mutual trust between the inspectors and licensee staff; top management meetings between the Director General of NISA and presidents of the nuclear power companies; nuclear power plant visits by senior NISA officials; regular meetings on nuclear safety management between NISA, JNES utilities and industry support organizations; and council meetings at which representatives of licensees and/or industry groups can express views. However, the IAEA Review team also formed the impression that NISA seems to direct and overrule operating organizations, rather than listening to them and evaluating their views. Many detailed decisions are made by NISA.

NISA's relationship management programme also extends to internal communications. Internal communications in NISA have been enhanced with regular weekly meetings for different areas of responsibility to exchange information on policy planning, operational and organizational issues supplemented as necessary with internal lectures to share experienced based knowledge. The IAEA Review Team was informed that most internal communication meetings are attended by the managerial level of NISA. Arrangements for resolving internal dispute are not in place and a system for raising internal concerns and allegations has not been formally established. Currently, the main vehicle for communication between the Director General and staff members is meetings in his office and the e-mail.

Finally, NISA is actively engaged in communications with other government departments and agencies. NISA is also actively engaged with international organizations and outside experts.

Conclusion

Most of the functions and responsibilities of the regulatory body are present in the Japanese regulatory framework.

NSC is a council established in the Cabinet Office and supervises NISA, and NISA is the regulatory body. By the stipulation of law, JNES conducts some inspections. However, the organizational arrangements may cause complexity and the responsibilities for nuclear safety among these entities, although defined in the relevant laws, seem intertwined.

Furthermore, NISA, NSC and JNES have tended in the past to focus their guidance and activities to a large extent on technical issues relating to hardware. While the importance of human and organizational factors is increasingly recognized, regulatory requirements and criteria covering all elements important to safety in operation, including human and organizational factors, are less well established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para. 3.3 (6 & 11) states that *"In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body:"*
(6) shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public;
(11) shall advise the government on matters related to the safety of facilities and activities;"

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2) **BASIS:** GS-R-1 para. 3.4 states that *"The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary:*
(1) environmental protection;
(2) public and occupational health;
(3) emergency planning and preparedness;
(4) radioactive waste management (including determination of national policy);
(5) public liability (including implementation of national regulations and international conventions concerning third party liability);
(6) physical protection and safeguards;
(7) water use and consumption of food;
(8) land use and planning; and
(9) safety in the transport of dangerous goods."

(3) **BASIS:** GS-R-1 para. 4.10 states that *"Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship, shall be fostered."*

G2 **Good Practice:** NISA's relationship management programme is a well-structured and comprehensive programme that reflects best practice.

G3 **Good Practice:** Communication with the public at the local level is well-structured and allows for regular and positive exchanges between NISA, the public and the operators.

G4 **Good Practice:** The public is involved in NISA's advisory sub-committees

(1) **BASIS:** GS-R-1 para. 4.6 states that *"The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions."*

S2 **Suggestion:** NISA should make further headway on developing a decision making process in order to obtain sound judgement based on information provided by licensees, inspectors or the public that can not necessarily be developed in a scientific manner. All issues should be taken into account so as to evaluate and judge safety in a more holistic manner.

(1) **BASIS:** GS-R-1 para. 4.10 states that **"***Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship shall be fostered."*

S3 **Suggestions:** It is suggested that NISA continue to foster relations with industry that are frank and open, yet formal and based on mutual understanding and respect.

3. ORGANIZATION OF THE REGULATORY BODY

This chapter includes discussions on the following Policy Dialogues:

- Policy Dialogue 2, NISA's Personnel
- Policy Dialogue 8, Internal communication

NISA's personnel allocated to the regulation of nuclear safety have increased rapidly since its foundation in 2001, to reach approximately 350 people today. To support the regulatory regime in Japan, JNES has a further approximately 460 personnel. In addition, NSC has a further approximately 110 personnel for its policy planning and supervising role.

NISA's staff numbers are subject to the general rules for personnel of METI and of the Japanese Government in general. The Ministry for Information and Coordination (MIC) has the final decision regarding the staff numbers, the number of divisions, the number of deputy-directors, etc. The current government has decided to reduce staff numbers in governmental administrative posts by 5% over the next five financial years, finishing in 2010. As a result of year-to-year negotiations with MIC it was noted that NISA's efforts to maintain the current staffing levels for nuclear safety were quite successful.

JNES is set up as an incorporated administrative organization whose role is to support NISA. In particular JNES is required to maintain strong expertise and is mandated to carry out specific inspections in support of NISA. This is a mechanism to supplement the resources and staffing available to NISA.

NISA employs two main categories of staff. The first category, known as 'policy makers', consists essentially of staff who were recruited to METI after university and whose career will require working in different departments of METI. The second category, known as 'experts', consists of staff who was recruited mid-career, essentially from the private sector and with substantial nuclear-related experience or expertise (manufacturers, operators, designers, academics, researchers, etc.). These experts are likely to assume successive positions within NISA on nuclear safety regulation activities until the end of their career. NISA is proactive in its recruiting efforts and confirmed that it had no immediate difficulties in recruiting staff but that there is a potential issue concerning the demographics of medium term staff which will need to be managed. This is particularly important for the experts who are recruited mid-career.

For both these categories of staff, a comprehensive set of training requirements and regular training programmes has been established for general nuclear safety and regulatory issues, as well as for detailed technical areas. However training for inspection of the attributes of quality management systems and for providing knowledge and appreciation of licensees' operational practices can be improved.

NISA adheres to the government-set rule that applies to personnel, namely a staff / job rotation every two to three years. NISA strives to retain its expertise and experience in two ways. First, the "experts" are rotated within NISA. Second, the "policy makers" are expected to stay at least three years. However they may rotate through other departments of METI. This may be considered only a temporary loss of the expertise, given that subsequent return to NISA remains possible. To date a limited number of staff have been rotated from NISA to JNES but no JNES staff have moved to NISA.

NISA is engaged in a process of continuous upgrading and improvement of its practices and procedures for nuclear safety regulation and is introducing new requirements and inspection techniques. In order to maintain effective nuclear safety regulation, this requires a continuity of view among the staff and even more so among senior management.

Conclusion

NISA is actively managing the recruitment and training of the staff allocated to nuclear safety regulation. However the current Government requirement for a 5% reduction in the administration and the policy of staff rotation pose a potential challenge to the continued effective regulation of nuclear safety in Japan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para. 4.7 states that *"…. the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts."*

(2) **BASIS:** GS-R-3 para. 4.3 states that *"Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence…."*

(3) **BASIS:** GS-R-3 para. 4.4 states that *"Senior management shall ensure that individuals … understand the consequences for safety of their activities….Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives."*

G5 **Good Practice:** NISA has a proactive recruitment, training and staff development policy which allows it to achieve and maintain high technical competence.

R2 **Recommendation:** NISA should enhance its training requirements and programmes to ensure that all aspects of inspection requirements, such as attributes of quality management systems, and knowledge and awareness of licensees' operational requirements and practices are adequately included.

(1) **BASIS:** GS-R-1 para. 4.1 states that *"…. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. …."*

(2) **BASIS:** GS-R-1 para. 4.8 states that *"…. the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants."*

(3) **BASIS:** GS-R-3 para. 4.1 states that *"Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R3 **Recommendation**: NISA should produce a workforce plan that clearly identifies its minimum staffing needs to discharge the functions and tasks required to secure effective nuclear safety regulation in Japan against the elements of its 5-year strategic plan. Future staff number / budget requests would then be based on these minimum resource needs plus any supplement required for additional work / tasks. (The workforce of the regulatory system JNES/NISA and NSC should be ensured considering respective functions –mandates, completeness, fairness, neutrality, etc. – for this issue.)

(1) **BASIS:** GS-R-1 para. 4.6 states that *"....The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions."*

(2) **BASIS:** GS-R-3 para. 4.4 states that *"Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives."*

S4 **Suggestion:** NISA should consider different staff / job rotation frequencies and patterns (particularly for its senior management) to further enhance its knowledge management and effectiveness of nuclear safety regulation of strategic and operational issues.

4. AUTHORIZATION

This chapter includes discussions on the following Policy Dialogues:

- Policy Dialogue 11, Authorization of New Plants

The authorization process – licensing and approval – for new plants or for modifications to existing plants has a strong legal basis supported by related ordinances, rules and standards. A staged approach is followed that distinguishes between the planning and design stage, the construction stage, the operation stage and the decommissioning stage, as initiated by the respective applications of the utility. The planning and design stage is completed by a licence for the basic design under the Law on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Nuclear Reactors. The application for construction is approved under the Electricity Utilities Industry Law in several steps and is based on compliance of the detailed design with technical standards.

In the first stage, licensing of the basic design review is conducted by NISA following a double check approach: a primary review performed by NISA and a secondary review by NSC and AEC. Both commissions provide opinions to METI that have to be taken into account before the licence may be granted. A licence is required for a site. The establishment of an additional plant at a site is subject to an amendment of the existing licence. Licences do not have time limitations. Licences are signed by Minister of METI.

For the submittal of the licensing documents by the applicant, detailed guidance has been developed by NISA using common international practices that have been adapted to national needs and have been extended step by step by additional items. A recent example for the voluminous set of documents submitted for licensing was shown and explained to the IRRS Review Team.

As part of its management system, NISA has developed internal rules for the 'Safety Examination of Applications for Reactor Establishment (Alteration) Licence'. The list of contents and basic approaches was presented to the IRRS team. The rules include a reference to all standards and guides that have to be applied. This review process is supported by independent analysis, as NISA requests JNES to crosscheck the licensee's analysis. The results are compiled in a safety review report that includes possible terms and conditions of the licence.

Based on NISA's review documentation, NSC and AEC perform a secondary review to provide opinions to METI. AEC provides an opinion on issues related to the peaceful use of nuclear material, on energy policy matters and on financing but not on safety matters.

NSC performs a scientific and objective evaluation by a comprehensive review of the documents submitted by the NISA. This evaluation is based on the latest scientific knowledge of disaster prevention, the technical capability to operate the nuclear reactor competently and the overall safety of the nuclear reactor

Finally the Minister of METI decides on the licence based on submissions from NISA integrating NSC's and AEC's opinions. So far no conflicting positions have emerged, as consensus has been achieved between the regulatory parties involved. Licences are signed by the Minister.

After having received a licence, the operator applies for the approval of the construction plan under Art.47 of the Electricity Utilities Industry Law. The application is submitted in several parts throughout the construction process, with each part covering the detailed design of specific systems, structures and components.

The respective regulations are contained in the two laws and associated ordinances, rules and standards. To enforce the requirements of the Electricity Utilities Industry Law, the detailed design documents are assessed for compliance with technical standards. Construction plans must

be assessed before installation or construction may commence. All structures and equipment are inspected after their installation by pre-service inspections. JNES performs assessments and inspections in support of NISA. To enforce the Law on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Nuclear Reactors, nuclear safety aspects are assessed for compatibility with the basic design licence and the respective nuclear safety ordinances and rules. Approvals are needed for the pre-service inspection, the fuel design, the fuel inspection and the safety management review for welding.

After completion of construction work, the operator applies for approval of the operational safety programme. A typical example of the structure and the content of this document was presented to the IRRS team. Approval by the competent minister is needed before fuel can be loaded to the nuclear reactors. Approvals are signed by the Minister of METI.

The same authorization procedure is followed for major modifications that have a safety significant impact on the basic design. For the modification of systems, structures and components, approvals are necessary as specified by the respective ordinance. For other modifications a notification procedure is practiced. The safety significance of modifications is assessed mainly using, a hardware based classification system. For the assessment of changes of management and operation there is no such formal classification of safety significance.

Alternative technical solutions to achieve safety objectives at least as good as those required by current technical standards are reviewed and authorized based on Article 3 of the Ordinance of the Ministry for Establishing Technical Standards for Nuclear Power Generation.

There are no legal regulations for the consideration of beyond the design basis, as Japanese plants are considered to be adequately safe as ensured by preventive measures. The regulatory body has strongly requested licensees to voluntarily implement severe accident management (SAM) and carry out probabilistic safety assessment (PSA) including preventive and mitigatory measures in line with the guide for SAM review prepared by METI. Accident management measures are taken by licensees on a voluntary basis.

Conclusion

Japan has a sound and well guided system for authorization of new plants as well as for modifications of plant design and operation. The regulatory procedures are based on two laws, one addressing nuclear safety and the other the safety and reliability of power supply.

Technical matters play the main role in the authorization process, while improvements towards an integrated review of all factors contributing to the safety, especially management and human factor issues are under development.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1, para. 5.4 states that *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization."*
(2)	**BASIS:** GS-R-1, para. 5.8 states that *"...the regulatory body shall define and make available to the operator the principles and criteria on which its judgements and decisions are based."*
(3)	**BASIS:** GS-R-1, para. 5.28 states that "*"Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards." (More guidance can be found in IAEA Safety Guides No. GS-G.1.4 and GS-G.4.1.)*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
G6	**Good practice:** NISA has developed detailed guidance on the format and content of documents to be submitted for licensing and approval applications and on the timing of such submittals in the different stages of the regulatory process. The regulations and standards to be applied in the different areas have clearly been stated.
S5	**Suggestion:** NISA should take care that the current IAEA safety standards are duly taken into account, especially regarding the development and updating of an overall safety analysis report or comparable overall safety documentation summarizing the overall licensing basis.
(1)	**BASIS**: GS-R-1 para. 5.4 states that *"For complex facilities (such as a nuclear power plant) authorization may be carried out in several stages, each requiring hold points, separate permits or licences. In such cases, each stage of the process shall be subject to review and assessment, with account taken of feedback from the previous stage" and § 5.10. ...The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, ...Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix. A.3 – A.5*
G7	**Good practice:** The regulatory process for the different stages of the basic licence and the following approval is well structured and guided by detailed requirements and standards.
(1)	**BASIS**: GS-R-1 para., 2.17. states that *"As the active commissioning processes move closer to completion, review and assessment should be concentrated on how the facility is operated and maintained, and on the procedures for controlling and monitoring operation and responding to deviations or other occurrences. Before authorizing routine operation, the regulatory body should review and assess the consistency of the results of commissioning tests. If the regulatory body finds inconsistencies in these results, it should assess any corrections of non-conformances and modifications to the design and operational procedures that were made as a result of the commissioning. ...*
S6	**Suggestion:** Before approval of the operational safety programme and start of routine operation, NISA should add an additional hold point for an integrated review of all factors essential for safety.
(1)	**BASIS**: GS-R-1 para. 5.5 states that "*The regulatory review and assessment will lead to a series of regulatory decisions. ...The regulatory body shall formally record the basis for these decisions".*
(2)	**BASIS**: GS-R-1 para. 5.10 states that "*The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny."*
G8	**Good practice:** NISA has developed its own programme for the licensing review and established an internal rule to perform the review, to interact with NSC and other stakeholders and to document the results of its reviews.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1 para. 5.2 states that *"…Alternatively, activities of a particular type may be authorized in general to be performed in strict accordance with detailed technical regulations…"*IAEA Safety Guide GS-G-1.2 on Review and Assessment of Nuclear Facilities by the Regulatory Body para. 3.31 states *"In some instances, the operator may propose an alternative approach to that suggested in a guide to achieving a safety objective. In such a case, the operator should be required to demonstrate that its proposed approach will provide an equivalent level of safety."*
S7	**Suggestion:** NISA should encourage licensees to use alternative technical solutions to achieve safety objectives at least as good as those required by current technical standards.
(1)	**BASIS:** GS-R-1 para. 5.3 states that*: "Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented.*
(2)	**BASIS:** GS-R-1 para. 5.7 states that *"Review and assessment shall be performed in accordance with the stage in the regulatory process and the potential magnitude and nature of the hazard associated with the particular facility or activity."*
S8	**Suggestion:** NISA should continue to develop the systematic approach to investigate the consideration of beyond design basis accidents, and the complementary use of PSA and severe accident management in the assessment process for risk reduction purposes.

5. REVIEW AND ASSESSMENT

This chapter includes discussions on the following Policy Dialogues:

- Policy Dialogue 9, Ageing Management
- Policy Dialogue 4, Operating Experience Feedback
- Policy Dialogue 3, Human and Organizational Factors and Qualitative Items
- Policy Dialogue 10, Risk Informed Regulations

Review and assessment for authorization of new facilities or major plant modifications is discussed in Chapter 4. This chapter addresses review and assessment of certain issues during plant operation.

5.1 PERIODIC SAFETY REVIEW

Licences for the Japanese NPPs are issued for an unlimited time. In order to ensure safe operation in the long term, all licensees are required to conduct a comprehensive periodic safety review (PSR) at intervals of less than10 years. This practice was started as a voluntary activity, but since 2003 it is based on a regulatory requirement. All NPP units of age more than 10 years have conducted a PSR at least once.

The two mandatory parts of PSR are

- Comprehensive evaluation of operating experiences; and
- Incorporation of the state-of-the-art technology into the design and practices.

These parts of the PSR are now specified in the operational safety programme that provides all legal requirements for plant operation and needs to be approved by NISA before fuel is loaded for the first time into the core. All items included in the operational safety programme are inspected on a rotating basis also by NISA as part of its regular operational safety inspections. Therefore, the results of licensee's PSR need not be submitted to NISA as a separate document. A voluntary part of the PSR is a probabilistic safety assessment (PSA). Most plants have provided a PSA at some scope and are working on its extension. The fourth part of PSR is the ageing management review which is discussed in the subsequent section and has a different time frame.

Conclusion

All important safety elements receive regularly due attention by both the licensee and NISA. The overall judgment of the plant safety status could be further enhanced by combining these observations periodically together and making an integrated assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para. 3.3 states that *"...the regulatory body shall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review;"*

S9 **Suggestion:** The PSR should be made a more focused and periodic effort to give a comprehensive picture of the plant safety status at certain intervals. All its conclusions should be reported to NISA in one summary report.

5.2 AGEING MANAGEMENT

Ageing management at the Japanese NPPs is implemented as part of the maintenance management programme. In addition, as required by NISA, a systematic review for establishing ageing management has been started for plants approaching the age of 30 years. Today ageing management review has been completed for all 12 plants that have exceeded the age of 30 years, and also for one out of the nine plants that are in the age group of 25-29 years. In the future, there will be a requirement to complete the ageing management review before the NPP reaches the age of 30 years, and within every 10 years thereafter. NISA has issued an ageing management implementation guideline which is being used by the utilities for their review.

Japan is active also in the international field in collecting information on observed ageing phenomena. For this purpose, Japanese regulators and utilities are co-financing database projects under the umbrella of OECD/NEA.

Conclusion

Ageing phenomena in general are carefully studied in Japan, and information on observed ageing is actively collected also from foreign plants. Systematic ageing review covering the entire hardware of the plant is conducted at the oldest plants. At younger plants the acceptable physical condition of separate equipment important for safety is confirmed as part of regular maintenance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para. 3.3 states that *"...the regulatory body shall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review;"*

G9 **Good Practice:** The support organization of the regulatory body, JNES, collects and maintains a database on observed ageing phenomena. New information from that database is regularly incorporated into a technical review manual that provides guidance on issues to be looked at as part of the ageing management review. The database and the technical review manual are at the disposal of both operating organizations and NISA, and the information is being used for improving maintenance programmes.

S10 **Suggestion:** Consideration should be given to extending the systematic ageing management review to all plants in operation, and not just plants approaching the age of 30 years.

5.3 OPERATING EXPERIENCE FEEDBACK (OEF)

Responsibility to investigate the causes of incidents and faults discovered in inspections lies with the licensees. The licensees also propose countermeasures to prevent recurrence and submit the relevant information to a database called NUCIA. This database is operated by Japan Nuclear Technology Institute (JANTI) which was established by the Japanese nuclear industry in May 2005 and employs 60 experts. JANTI shares the information among all licensees, carries out analysis and assessment of the incident/fault information and issues recommendations on rectification measure for preventing recurrence. All power plants are expected to respond to recommendations and inform JANTI about their actions. In an agreement signed in May 2007, all power plants commit to providing information on incidents and faults that exceed commonly agreed criteria. These criteria set a significantly lower threshold for reporting than the mandatory

criteria for reporting to NISA. In addition, voluntary reporting of other events of potential interest to others is encouraged. In addition to collecting data and information on Japanese nuclear facilities, JANTI evaluates and disseminates in a similar manner the information received from WANO, INPO and some other international sources.

JANTI has established a good co-operation with JNES that operates a parallel system on behalf of the regulators. The two organizations have a monthly meeting for exchange of information. A reason of concern is the separation of industry system from the regulatory system (a similar concern is shared worldwide by all countries operating nuclear facilities). Information in NUCIA is divided into information in the public domain and information in the proprietary domain that is accessible to NUCIA members only. For instance, international experience from WANO and INPO is not accessible to NISA or JNES. Contacts to the IAEA's system called IRS have been arranged through JNES but dissemination of the IRS information to the industry has not functioned properly (report compilations have been sent in CD-ROM form by JNES). JNES informed the IAEA Review Team that it aims now to give a direct access to the web based IRS to all licensees and JANTI.

At a higher level of severity of incidents/faults, there is a clear process established by METI ordinance for notifying or reporting major events to NISA. NISA assesses the results of the licensee's investigations and the adequacy of countermeasures. In complicated cases NISA asks JNES to support in assessment. NISA makes the press releases, if so decided, and reports the causes and countermeasures to the NSC. In case of serious events the NSC may set up its own investigation group.

For coordinating the collection and evaluation of the domestic and foreign operating experience on the regulatory side, and for considering its use in development of regulations, the NISA and JNES have established a high level review group.

Major domestic events have received due regulatory attention, and lessons learned have been used efficiently to improve the regulations as well as the management practices and equipment at NPPs. Also events outside the nuclear facilities such as a large earthquake in 1995 have led to new improved safety standards and consequently safety enhancing measures at the NPPs. However, events that did not receive significant public attention, and events at foreign facilities have usually not led to countermeasures. One reason has been the limited use of resources for evaluating operating experience, and lack of systematic inspection and enforcement of licensees' activities by NISA. As discussed above, the OEF process has recently been improved and additional resources have been allocated to it.

Although all events with potential importance for learning lessons are now shared between the licensees, not all are reported to NISA. One reason is that the list of events to be reported is not exhaustive, and there has not been a common culture of voluntary reporting beyond what is formally required. In some cases in the past there have even been planned cover-ups of the events. When this became known to METI, it ordered an investigation in the whole energy industry to find out the extent of such cover-up practices. The investigation was based on very extensive interviews of employees, and it produced a lot of new information on past events that had not been used for learning lessons. This was a most positive example of a successful fact finding effort. NISA indicated that it has not observed indications of cover-up of events or licensee's own findings after the improved inspection process involving resident inspectors was implemented.

It seems that recognition of the relevance of foreign experience is difficult if similar incidents or faults have not been observed at the Japanese plants. Examples are the several feed water line breaks and a sump clogging event. Prompt actions to develop countermeasures were started when the elevated risk of such events was observed later also from experience noted in Japanese nuclear power plants.

Conclusion

The licensees and the regulators have each developed good operating experience feedback systems to address events that have happened in Japan. However, there is very little interaction between the licensee and regulator systems.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** In section 3.3, *"...the regulatory body shall ensure that operating experience is appropriately analysed and that lessons learned are disseminated"*

G10 **Good Practice:** Major events that have indicated increased nuclear safety risks have been thoroughly investigated, and appropriate countermeasures have been enforced by revised regulations.

R4 **Recommendation:** NISA should more clearly define its expectations with respect to reporting of minor inspection findings and events, in order to screen them for early identification before they become a problem.

R5 **Recommendation:** NISA should ensure by means of inspection and enforcement that licensees have efficient processes for learning lessons from other domestic facilities and from foreign facilities.

S11 **Suggestion:** NISA should build on the positive experience gained in finding the past unreported events and should encourage open notification of any findings that may provide useful lessons to other licensees. It should also encourage effective use of the NUCIA database by all licensees.

5.4 HUMAN AND ORGANIZATIONAL ISSUES

The importance of human and organizational factors is now well recognized by NISA. In accordance with NISA's official values, NISA staff put emphasis on judgments made on a scientific rational basis. The incorporation of human and organizational factors on safety in operation is still in development.

NISA activities to develop guidance and to perform review and assessment and inspections in the area of human and organizational performance have been reactions to incidents that have raised major concern among the general public.

Following the incidents at JCO in 1999, a statutory allegation system was set up which provides a mechanism whereby licensee staff may make reports directly to the regulatory body. Subsequently, some 36 allegation reports have been received from licensee personnel. NISA reviews these reports. Several reports revealed deficiencies on the part of licensees including data falsification by TEPCO. Thus, the allegations program is serving its purpose and this is a commendable practice that should be continued by NISA.

In response to the further disclosures of data falsification by utilities, NISA requested the performance of comprehensive checks of power-generating facilities, in order to determine if similar cases have occurred in the past. An action plan was developed by NISA based on its analysis of the responses received. NISA requires licensees to implement the necessary measures for ensuring compliance with NISA's requirements.

Several required actions under this plan are related to human and organizational factors, including requirements for:

- Conduct of root cause analysis;
- Development, verification, adherence and review of procedural manuals;
- Procurement control measures necessary for sharing safety technology information.

Further initiatives aimed at enhancing the licensee's operational safety programme and the quality assurance requirements and the regulatory oversight, are described in the following paragraphs.

The licensing process for power reactors requires the assessment of nuclear operator's 'technical capability'; the legal basis is found in the "Law on Regulation of Nuclear Reactors". The review process is conducted by NISA/NSC, based on the document on "Technical Capability Assessment Criteria for a Nuclear Operator", which was developed by the NSC.

The requirement for a quality assurance programme to be included by the licensee in its operational safety programme was established in 2003.

Additional elements, including safety culture and communication of safety information, will be added to this programme based on NISA's action plan developed in response to the falsification issues.

Each licensee develops its own operational safety programme, based on the internal programs and procedures. The operational safety programme is reviewed and approved by NISA at the pre-operation stage. NISA verifies also licensee's compliance with the programme through the operational safety inspection; these inspections are conducted every quarter, but it appears that they are not focused on assessing licensees' compliance with human and organizational factors.

A set of guidelines was developed by NISA and JNES for assessing the safety culture in operational safety inspections. Another guideline, addressing the evaluation of corrective actions taken by licensees for correcting non-conformances caused by human errors is under development.

Conclusion

NISA is continuing to develop its assessment criteria for evaluating human organizational factors. In spite of the strong efforts made, the change from the traditional hardware oriented assessment and inspection seems to be a slow process and requires improvement of the mutual trust and understanding between NISA and the licensees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para. 5.3 states that *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented. Thus, for example, a dental X ray machine may require only registration with the regulatory body, whereas for a radioactive waste repository a multistage authorization process may be required."*

G11 **Good Practice:** NISA is proactive in seeking to include the assessment of human and organizational factors in its review and assessment and inspection practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R6	**Recommendation:** NISA should continue to review and revise its regulatory requirements to provide assurance that licensees' operational safety programmes are comprehensive and address all elements relevant to safety in operation, including human and organizational factors.
S12	**Suggestion:** NISA should continue to develop and implement regulatory guidance and criteria for consistently reviewing and inspecting arrangements to address the impacts of human and organizational factors on safety in operation.
S13	**Suggestion:** NISA should foster good mutual understanding and trust building between its staff and the licensees.

5.5 RISK INFORMED REGULATIONS

NSC issued in November 2003 a policy document entitled "Basic Policy in Introducing Nuclear Safety Regulations, Utilizing Risk Information". The regulatory policy is to utilize risk information for improvements in rationality, consistency and transparency of regulations and for allocating regulatory resources in an optimum manner.

In line with the new policy, risk assessment has been used as a tool supporting certain regulatory decisions. Specific examples of improved risk insight were presented to the team, such as:

- Planning accident management measures to reduce the estimated reactor core damage frequency;
- Development of the new guides for seismic design; and
- Directing the focus of safety inspections to issues that are most important for ensuring nuclear safety.

As a necessary pre-requisite for the increased use of risk informed regulation, NISA emphasizes the high quality of plant specific PSAs. NISA and JNES have developed guides for assuring PSA analysis quality and this guidance has been published in 2006. Failure data for improving the accuracy of probabilistic calculations is collected from both domestic and foreign sources. JNES is collecting data especially on the frequencies of initiating events from the event reports submitted to NISA according to the legislation. Industry organizations are collecting data on equipment failures from each power company.

The team observed with satisfaction the NISA concept of risk information utilization: rather than considering the risk information to replace conventional deterministic safety assessments, it is more appropriate to consider it as a reference to improve the scientific rationality by adding information which could not be gained with the conventional methods. Furthermore, NISA emphasizes the continued importance of maintaining defence in depth and ensuring safety margins that are the key elements in the current concept for ensuring safety.

Conclusion

The basic policy of utilization of risk information in nuclear regulation is sound. Further enhancement of nuclear safety can be expected when the plans presented for increasing utilization of risk information in regulation are implemented. Implementation of the new approach is supported in a systematic manner by the parallel development of policy, guidance, practices and PSA quality.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

BASIS: GS-R-1 para. 5.9 states that *"A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:*

(1) the available information demonstrates the safety of the facility or proposed activity;

(2) the information contained in the operator's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and

(3) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety."

G12 **Good Practice:** Implementation of risk informed regulation is supported by a systematic build up of infrastructure: basic concepts and policy, improvement and quality assurance of PSA models, and collection of failure data from all licensees for the use of these models.

6 INSPECTION AND ENFORCEMENT

This chapter includes discussions on the following Policy Dialogue:

- Policy Dialogue 6, NISA's Organizational Structure and Inspection System (Inspection Practices and Resident Inspectors)

The inspection and enforcement programmes are overseen by the regulatory body, Nuclear and Industrial Agency (NISA), with inspections performed for NISA by the Japanese Nuclear Energy Safety Organization (JNES). Inspections are performed by inspectors at JNES, from NISA headquarters, and by inspectors working for NISA and located as resident inspectors near the site of each nuclear power plant. The inspection programme for NISA is centrally managed by the Director of the Nuclear Power Reactor Inspection Division.

Licences for nuclear power plants have no expiration date, so the inspection programme is established with several parts to ensure the plant is constructed as designed and operated throughout its lifetime with a focus on safety. Inspection plans that are developed for each specific type of inspection and an overall, annual inspection plan for each nuclear power reactor unit take into account areas to inspect based on the significance of the safety area and issue. Areas to be inspected also factor in the licensee's schedule for outages to review the adequacy of design of equipment, periodic safety and management reviews, and previous inspection findings. Until lessons were learned from events occurring in the period 1999 through 2002, the inspection programme primarily focused on inspection of hardware to determine whether it met its design and function. Since 2003, NISA has embarked upon changes to also focus the inspection programme on the adequacy of the licensee's operation of the nuclear plant. The inspection programme for operating reactor units consists of (1) periodic inspections, (2) periodic safety management reviews initiated around 2003, (3) operational safety inspections started in 2000, (4) resident inspector operational safety investigations initiated in 2000. The inspection programme focused on operational safety is still in the early stages of implementation and consequently, the operators and NISA inspectors are adjusting to determine the correct scope and amount of inspection. The current inspection programme is also undergoing a major change in scope, with key changes being made in response to several events. Before an event at JCO, this check was not being systematically completed. Other changes being planned include more operational focus to examine a licensee's maintenance and quality assurance programmes. Since the current programme has undergone significant changes in the last few years, there is no single document that provides an integrated description of the parts of the programme. NISA is working on an inspection manual to tie all the guidance and the programme together.

The inspection programme is very structured in the law, and includes the type and frequency of inspections and the required presence of NISA inspectors in order to complete certain tests and surveillances. Because of this, NISA cannot easily change the inspection type or frequency. This also affects the operator's conduct of the test or surveillance based on the availability of NISA inspectors. In addition, changes to address identified lessons learned take a long time to implement and incorporate into the programme.

The current inspection programme limits the ability of inspectors and NISA to have unfettered access to perform inspections on a continual basis. There are only certain windows where access is allowed for inspection by law. Currently, inspectors, including resident inspectors, may only conduct interviews and request certain information from licensees or operators at specified times. Certain unfettered access to continually perform inspections is authorized in some cases only by a 'gentlemen's agreement' with the operator. In general, inspectors are allowed access to the facility at all times, but are limited to actually performing inspections at times specified by law. NISA is working on improving this area by allowing observations at these non-inspection times, termed 'inspector investigations'.

NISA has been timely in responding to events and inspection findings based on the seriousness and risk of the problem in each instance. Inspection findings are reported to the licensees or operators by a meeting at the end of each inspection on-site with operator representatives. These findings are also signed out in draft by the chief resident inspector with a final report issued by NISA headquarters. Reports drafted by inspectors working for JNES are provided to NISA for issue to the licensees. There is no systematic process for sharing the results of the inspection reports internally within NISA; however, NISA inspectors may obtain and read reports of inspections by NISA inspectors at other sites by way of the NISA network, once the report has been issued. Inspection findings are followed up with the licensee to confirm correction and closure of the issue at the next inspection. NISA has various levels of enforcement that are taken in response to the significance of the event or inspection finding. There are gradations of violations also based on the significance of the issue. NISA can also issue orders to a licensee to cease operations; the basis for this is clear if there is a hardware or equipment problem. The basis is not as clear if there is an identified operational safety performance problem other than hardware.

Inspectors are provided guidance for performing inspections in the construction and operational phases at the nuclear power plants by procedures and internal guidance documents. The guidance for the periodic and operational safety type inspections is clear and addresses the key safety items to review. NISA has a well defined qualification and training programme for inspectors from NISA. The inspector expertise on operational safety is limited and it is difficult to increase continuity of knowledge because the programme is in early transition and the policy of rotating inspectors after two to three years hampers the gaining of experience in this area. All inspectors are brought together four times per year to share lessons learned and inspection findings.

The system of inspections has in the past been based on verification of testing and system functionality, which limited interaction between operators and inspector staff. With the new operational safety inspection programme there is a need for more communication and interaction to obtain information without reducing the flow of information.

Conclusion

The country of Japan has a systematic and robust approach to the inspection and enforcement of nuclear power plants in the construction and operational phases that is in consistent, in general, with IAEA safety requirements in GS-R-1. NISA is in the process of implementing several changes to the inspection programme which are a proactive response to events and issues identified since 2002. These multiple changes present several challenges for NISA, industry and operators.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
(1) **BASIS:** GS-R-1, para. 5.13 (4) and (5) state that *"The main purposes of regulatory inspection…are to ensure that:* *(4) deficiencies and deviations are identified and are corrected or justified without undue delay;delay; and* *(5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate;"* G13 **Good practice:** NISA holds counterpart type meetings with all nuclear power plant inspectors four times per year to share inspection findings and lessons learned.
G14 **Good practice:** NISA has a well defined and clear code of ethics and conduct for individuals with a role in the nuclear power plant inspection programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1, para. 5.15, states that *"Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity. If the regulatory body uses the services of consultants for the inspections, then it shall have the responsibility for taking any actions on the basis of these inspections."*

R7 **Recommendation:** NISA should ensure that its inspectors have the authority to carry out inspections at the site at any time, on a continual basis. This would ensure that inspectors have unfettered access to the site, to interview people, and to request the review of documents at any time rather than just at prescribed inspection times as in the law. This applies to both the construction and the operational inspection programmes.

(1) **BASIS:** GS-R-1, para. 5.14, states that *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*

S14 **Suggestion:** NISA should establish a process with more flexibility to change the type and frequency of inspections without having to change the law.

(1) **BASIS:** GS-R-1, para. 5.18 states that "*Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance. Thus there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization. In all cases the operator shall be required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed time-scale, and to take all necessary measures to prevent recurrence. The regulatory body shall ensure that the operator has effectively implemented any remedial actions."*

(2) **BASIS:** GS-R-1, para. 5.21 states that "*In the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctioning at or damage to a facility, the regulatory body shall direct the operator to curtail activities and may suspend or revoke the authorization. The operator shall be directed to eliminate any unsafe conditions".*

R8 **Recommendation:** NISA should clarify the basis for authority to shut down a nuclear power plant in instances of poor performance, in addition to the existing clear law for shutting down due to hardware type problems.

S15 **Suggestion:** NISA modifies the inspection programme based on events, but should be more proactive in doing this on the basis of inspection findings not only from the nuclear power plant being inspected, but also from experiences derived from other nuclear power plants.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1, para. 5.10 states that *"The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout. Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix."*

(2) **BASIS:** GS-R-1, para. 5.12 states that *"Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations. In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator. Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements."*

S16 **Suggestion:** NISA should include inspections of the vendor and the manufacturers' programmes for quality assurance in the construction inspection programme.

7 REGULATIONS AND GUIDES

This chapter includes discussion on the following Policy Dailogues

- Policy Dialogue 12, Performance based regulations

A legislation framework for nuclear safety including an extensive set of detailed very prescriptive legislative documents has been established in Japan. The NSC formulates fundamental policy on important nuclear safety issues and has a role in developing guides. NISA is the regulatory body in Japan and is actively involved in developing technical standards and acceptance criteria. The nuclear safety legislative framework related to regulations and guides can be divided into four levels.

Level 1 Atomic Energy Basic Law

Japan has enacted the Atomic Energy Basic Law as its basic law on the utilization of nuclear energy. The basic policy is that the research, development and utilization of nuclear energy shall be limited to peaceful purposes, on the basis of the highest priority of ensuring safety, and performed on a self-controlled basis.

Level 2 Important laws under the basic law

There are two important laws, which are used in parallel, for the regulation of nuclear power plants: the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors ('Reactor Regulation Law'), which is focused on nuclear safety, and the Electricity Utilities Industry Law, which is focused on ensuring reasonable management of the electricity business and ensuring safety of facilities.

Under the reactor regulation law, some significant regulations are established, such as those on:

- Approval of the operational safety programme
- Approval of the programme on physical protection of nuclear Material and facilities
- Operational safety inspections
- Physical protection of nuclear material and inspection of facilities

The Electricity Utilities Industry Law provides requirements on construction plans, safety management review of welding, fuel assembly inspection, pre-service inspection, periodic inspection and periodic safety management review.

Level 3 NSC Safety Regulatory Guides and Technical Standards (Ministerial Order)

NSC safety regulatory guides

Since 1964, the NSC has issued 73 guides (18 guides for NPP safety review) and relevant reports on nuclear safety review for siting, design, safety evaluation, dose targets and technical competence. The NSC developed action plans for systematization of guides on safety review. The safety regulatory guides are required to follow certain main objectives and principles. Guides:

- Should adhere to the safety goals (interim) issued by NSC in 2003;
- Should follow the basic policy to introduce risk-informed regulation issued by NSC in 2003;
- Should be systematic and rational;
- Should be based on Safety Fundamentals;
- Should maintain defence-in-depth;
- Should use risk information; and
- Should reflect world standards and harmonization.

The development/revision of guides is initiated by NSC, which requires study by the Special Subcommittee for Nuclear Safety Guides, with participation as observers from administrative government agencies. Upon finalization of the draft guides, NSC conducts public consultation, addresses the comments and finalizes the guides. The NSC guides represent the basis for NISA's review of the application to obtain an establishment licence for an NPP, as well as for NSC's secondary review.

Technical standards (ministerial order)

Draft standards are prepared by NISA and discussed with subcommittees and working groups set up under the Nuclear and Industrial Safety Subcommittee. The public is consulted and electric utilities are invited to provide their opinions, as necessary. Upon ministerial approval, the technical standard is published and this is reported to the NSC. Recently, NISA developed performance-based standards, during which process IAEA safety standards were referred to.

Level 4 Academic society and association standards

To meet the requirements set by the technical standards, NISA has issued public documents and has endorsed a number of private consensus standards, which are used as acceptance criteria.

Academic societies and associations, such as the Japan Society of Mechanical Engineers, the Atomic Energy Society of Japan, the Electric Association, the Thermal and Nuclear Power Engineering Society in Japan, publish private consensus standards with reference to the international nuclear community, such as the ASME code. Before applying academic society and association standards as regulatory criteria, NISA deliberates the appropriateness of the formulation process, technical bases of standards, and the consistency with regulatory requirements. The endorsement of these standards is prepared by NISA in consultation with the concerned advisory committees, including participation from academic experts affiliated to universities and research institutions. The public is consulted and the committee meetings are open.

Conclusion

The knowledge available in all Japanese nuclear organizations is effectively used for producing regulations and guides. For example technical support organizations and research institutes, such as JNES, give important input. Current regulations, guides, implementation rules and standards in Japan are systematic, and they cover all aspects of the safety for nuclear power plants.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** S-R-1, para. 3.2 states that *"Regulatory body shall establish, promote or adopt regulations and guides upon which its regulatory actions are based."*

G15 **Good practice:** NISA is developing performance-based standards referring to IAEA safety standards.

S17 **Suggestion:** The process used for developing and updating standards should continue to be streamlined, in order to reduce the time needed for their issue.

R9 **Recommendations:** As the regulatory body in Japan, NISA should take major responsibility in the development and endorsement of safety regulations and guides.

8. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

This chapter includes discussions on the following Policy Dialogues:

- Policy Dialogue 5, Strategic planning and management system

NISA recognizes the importance of adopting a comprehensive quality management system and has to date set out its management policy and developed its quality management manual. The management policy sets out the fundamental philosophy by which NISA performs its activities, while the quality management manual is a set of high level guidelines for NISA to undertake its activities systematically and effectively. A number of items supporting these documents were discussed under policy items 7 and 8; these are therefore also summarized under this section. NISA acknowledges that the establishment of a comprehensive quality management system has just begun.

To implement the comprehensive quality management system NISA has organized a Quality Management Committee chaired by the Director General. This Committee approves and carries out the subsequent review of the annual plan. It is clear within the top management of NISA that the quality management system is a tool which is used to achieve standardization and efficiency, and that the issue is therefore management and not the production of the descriptions of individual activities.

A key element of the system is NISA's annual plan. As part of the phased implementation of its comprehensive quality management system, NISA has prepared a five year 'Strategic Plan' ("Mid Term Goals and Actions Taken in 2007"). The strategic plan was developed based on the annual divisional plans, which are subsequently broken down into individual objectives for staff.

Futher development of NISA's management system should also consider and address the development and implementation of a monitoring and measurement system including process measurement criteria, performance indicators and other appropriate methods and tools. The results of monitoring activities should be used to inform the regulatory plans and activities.

Although some process instructions and guides are available, particularly for periodic and operational safety inspection, these do not appear to be available for all key process tasks/activities nor do they appear to be linked to an overall process map for NISA as a whole or nuclear safety regulation in particular.

As part of its management policy NISA has established two key activities relating to 'relationship management' and 'knowledge sharing' and has created the Nuclear Safety Public Relations and Training Division. 'Relationship management' is focused on supplying information to the public and outside organizations to further improve public confidence and trust in the nuclear regulatory regime. 'Knowledge sharing' is focused sharing information within the organization in order to improve the quality and effectiveness of NISA activities.

'Relationship management' has introduced new initiatives such as enhanced participative public hearings and dialogues, use of newsletters and email newsletters (with approximately 1000 subscribers) and providing information through CATV (NISA-TV). NISA is also actively engaged with international organizations and outside experts. A number of initiatives have been introduced to improve information exchange and discussion with licensees at all levels. These initiatives range from the introduction of a 'pocket handbook' with 10 rules for inspectors to promote mutual trust between the inspectors and licensee staff; plant visits by NISA senior officials to exchange views and raise awareness of safety; bi-monthly meetings on nuclear power plant management with nuclear energy managers of utility companies discussing current topics of mutual interest to 'top management meetings' between the Director General of NISA and Presidents of the Nuclear Power Companies. Finally internal communications in NISA have been enhanced with regular weekly meeting for different areas of responsibility to exchange information on policy planning,

operational and organizational issues supplemented with as required internal lectures to share experienced based knowledge.

'Knowledge Sharing' has been introduced to implement a comprehensive system for the sharing of the accumulated intellectual property and outside publications to all staff in NISA through the library and internal intranet.

Conclusion

NISA is being extremely proactive in seeking to establish a comprehensive Quality Management System; much remains to be done.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-3, para. 3.1 states that *"Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities."*

(2) **BASIS:** GS-R-3, para. 3.2 states that *"Senior management shall develop individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations."*

(3) **BASIS:** GS-R-3, para. 3.12 states that *"Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved."*

G16 **Good Practice:** The establishment of the Quality Management Committee chaired by the Director General of NISA to oversee the activities necessary to establish as well as oversee the implementation of the QMS demonstrates the commitment that NISA attaches to this activity.

(1) **BASIS:** GS-R-1, para. 4.5 states that *"The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken."*

(2) **BASIS:** GS-R-3, para. 2.1 states that *"A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety……"*

G17 **Good Practice:** NISA is being extremely proactive in seeking to establish a comprehensive Quality Management System.

R10 **Recommendation:** NISA should continue the development of its comprehensive Quality Management System (QMS) concentrating on its practical implementation rather than on its philosophical and conceptual rationale. As a first step the QMS should take account of the five year strategic plan in the formulation of the Divisional Annual Plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(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. 2.10 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."*

(3) **BASIS:** GS-R-3, para. 3.6 states that *"The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised."*

S18 **Suggestion:** NISA should develop an overall process map, including interactions and relationships with NSC and JNES, in order to effectively and quickly implement the practical elements of the QMS. To be implemented effectively this will need to be undertaken in consultation with NSC and JNES.

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1. **YAMADA,** Tomoho	Nuclear and Industrial Safety Agency (NISA)	yamada-tomoho@meti.go.jp
2. **YAGI,** Masahiro	Nuclear and Industrial Safety Agency (NISA)	yagi-masahiro@meti.go.jp

APPENDIX II – MISSION PROGRAMME - MAIN MISSION

MISSION PROGRAMME		
Sunday, 24 June 2007		
15: 00 – 18:00	**IRRS Review Team entrance meeting at the Grand Prince Akasaka Hotel (meeting room 1550)**	
Monday, 25 June 2007		
09:00 – 09:50	**ENTRANCE MEETING AT NISA HEADQUARTERS**	
	Welcome and introduction	***Mr. Hirose***
	Opening remarks	***Mr. Lacoste***
	Introduction of experts	
	Results from the IRRS preparatory mission	***Mr. Caruso***
	Agenda of the mission	***Mr. Ito***
	Working arrangements	***Mr. Yagi***
09:50 – 13:00	**PRESENTATIONS BY JAPAN**	
	Roles and responsibilities of NISA	***Mr. Hirose***
	Roles and responsibilities of NSC	***Mr. Soda***
	Roles and responsibilities of JNES	***Mr. Nariai***
	Questions and answers	
	Outline of the Japanese regulatory system	***Mr. Hiraoka***
	Recent issues in nuclear safety regulations in Japan	***Mr. Hiraoka***
14:00 – 16:30	**TOPIC 1 – INSTITUTIONAL MATTERS**	***GROUP A***
	Presentation	***Mr. Yamashita***
		Mr. Akeno
	Comments from the IAEA Review Team	***Mr. Lacoste***
	Discussion on Topic 1, Module 1	
	Parallel Session	
	TOPIC 11 – AUTHORIZATION OF NEW PLANTS	***GROUP B***
	Presentation	***Mr. Moriyama***
		Mr. Nayuki
	Comments from the IAEA Review Team	***Mr. Laaksonen***
	Discussion on Topic 11, Module IV	
17:00 – 18:30	**IAEA REVIEW TEAM MEETING**	
19:00	***Dinner hosted by NISA***	
Tuesday, 26 June 2007		
08:15-9:30	**IAEA REVIEW TEAM MEETING**	
09:30 – 12:30	**TOPIC 3 – HUMAN AND ORGANIZATIONAL FACTORS AND QUALITATIVE ITEMS**	
	Presentation	***Mr. Nakamura***
	Comments from the IAEA Review Team	***Mr. Lacoste***
	Discussion on Topic 3, Module II	
	Parallel Session	
	TOPIC 6 – NISA'S ORGANIZATIONAL STRUCTURE AND INPSECTION SYSTEM (INSPECTION PRACTICES AND RESIDENT INSPECTORS)	
	Presentation	***Mr. Nei***
	Comments from the IAEA Review Team	***Mr. Laaksonen***
	Discussion on Topic 6, Module VI	
13:30 – 16:30	**TOPIC 2 – NISA's PERSONNEL**	
	Presentation	***Mr. Yamashita***

MISSION PROGRAMME		
	➔ Comments from the IAEA Review Team	***Mr. Lacoste***
	➔ Discussion on Topic 2, Module III	
	Parallel Session	
	TOPIC 9 – AGING MANAGEMENT	
	➔ Presentation	***Mr. Nei***
	➔ Comments from the IAEA Review Team	***Mr. Laaksonen***
	➔ Discussion on Topic 6, Module VI	
17:00 -	**IAEA REVIEW TEAM MEETING**	
Drafting of Report		
Wednesday, 27 June 2007		
08:15-9:30	**IAEA REVIEW TEAM MEETING**	
09:30 – 12:30	**TOPIC 7 – TRANSPARENCY AND OPENNESS**	
	➔ Presentation	***Mr. Ito***
	➔ Comments from the IAEA Review Team	***Mr. Lacoste***
	➔ Discussion on Topic 7, Module I	
	TOPIC 8 – INTERNAL COMMUNICATION	
	➔ Presentation	***Mr. Yamada***
	➔ Comments from the IAEA Review Team	***Mr. Lacoste***
	➔ Discussion on Topic 8, Module III	
	Parallel Session	
	TOPIC 4 – OPERATIONAL EXPERIENCE FEEDBACK	
	➔ Presentation	***Mr. Nei***
	➔ Comments from the IAEA Review Team	***Mr. Laaksonen***
	➔ Discussion on Topic 4, Module V	
13:30 – 16:30	**TOPIC 5 – STRATEGIC PLANNING AND MANAGEMENT SYSTEM**	
	➔ Presentation	***Mr. Ito***
	➔ Comments from the IAEA Review Team	***Mr. Lacoste***
	➔ Discussion on Topic 5, Module VIII	
	Parallel sessions	
	TOPIC 10 – RISK INFORMED REGULATIONS	
	➔ Presentation	***Mr. Nakamura***
		Mr. Nayuki
	➔ Comments from the IAEA Review Team	***Mr. Laaksonen***
	➔ Discussion on Topic 10, Module V	
	TOPIC 12 – PERFORMANCE-BASED REGULATION	
	➔ Presentation	***Mr. Nakamura***
		Mr. Nayuki
	➔ Comments from the IAEA Review Team	***Mr. Laaksonen***
	➔ Discussion on Topic 12, Module VII	
17:00 – 19:00	**IAEA REVIEW TEAM MEETING**	
Dinner Hosted by NSC		
Thursday, 28 June 2007		
07:30 (full day observations, arrival at hotel ~21:00)	DIRECT OBSERVATIONS	
	➔ Kahiwazaki Kariwa Nuclear Safety Inspector Office	***Mr. Mallet*** ***Mr. Grant*** ***Mr. Gray*** ***Mr. Louet***
	➔ Tokyo Electric Power Company Kashiwazaki Kariwa Nuclear Power Station	***Mr. Mallet*** ***Mr. Grant***

MISSION PROGRAMME		
		Mr. Gray ***Mr. Louet***
10:00 – 12:00	➔ Interview with Nuclear Safety Commission	***Mr. Lacoste*** ***Mr. Caruso***
	Parallel Session	
	➔ Interview with JNES	***Mr. Laaksonen***
13:30 -	➔ Interview with ARNE	***Mr. Lacoste*** ***Mr. Caruso***
	➔ Interview with Dr. Madarame, member of Nuclear and Industrial Subcommittee, the Advisory Committee for Natural Resources and Energy	***Mr. Lacoste*** ***Mr. Caruso***
	Parallel Sessions	
	➔ Interview with the Federation of Electric Power Companies of Japan	***Mr. Laaksonen***
	➔ Interview with the Japan Nuclear Technology Institute	***Mr. Laaksonen***
17:30 -	**IAEA REVIEW TEAM MEETING (for experts who remained in Tokyo)**	
	Drafting of Report	
Friday, 29 June 2007		
A.M. – 12:30	➔ Finalizing the draft IRRS Japan Report at meeting room 1550 at the hotel.	***IRRS REVIEW TEAM***
12:30	➔ Delivery of the draft IRRS Report to NISA	***NISA***
	➔ Deliberation on the Japanese side	***NISA***
12:30 -17:00	➔ Social activity	***IRRS TEAM***
17:00	➔ Discussion on the draft report	***IRRS TEAM***
Saturday, 30 June 2007		
08:00 – 09:30	➔ Review of comments received by NISA (meeting room 1550 at the hotel)	***IAEA REVIEW TEAM***
09:45 – 12:00	➔ Discussion on the draft report	***Mr. Lacoste*** ***Mr. Laaksonen*** ***Mr. Caruso***
13:30 – 14:30	➔ Plenary meeting – Discussion on the draft IRRS report	***IAEA REVIEW TEAM***
14:30 – 16:30	➔ Exit meeting	
Sunday, 1 July 2007		
	Departure from Japan	

APPENDIX III – SITE VISITS

1.	***Kahiwazaki Kariwa Nuclear Safety Inspector Office***
2.	***Tokyo Electric Power Company Kashiwazaki Kariwa Nuclear Power Station***
3.	***Nuclear Safety Commission***
4.	***JNES Headquarters***
5.	***ARNE Headquarters***
6.	***Nuclear and Industrial Subcommittee, the Advisory Committee for Natural Resources and Energy***
7.	***Federation of Electric Power Companies of Japan***
8.	***Japan Nuclear Technology Institute***

APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Lead Counterparts
1.	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**	• Mr. Ian **GRANT** • Mr. Charles-Antoine **LOUET**	• Mr. **YAMASHITA** • Mr. **AKENO** • Mr. **ITO**
2.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	• Mr. Ian **GRANT** • Mr. Seong-Ho **NA**	• Mr. **NAKAMURA**
3.	**ORGANIZATION OF THE REGULATORY BODY**	• Mr. Rob **GRAY** • Mr. Charles-Antoine **LOUET**	• Mr. **YAMASHITA** • Mr. **YAMADA**
4.	**AUTHORIZATION**	• Mr. Liu **HUA** • Mr. Michael **HERTTRICH**	• Mr. **MORIYAMA** • Mr. **NAYUKI**
5.	**REVIEW AND ASSESSMENT**	• Mr. Bruce **MALLET** • Mr. Juan **EIBENSCHUTZ**	• Mr. **NEI** • Mr. **NAKAMURA** • Mr. **NAYUKI**
6.	**INSPECTION AND ENFORCEMENT**	• Mr. Bruce **MALLET** • Mr. Juan **EIBENSCHUTZ**	• Mr. **NEI**
7.	**REGULATIONS AND GUIDES**	• Mr. Liu **HUA** • Mr. Michael **HERTTRICH**	• Mr. **NAKAMURA** • Mr. **NAYUKI**
8.	**MANAGEMENT SYSTEM FOR REGULATORY BODY**	• Mr. Rob **GRAY** • Mr. Seong-Ho **NA**	• Mr. **ITO**

APPENDIX V – SUMMARY OF GOOD PRACTICES, RECOMMENDATIONS AND SUGGESTIONS IDENTIFIED BY THE IRRS MISSION

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
1	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**	G1	**Good Practice:** Japan is continuously making efforts to update and improve its legislative and governmental framework with the aim of strengthening arrangements for nuclear safety in the light of incidents which have occurred and to prevent recurrence.
		R1	**Recommendation:** The role of NISA as the regulatory body and that of NSC, especially in producing safety guides, should be clarified.
		S1	**Suggestion:** NISA is effectively independent from ANRE, in correspondence with the GS-R-1. This situation could be reflected in the legislation more clearly in future.
2	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	G2	**Good Practice:** NISA's relationship management programme is a well-structured and comprehensive programme that reflects best practice.
		G3	**Good Practice:** Communication with the public at the local level is well-structured and allows for regular and positive exchanges between NISA, the public and the operators.
		G4	**Good Practice:** The public is involved in NISA's advisory sub-committees
		S2	**Suggestion:** NISA should make further headway on developing a decision making process in order to obtain sound judgement based on information provided by licensees, inspectors or the public that can not necessarily be developed in a scientific manner. All issues should be taken into account so as to evaluate and judge safety in a more holistic manner.

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
		S3	**Suggestions:** It is suggested that NISA continue to foster relations with industry that are frank and open, yet formal and based on mutual understanding and respect.
3	**ORGANIZATION OF THE REGULATORY BODY**	G5	**Good Practice:** NISA has a proactive recruitment, training and staff development policy which allows it to achieve and maintain high technical competence.
		R2	**Recommendation:** NISA should enhance its training requirements and programmes to ensure that all aspects of inspection requirements, such as attributes of quality management systems, and knowledge and awareness of licensees' operational requirements and practices are adequately included.
		R3	**Recommendation**: NISA should produce a workforce plan that clearly identifies its minimum staffing needs to discharge the functions and tasks required to secure effective nuclear safety regulation in Japan against the elements of its 5-year strategic plan. Future staff number / budget requests would then be based on these minimum resource needs plus any supplement required for additional work / tasks. (The workforce of the regulatory system JNES/NISA and NSC should be ensured considering respective functions – mandates, completeness, fairness, neutrality, etc. – for this issue.)
		S4	**Suggestion:** NISA should consider different staff / job rotation frequencies and patterns (particularly for its senior management) to further enhance its knowledge management and effectiveness of nuclear safety regulation of strategic and operational issues.

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
4	**AUTHORIZATION**	G6	**Good practice:** NISA has developed detailed guidance on the format and content of documents to be submitted for licensing and approval applications and on the timing of such submittals in the different stages of the regulatory process. The regulations and standards to be applied in the different areas have clearly been stated.
		S5	**Suggestion:** NISA should take care that the current IAEA safety standards are duly taken into account, especially regarding the development and updating of an overall safety analysis report or comparable overall safety documentation summarizing the overall licensing basis.
		G7	**Good practice:** The regulatory process for the different stages of the basic licence and the following approval is well structured and guided by detailed requirements and standards.
		S6	**Suggestion:** Before approval of the operational safety programme and start of routine operation, NISA should add an additional hold point for an integrated review of all factors essential for safety.
		G8	**Good practice:** NISA has developed its own programme for the licensing review and established an internal rule to perform the review, to interact with NSC and other stakeholders and to document the results of its reviews.
		S7	**Suggestion:** NISA should encourage licensees to use alternative technical solutions to achieve safety objectives at least as good as those required by current technical standards.

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
		S8	**Suggestion:** NISA should continue to develop the systematic approach to investigate the consideration of beyond design basis accidents, and the complementary use of PSA and severe accident management in the assessment process for risk reduction purposes.
5	**REVIEW AND ASSESSMENT**	S9	**Suggestion:** The PSR should be made a more focused and periodic effort to give a comprehensive picture of the plant safety status at certain intervals. All its conclusions should be reported to NISA in one summary report.
		G9	**Good Practice:** The support organization of the regulatory body, JNES, collects and maintains a database on observed ageing phenomena. New information from that database is regularly incorporated into a technical review manual that provides guidance on issues to be looked at as part of the ageing management review. The database and the technical review manual are at the disposal of both operating organizations and NISA, and the information is being used for improving maintenance programmes.
		S10	**Suggestion:** Consideration should be given to extending the systematic ageing management review to all plants in operation, and not just plants approaching the age of 30 years.
		G10	**Good Practice:** Major events that have indicated increased nuclear safety risks have been thoroughly investigated, and appropriate countermeasures have been enforced by revised regulations.
		R4	**Recommendation:** NISA should more clearly define its expectations with respect to reporting of minor inspection findings and events, in order to screen them for early identification before they become a problem.

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
		R5	**Recommendation:** NISA should ensure by means of inspection and enforcement that licensees have efficient processes for learning lessons from other domestic facilities and from foreign facilities.
		S11	**Suggestion:** NISA should build on the positive experience gained in finding the past unreported events and should encourage open notification of any findings that may provide useful lessons to other licensees. It should also encourage effective use of the NUCIA database by all licensees.
		G11	**Good Practice:** NISA is proactive in seeking to include the assessment of human and organizational factors in its review and assessment and inspection practices.
		R6	**Recommendation:** NISA should continue to review and revise its regulatory requirements to provide assurance that licensees' operational safety programmes are comprehensive and address all elements relevant to safety in operation, including human and organizational factors.
		S12	**Suggestion:** NISA should continue to develop and implement regulatory guidance and criteria for consistently reviewing and inspecting arrangements to address the impacts of human and organizational factors on safety in operation.
		S13	**Suggestion:** NISA should foster good mutual understanding and trust building between its staff and the licensees.
		G12	**Good Practice:** Implementation of risk informed regulation is supported by a systematic build up of infrastructure: basic concepts and policy, improvement and quality assurance of PSA models, and collection of failure data from all licensees for the use of these models.

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
6	**INSPECTION AND ENFORCEMENT**	G13	**Good practice:** NISA holds counterpart type meetings with all nuclear power plant inspectors four times per year to share inspection findings and lessons learned.
		G14	**Good practice:** NISA has a well defined and clear code of ethics and conduct for individuals with a role in the nuclear power plant inspection programme.
		R7	**Recommendation:** NISA should ensure that its inspectors have the authority to carry out inspections at the site at any time, on a continual basis. This would ensure that inspectors have unfettered access to the site, to interview people, and to request the review of documents at any time rather than just at prescribed inspection times as in the law. This applies to both the construction and the operational inspection programmes.
		S14	**Suggestion:** NISA should establish a process with more flexibility to change the type and frequency of inspections without having to change the law.
		R8	**Recommendation:** NISA should clarify the basis for authority to shut down a nuclear power plant in instances of poor performance, in addition to the existing clear law for shutting down due to hardware type problems.
		S15	**Suggestion:** NISA modifies the inspection programme based on events, but should be more proactive in doing this on the basis of inspection findings not only from the nuclear power plant being inspected, but also from experiences derived from other nuclear power plants.

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
		S16	**Suggestion:** NISA should include inspections of the vendor and the manufacturers' programmes for quality assurance in the construction inspection programme.
7	**REGULATIONS AND GUIDES**	G15	**Good practice:** NISA is developing performance-based standards referring to IAEA safety standards.
		S17	**Suggestion:** The process used for developing and updating standards should continue to be streamlined, in order to reduce the time needed for their issue.
		R9	**Recommendations:** As the regulatory body in Japan, NISA should take major responsibility in the development and endorsement of safety regulations and guides.
8	**MANAGEMENT SYSTEM FOR REGULATORY BODY**	G16	**Good Practice:** The establishment of the Quality Management Committee chaired by the Director General of NISA to oversee the activities necessary to establish as well as oversee the implementation of the QMS demonstrates the commitment that NISA attaches to this activity.
		G17	**Good Practice:** NISA is being extremely proactive in seeking to establish a comprehensive Quality Management System.
		R10	**Recommendation:** NISA should continue the development of its comprehensive Quality Management System (QMS) concentrating on its practical implementation rather than on its philosophical and conceptual rationale. As a first step the QMS should take account of the five year strategic plan in the formulation of the Divisional Annual Plans.

	Areas	IAEA Comment No *G: Good practices,* *R: Recommendations,* *S: Suggestions*	*Good Practices, Recommendations or Suggestions*
		S18	**Suggestion:** NISA should develop an overall process map, including interactions and relationships with NSC and JNES, in order to effectively and quickly implement the practical elements of the QMS. To be implemented effectively this will need to be undertaken in consultation with NSC and JNES.

APPENDIX VI – REFERENCE MATERIAL PROVIDED BY JAPANESE AUTHORITIES

[1] Presentation 1: Implementation of the IRRS in Japan

[2] Presentation 2: How to Proceed

[3] Presentation 3: The Role of NISA

[4] Presentation 4: Overview of the Nuclear Safety Commission (NSC)

[5] Presentation 5: Activity of JNES

[6] Presentation 6: Outline of the Japanese Regulatory System

[7] Self-Assessment Modules I to VIII

[8] Nuclear Safety Regulations on NPPs

[9] Legislation documents

[10] Management Policy

[11] Recent Five years of NISA

[12] Policy Dialogue

[13] Quality Management Dialogue

[14] IRRS Questionnaire

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

[1] ***IAEA Safety Requirements No. GS-R-1*** *– Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*

[2] ***IAEA Safety Guide No. GS-G-1.1 -*** *Organization and Staffing of the Regulatory Body for Nuclear Facilities*

[3] ***IAEA Safety Guide No. GS-G-1.2 -*** *Review and Assessment of Nuclear Facilities by the Regulatory Body*

[4] ***IAEA Safety Guide No. GS-G-1.3 -*** *Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*

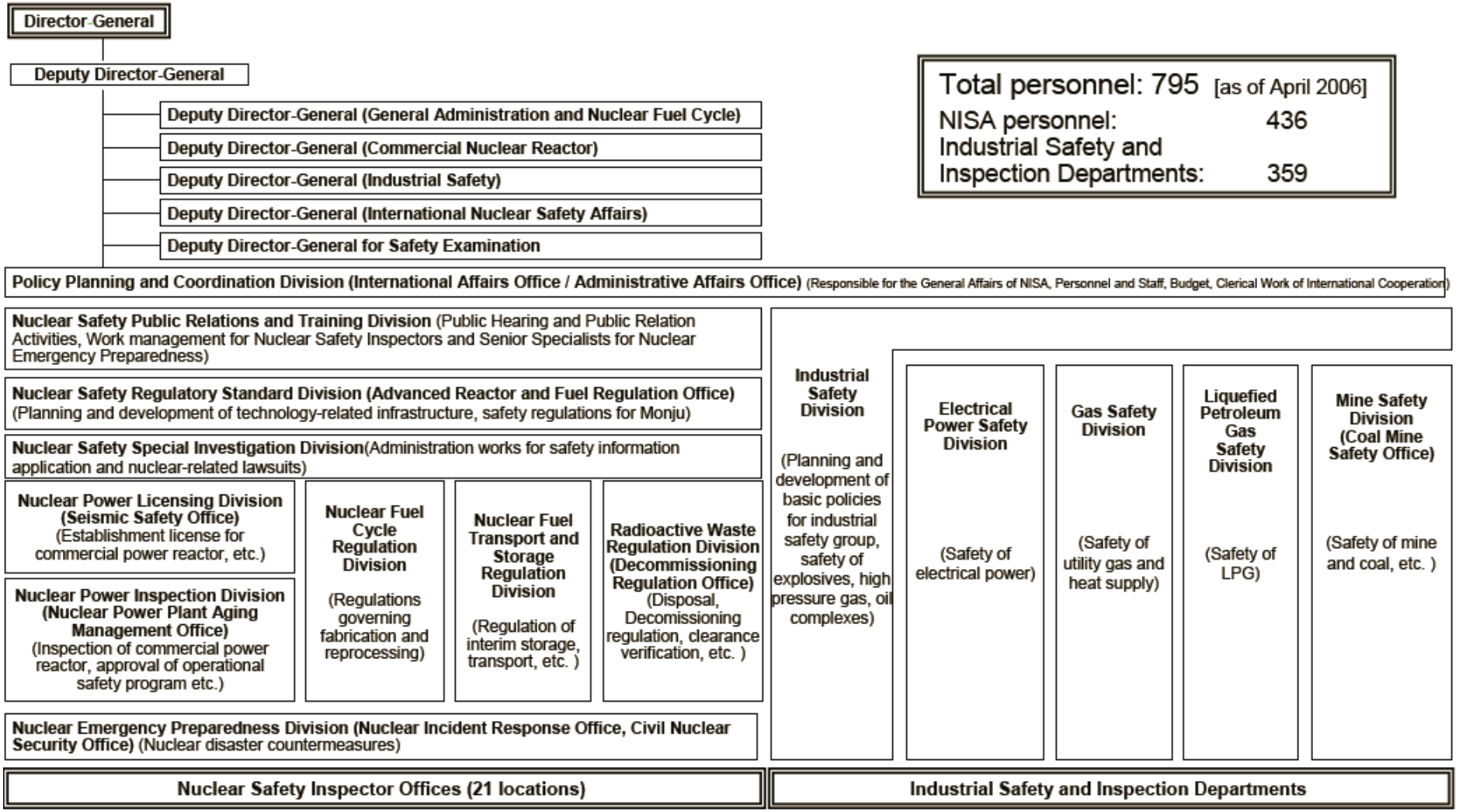
[5] ***IAEA Safety Guide No. GS-G-1.4 -*** *Documentation for Use in Regulating Nuclear Facilities*

[6] ***IAEA Safety Requirements No. GS-R-3*** *– The Management System for Facilities and Activities*

[7] ***IAEA Safety Guide No. GS-G-3.1 –*** *Application of the Management System for Facilities and Activities*

[8] ***IAEA Safety Fundamentals No. SF-1*** *–Fundamental Safety Principles*

APPENDIX VIII – NISA ORGANIZATIONAL CHART



APPENDIX IX – LIST OF JAPANESE COUNTERPARTS FOR THE PREPARATORY MISSION

1.	Mr. Kenkichi **HIROSE**	Director General, NISA
2.	Mr. Nobuaki **TERASAKA**	Deputy Director General for Nuclear and Industrial Safety Policy, NISA
3.	Mr. Yasuhisa **KOMODA**	Deputy Directory General for Nuclear Fuel Cycle, NISA
4.	Mr. Kiyoharu **ABE**	Deputy Director General for International Nuclear Safety Affairs, NISA
5.	Mr. Eiji **KIRAOKA**	Deputy Director General for Safety Examination, NISA
6.	Mr. Satoshi **ITO**	Director, Nuclear Safety Public Relations and Training Division, NISA
7.	Mr. Tomoho **YAMADA**	Director for Safety Examination, NISA
8.	Mr. Masahiro **YAGI**	Director, International Affairs Office, NISA
9.	Mr. Kunihisa **SODA**	Commissioner, NSC
10.	Mr. Shoichiro **KATAYAMA**	Secretary General, NSC
11.	Mr. Takao **KATO**	Director, Management and Coordination Division, NSC
12.	Mr. Tetsuo **NAYUKI**	Director, Regulatory Guides and Review Division, NSC
13.	Mr. Masahiro **AOKI**	Director, Radiation Protection and Accident Management Division, NSC
14.	Mr. Terumi **AOKI**	Director, Subsequent Regulation Review Division, NSC
15.	Mr. Takashi **NISHIYAMA**	Deputy Director, Management and Coordination Division, NSC
16.	Mr. Hideki **NARIAI**	President, JNES
17.	Mr. Katsuhiro **SOGABE**	Vice-President, JNES
18.	Mr. Masatoshi **TORIIHARA**	Vice-President, JNES
19.	Mr. Zentaro **YAMASHITA**	Special Assistant to the Director General, NISA
20.	Mr. Koichiro **NAKAMURA**	Director, Nuclear Safety Regulatory Standard Division, NISA
21.	Mr. Yoshinori **MORIYAMA**	Director, Nuclear Power Licensing Division, NISA
22.	Mr. Ryo **IMOTO**	Director, Nuclear Emergency Preparedness Division, NISA
23.	Mr. Hisanori **NEI**	Director, Nuclear Power Inspection Division, NISA
24.	Mr. Masanobu **KATO**	Deputy Director, International Affairs Office, NISA
25.	Mr. Hiroshi **TANI**	Deputy Director, International Affairs Office, NISA
26.	Ms. Kazuku **NAGURA**	Assistant Director, International Affairs Office, NISA

APPENDIX X – MISSION PROGRAMME - PREPARATORY MISSION

Monday, February 5th, 2007				
	ROOM 450		**ROOM 439-A**	
9:00 - 10:00	**Entrance Meeting** • Welcome and introduction (Japan)(10) • Introduction (IAEA)(5) • Implementation of IRRS(15) • How to proceed the preparatory meeting(20) • Working arrangements (10)	Mr. Hirose Mr. Hirose Mr. Ito Mr. Yagi		
10:00 - 10:40	**IAEA Presentation** • Explanation of how the IRRS review process works • Explanation of the roles and responsibilities of the IRRS team members and the way they should interact with the regulatory body, other organizations and facility representatives • Explanation of the role of the liaison officer and the counterparts during the review • Relationship of the final report and the policy/technical discussion • Q&A			
10:40 - 10:50	**Coffee Break**			
10:50 - 12:00	**Japanese Presentation** • Roles and Responsibilities of NISA (8) • Roles and Responsibilities of NSC (8) • Roles and Responsibilities of JNES (8) • Outline of the Japanese regulatory system (8) • Q&A(30)	Mr. Hirose Mr. Katayama Mr. Nariai Mr. Hiraoka		

Monday, February 5th, 2007				
13:30 - 16:30	**Module1;** **Legislative and Governmental Responsibilities** ・ General presentation (60) Outline of the regulatory system "The regulatory system for commercial power reactor" Result of the self-assessment Key topics "Effective independence of the regulatory body" (proposed topic for policy dialogue) "Functions of NSC" ・ Q&A(110) ・ Summary (10)	Mr. Yamashita Mr. Kato	**Module6;** **Inspection and Enforcement** ・ General presentation (60) Outline of the regulatory system "Outline of the inspection system" Result of the self-assessment Key topics "New inspection system" "Ageing management measures" (proposed topics for policy dialogue) "PSR" "Feedback from operating experiences" ・ Q&A(110) ・ Summary(10)	Mr. Nei
16:30 -	**Review Team Meeting (ROOM 323)**			
Tuesday, February 6th, 2007				
	ROOM 450		**ROOM 439-A**	
9:00 - 12:00	**Module2;** **Responsibilities and Functions of the Regulatory Body** ・ General presentation (60) Outline of the regulatory system "Regulatory process and safety guides and criteria" Result of the self-assessment Key topics "Communications" "Nuclear safety infrastructure" ・ Q&A(110) ・ Summary (10)	Mr. Nakamura	**Module4 and 5 (Integrated Session);** **Authorization, Review and Assessment** ・ General presentation (90) Outline of the regulatory system "Overview of the authorization process, review and assessment" Result of the self-assessment Key topics "Revision of NSC seismic design guide" "Sump screen/strainer clogging" "Accident management" ・ Q&A (30)	Mr. Moriyama Mr. Imoto

Tuesday, February 6th, 2007				
13:30 - 16:30	**Module8; Management System for the Regulatory Body** ・ General presentation (60) Outline of the regulatory system "Outline of NISA management system" Result of the self-assessment Key Topic "Management system for the regulatory body" (proposed topic for policy dialogue) ・ Q&A(110) ・ Summary(10)	Mr. Ito	**Module4 and 5 (Integrated Session); Authorization, Review and Assessment** ・ Q&A(170) ・ Summary(10)	Mr. Moriyama
16:30 -	**Review Team Meeting (ROOM 323)**			
Wednesday, February 7th, 2007				
	ROOM 450		**ROOM 439-A**	
9:00 - 12:00	**Module3; Organization of the Regulatory Body** ・ General presentation (60) Outline of the regulatory system "Organization of NISA" Result of the self-assessment Key topic "Enhancement of human development and training program" (proposed topic for policy dialogue) ・ Q&A(110) ・ Summary(10)	Mr.Yamashita Mr.Ito	**Module7; Development of Regulation and Guides** ・ General presentation (60) Outline of the regulatory system "Development of regulations and guides" Result of the self-assessment Key topic "Use of risk information" "Performance definition of technical requirements and endorsement of academic society and association standards" (proposed topics for policy dialogue) ・ Q&A(110) ・ Summary(10)	Mr. Nakamura
13:30 -	**Review Team Meeting (ROOM 323)**			

Thursday, February 8th, 2007				
	ROOM 450		**ROOM 439-A**	
9:30 - 12:30	**Plenary Session** ・ Review Team presentation of which regulatory technical and policy areas will be reviewed in the main mission (60) ・ Discussion (60) (Preparation of "List of Items for Policy Dialogue" and "List of Items for Technical Assessment") ・ Confirmation of which regulatory technical and policy areas will be reviewed(20) ・ Confirmation of preparation required before the main meeting(20) ・ Agreement with an outline schedule for the mission (including site visits) (20)	Mr. Yamada Mr. Yamada Mr. Ito		
13:30 - 15:30	**Discussion of the practical and logistical aspects of the Review** ・ Confirmation on the material that the regulatory body needs to provide (30) ・ Explanation of IAEA policies, e.g. funding, contact with the mass media (60) ・ How policy dialogue will be evaluated and written in the final report etc. (30)			
15:30 -	**Exit Meeting** ・ Closing Remark	Mr. Hirose		

APPENDIX XI - LIST OF POLICY AND TECHNICAL ASPECTS(POLICY DIALOGUES) IDENTIFIED BY THE PREPARATORY MISSION

1 Institutional Matters at NISA, NSC, METI, ANRE and NISA/JNES (Modules1, 4, 5, 6, 7)

2 NISA's Personnel (Module 3)

3 Human and Organizational Factors and Qualitative Items (Modules 2, 5, 6)

4 Operating Experience Feedback (Module 5)

5 Strategic Planning and Management System (Module 8)

6 NISA's organizational structure and inspection system (inspection practices and resident inspectors) (Modules 3, 6)

7 Transparency and Openness (Module 1)

8 Internal Communication (Module 3)

9 Ageing Management (Module 5)

10 Risk Informed Regulations (Module 5)

11 Authorization of New Plants (Module 4)

12 Performance-Based Regulation (Module 7)

13 IRRS Methodology/Feedback from the IRRS Mission to Japan

(Note)
- Team A covers organizational and institutional matters and Team B technical and practical matters.
- Issue13 for Exit Meeting is "IRRS Methodology."

APPENDIX XII – INFORMATION REQUESTED TO BE PREPARED FOR THE MAIN IRRS MISSION

The following list represents only examples of the information that was requested to be prepared and presented in the IRRS mission. Additional material, information, documents, regulatory outputs and objective evidence useful to understand and support each module was to be identified and presented by NISA and the related organizations, as deemed necessary.

Module 1 Legislative and Governmental Responsibilities

This module was explained in detail during the presentation and in the advance reference material provided by NISA and NSC to the IAEA.

Institutional issues - tasks and mutual relations of NISA, NSC, METI, ANRE, JNES

1. Prepare a presentation providing specific examples of the interactions between NISA-NSC, NISA-METI, NISA-ANRE and NISA-JNES. This presentation should explain how NISA discharges its responsibilities and how work done by the organizations mentioned is assigned, reviewed and approved.
2. Prepare specific examples on how NISA discharges its statutory and operational obligations, as defined in GS-R-1.

Module 2 Responsibilities and Functions of the Regulatory Body

Transparency and public communication

1. The IAEA has not yet developed specific guidance on providing information to and communicating with the public. However, this subject was discussed at the preparatory meeting, as part of the IRRS policy issues and NISA was requested to prepare a presentation to explain how NISA is addressing transparency and communication issues for building public confidence.

Regulating human and organizational issues

2. The preparatory mission got an impression that scientific issues and rational judgment is well addressed in the Code of Conduct of NISA. In order to review how NISA is taking into account 'soft' or 'qualitative' issues, a presentation on regulatory oversight of human and organizational issues, and specific examples where decisions based on qualitative evaluations were taken, was requested.

NISA's involvement in operating experience feedback

3. A presentation was requested describing how NISA ensures that operating experience (from Japanese NPPs and Foreign NPPs) is appropriately analysed, lessons learned are disseminated and the corrective actions are taken.

Module 3 Organization of the Regulatory Body

NISA's personnel

1. A presentation was requested on NISA personnel rotation policy, human resources considering the governmental constrains, internal responsibilities at all staff levels and career competency.

NISA's organizational structure and inspection system

2. A presentation was requested about the interaction between headquarter and resident inspectors and JNES staff. In addition, an explanation was requested of the responsibilities of the resident inspectors and their powers (e.g. for enforcement).

3. A short note was requested about the benefits of combining nuclear and industrial safety to allow NISA to better discharge its responsibilities as a regulatory body.

Internal communication

4. A presentation was requested about the communication between NISA and the operating organization (licensee) at all levels, providing examples on how work priorities are communicated among the staff and examples of culture of mutual trust among the staff

Module 4 Authorization

Licence for establishment of a reactor and construction plan approvals

1. A presentation was requested to explain the tasks and mutual interaction of NISA and NSC in authorization of new reactors.
2. The preparatory mission got an impression that a very comprehensive review of NPP's basic design is done before issuing a licence for establishment of a reactor (volume and scope of submitted and reviewed information seems larger than, for instance, the well known scope specified in the USNRC Reg. Guide 1.70). In order to confirm that impression, it was proposed that a full set of licensing documentation (in original language), submitted for a recent licence be shown and presented to the IRRS mission.
3. A presentation was requested on the Construction Plan Approval process, which was to include:
   - What is the typical content of a construction plan (e.g., detailed drawings, material specifications, strength calculations, description of manufacturing process, equipment specific detailed quality control plan, hold points for regulatory inspections, etc.)
   - What is the scope of construction plans to be submitted to NISA for approval (e.g., all safety classified equipment in safety classes 1, 2, and 3)?
   - In what kind of packages are the plans submitted for NISA review (e.g., separate structures and components, structures and component grouped in some manner a one submittal); in what kind of packages they are approved by NISA?
   - What is the timely connection between submittal or approval of a construction plan and start of construction / manufacturing of the respective structure or component (is start of construction / manufacturing permitted before submittal/approval of the plant)?
   - What is the typical time needed by NISA for approving submitted documentation?
   - How does NISA verify that construction plans are followed during construction/manufacturing?

Authorization of first start-up of an NPP

1. A presentation was requested that explains approvals and verifications needed before NISA is ready to authorize start of operation. An explanation was also requested of which measure is considered as start of operation'' (e.g. start of first fuel loading into the core) and how the start of operation is authorized.

Authorization of plant modifications

1. A short presentation was requested that explains the regulatory approval process for modifications and the type of modifications that need regulatory approval.

Module 5 Review and Assessment

1. A short presentation was requested on tasks and mutual interaction of NISA and JNES in review and assessment tasks.
2. A presentation was requested that explains how NISA (and possibly JNES) is involved in assessment of human and organizational issues and in granting specific approvals for:
   - Licensing / approving individuals to certain tasks: plant manager, reactor operators, etc.
   - Atructure of plant organization and available human resources (number, competences)
3. A presentation was requested on assessment of national and foreign operating experience (OE) that addresses:
   - NISA's screening and assessment process for nationally reported operating experience, and measures to ensure adequate feedback to all relevant plants.
   - NISA's screening and assessment process for internationally reported operating experience (e.g., IRS reports), and measures to ensure adequate feedback to all relevant plants.
   - Submitting of internationally reported OE to NPP's
   - Assessment of the licensee's OEF activities.
4. A presentation was requested of NISA's policy of requiring or encouraging safety upgrades at operating plants (i.e. improvements in the hardware or management), including the following situations:
   - Operating experience has shown weaknesses, indicating that the plant may not meet its design targets - example: sump screen clogging issue
   - There are indications of earlier safety margins being possibly too small, and a change has been made in a safety standard - example: revised seismic safety guide
   - There is a general desire to enhance the safety level of the plant - example: severe accident management
5. A presentation was requested of the ongoing and planned use of PSA for safety assessment in various stages of plant life, as needed to get views and comments on NISA's current and planned use from peers.
6. A presentation was requested of the regulatory requirements and regulatory involvement in assessment of aging, as needed to get views and comments on NISA's current and planned use from peers.

Module 6 Inspection and Enforcement

1. A short presentation was requested on tasks and mutual interaction of NISA and JNES in inspection and enforcement tasks.
2. Presentations on each type of the following inspections during operation were requested:
   - The contents of the quarterly inspection to verify compliance with the operational safety programme
   - The contents of the periodic safety management review conducted by JNES
   - Conduct of the periodic inspection of equipment and structures: what is the role of licensee versus regulator, what is the scope of this inspection (inspections done in the USA according to ASME code sec.11 or does it cover a much wider scope of inspections of components in various safety classes)

3. A presentation was requested on the scope of inspections of structures and components that JNES or NISA inspectors conduct (or witness on regular or random basis), in addition to the inspections mentioned under item 2 above:
   - Inspections during construction in factories or on plant site
   - Inspections during operation
4. A presentation was requested on investigation of abnormal events: which organization makes the investigations: JNES, NISA, NSC, licensee?

Module 7 Development of Regulation and Guides

1. A presentation was requested that explains the tasks and mutual interaction of NISA and NSC in development of such regulations and guides where both organizations are involved. The presentation was to address the following aspects of the process:
   - Initial drafting,
   - Providing comments,
   - Putting into final form, or
   - Approving and issuing.
2. A discussion was to be introduced on the specific features of performance based regulations, as needed to get views and comments on NISA's approach from peers.
3. A discussion was to introduced on the specific features in developing, endorsing and using of industry standards, as needed to get views and comments on NISA's approach from peers.
4. In order to clarify the purpose and nature of each type of your regulations, a comprehensive list and some English translated example(s) of the following regulations were to be provided:
   - Enforcement Rules of Commercial Reactors that explain what information needs to be submitted for licence review and for construction plan review.
   - Technical Requirements (Ministerial Orders) that provide performance requirements for design, for operation, and other corresponding requirements if any.
   - Regulatory Guides of NSC.
   - Academic Society and Association Standards that have been endorsed by NISA, and an example of a NISA endorsement document.
   - NISA internal guides that the staff is advised to use as a support for the safety reviews.

Module 8 Management System

1. A presentation was requested explaining how the organizational goals of NISA, strategies, plans and objectives ("business plan") are translated into activities carried out by NISA, etc., and how the activities plans are reviewed, approved and modified as necessary.
2. A presentation was requested explaining how the processes of the management system are identified, how their sequence and interaction are determined, and how these processes are developed, planned, implemented and assessed.
3. A presentation was requested describing the hierarchical structure and what types of documents, such as (examination) guidelines, procedures, work instructions, checklists, etc.

are used by NISA staff for conducting regulatory activities,. Copy/example(s) of each type of document were to be made available for review.

4. One copy of an evaluation report produced by the Nuclear and Industrial Safety Subcommittee and of an audit report produced by NSC on the work of NISA were to be made available for review.

	25(Mon)		26(Tue)		27(Wed)		28(Thu)		29(Fri)		30(Sat)		Policy Dialogue Issue
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	
A (Organizational and Institutional matters) Module1,2,3,8	Overall Presentations	1	2	3	5	7,8	Direct Observations and Interviews Site Area Team ・ Resident Inspectors ・ Licensee Tokyo Team ・ NISA ・ NSC ・ JNES etc.		Review Team Meeting	Deliberation on Japanese Side	Plenary Meeting	Exit Meeting 13	1 2 3 5 7 8
		M1	*M3*	*M2*	*M8*	*M1,3*							
B (Technical and practical matters) Module 4,5,6,7		11	6	9	4	10,12							4 6 9 10 11 12
		M4	*M6*	*M5*	*M5*	*M7*							
		Policy Dialogue and Technical Discussions if any for each topic IRRS Review team meeting every day: 17:00-18:00					NPP, Inspector Offices, NSC,JNES,etc.		(Review Team) AM: Drafting report PM : Social Event				

(Note)

- Team A covers organizational and institutional maters and Team B technical and practical matters
- Issue13 for Exit Meeting is “IRRS Methodology.”
- M1-M8: Module that most relates to each topic
- Agenda of policy discussion; 1. Result of the pre-mission (IAEA), 2. Presentation on the topics including answers to the homework (Japan), 3. Dialogue (including technical discussions if any)
- Each of the review teams (A and B) will be subdivided into two sub-teams on Thursday, so the review will be conducted in four parallel sessions (two in Tokyo, two on-site)