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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO JAPAN

Tokyo, Japan
10-22 January 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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REPORT OF THE
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TO
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Mission dates:	*10 to 22 January 2016*
Regulatory body visited:	Nuclear Regulation Authority (NRA)
Location:	1-9-9, Roppongi, Minato-ku, Tokyo, Japan 106-8450
Regulated facilities and activities in the mission scope:	*NPPs, Research Reactors, Radioactive Waste Facilities, Decommissioning, Fuel Cycle, Radiation Sources, Emergency Preparedness and Response, Occupational Radiation Protection, Control of Radioactive Discharges, Materials for Clearance; Environmental Monitoring for Public Radiation Protection*
Organized by:	*International Atomic Energy Agency (IAEA)*

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The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of Japan to the IAEA, an international team of senior nuclear and radiation safety experts met with representatives of the Nuclear Regulation Authority (NRA) of Japan from 11 to 22 January 2016, to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at the NRA Headquarters in Tokyo. The purpose of the IRRS mission was to perform a peer review of Japan's national framework for regulation of nuclear and radiation safety.

The agreed scope of this IRRS mission included all facilities and activities regulated by NRA, in some cases in collaboration with other regulatory bodies, with the exception of off-site emergency preparedness as well as medical and transport facilities and activities. Current activities at the Fukushima Daiichi site was not included in the scope of this mission; the IRRS mission recognised that in recent years, several IAEA missions have been undertaken in Japan related to the accident at the Fukushima Daiichi nuclear power plant. Nevertheless, the IRRS team observed the regulatory inspection activities at the Fukushima Daiichi site, as part of its review of NRA's approach to inspections.

The IRRS team reviewed Japan's regulatory framework for safety against the IAEA safety standards. The mission also provided an opportunity for exchange of information and experience between the IRRS team members and the Japanese counterparts.

The IRRS team consisted of 19 senior regulatory experts from 17 IAEA Member States and five IAEA staff members. The IRRS team reviewed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; interface between nuclear safety and nuclear security; occupational radiation protection, control of radioactive discharges, environmental monitoring for public radiation protection, fuel cycle, waste management and decommissioning.

The mission included observations of regulatory activities and interviews and discussions with NRA commissioners, representatives from management and staff, representatives of other regulatory bodies and government, and with representatives of regulated entities. Meetings were held with: Cabinet Secretariat (CAS); Office for the Nuclear Emergency Preparedness (Cabinet office) (CAO); Ministry of Education, Culture, Sports, Science and Technology (MEXT); Ministry of Health, Labour and Welfare (MHLW); Ministry of Economy, Trade and Industry (METI); Ministry of Environment (MOE); Japan Atomic Energy Agency (JAEA); National Institute of Radiological Sciences (NIRS)); Tokyo Electric Power Company (TEPCO); Kansai Electric Power Company (KEPCO) and Japan Nuclear Safety Institute (JANSI). The IRRS team visited: Takahama Nuclear Power Plant and municipality; Fukushima Daiichi site, Rokkasho Reprocessing Plant; JAEA Tokai JRR-3 Research Reactor; and JAEA Tokai Facility for Radioactive Sources.

The IRRS mission included two policy discussions: (1) feedback on the implementation of the back-fitting system; and (2) human resources development programme.

In preparation for the IRRS mission, Japan had conducted a self-assessment and prepared a preliminary action plan to address weaknesses that had been identified. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. The IRRS team received outstanding support and cooperation from NRA's management and staff throughout the mission.

The IRRS team made the following general observations relevant to recent changes in the legal, Governmental and regulatory framework for nuclear and radiation safety; these were recognized as good practices:

- The Government of Japan has put in place a framework which established and supports NRA as a new effective independent and transparent regulatory body with increased powers.
- NRA made a prompt and effective incorporation of the lessons learnt from the TEPCO Fukushima Daiichi accident in the areas of natural hazards, severe accident management, emergency preparedness and backfitting of existing facilities, into the Japanese legal framework.

The strengthened regulatory framework has been applied in strict and transparent manner when reviewing facilities' applications, e.g. for restart of power reactors; the approach taken by NRA makes contribute to restoring public trust in the regulatory oversight of nuclear and radiation safety.

The IRRS team emphasises that the government and NRA should continue their efforts to implement the new regulatory framework to strengthen nuclear and radiation safety. This is important, for example, for operational safety considering the potential restart of a number of nuclear installations. In this specific case, attention should be given to the fact that nuclear installations have been shut down for an extended period of time.

The IRRS team made recommendations and suggestions to the government and/or NRA, as applicable, which indicate where improvements are necessary or desirable in order to progressively align the framework with the IAEA safety standards. These include:

- To attract competent and experienced staff, and develop competencies relevant to nuclear and radiation safety through education, training, research and enhanced international cooperation.
- To amend relevant legislation with the aim of allowing NRA to improve the effectiveness of its inspections.
- To continue and strengthen the promotion of safety culture including a questioning attitude, to achieve a high level of safety. This is equally applicable to NRA and regulated entities.
- To develop and implement an effective, collaborative process for the exchange of regulatory information with other regulatory authorities, to provide coordinated and effective regulatory oversight on nuclear and radiation safety.
- To complete, document and fully implement the integrated management system for all regulatory and supporting processes needed to deliver NRA mandate.
- To give greater priority to the oversight of the implementation of radiation protection measures.
- To develop requirements and guidance for emergency preparedness and response in relation to radiation sources.
- To establish requirements to consider decommissioning during all life stages of facilities and activities and criteria for the release of sites and termination of licensee's responsibility.

The IRRS team noted that several of these issues were identified by NRA during its self-assessment and that many relevant actions had already been included in the action plan.

The IRRS team findings are summarized in Appendix VI.

An IAEA press release was issued at the end of the IRRS Mission.

I. INTRODUCTION

At the request of the Government of Japan, an international team of senior safety experts met representatives of the Nuclear Regulation Authority (NRA) of Japan from 11 to 22 January 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Japan's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Japan in December 2013. A preparatory mission was conducted 6-7 July 2015 at NRA Headquarters in Tokyo to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Japan and their related safety aspects and to agree the scope of the IRRS mission. Where specific facilities and activities would not be included in the scope of the IRRS mission, Japan undertook to provide explanation for the exclusion.

The IRRS team consisted of 19 senior regulatory experts from 17 IAEA Member States, 4 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; interface with nuclear security; occupational radiation protection, control of radioactive discharges, materials for clearance, environmental monitoring for public radiation protection, fuel cycle, waste management and decommissioning. In addition, policy issues were discussed: feedback on the implementation of the back-fitting system and human resources development programme.

The NRA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of NRA's self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Japan's advance reference material, conduct of interviews and discussions with NRA commissioners, representatives from management and staff and direct observation of NRA's regulatory activities at regulated facilities. Meetings with Cabinet Secretariat (CAS), Office for the Nuclear Emergency Preparedness (Cabinet office) (CAO), Ministry of Education, Culture, Sports, Science and Technology (MEXT), Ministry of Health, Labour and Welfare (MHLW), Ministry of Economy, Trade and Industry (METI), Ministry of Environment (MOE), Japan Atomic Energy Agency (JAEA), National Institute of Radiological Sciences (NIRS), Tokyo Electric Power Company (TEPCO), Kansai Electric Power Company (KEPCO), Japan Nuclear Safety Institute (JANSI), etc. were also organized. Furthermore, some IRRS team members visited some nuclear facilities and interviewed site executives, staff, and NRA regional inspectors, etc. (see Appendix III).

All through the mission the IRRS team received excellent support and cooperation from the NRA's management and staff.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Japan's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Japan with the exception of the medical and transport facilities and activities. It is expected that this IRRS mission will facilitate regulatory improvements in Japan and other Member States, utilising the knowledge gained and experiences shared between the NRA and IRRS reviewers and the evaluation of Japan's regulatory framework for nuclear safety, including its good practices.

The key objectives of this mission were to enhance the national, legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements; and

k) providing feedback on the use and application IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Japan, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 6 to 7 July 2015. The preparatory meeting was carried out by the appointed Team Leader Mr Philippe Jamet, Deputy Team Leader Mr Carl-Magnus Larsson and the IRRS IAEA team representatives, Mr Gustavo Caruso and Mr Ahmad Al Khatibeh.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of the NRA represented by NRA Chairman Mr Shunichi Tanaka, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants;
- Research reactors,
- Fuel cycle facilities;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Occupational radiation protection;
- Public and environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal); and
- Selected policy issues.

The NRA made presentations on the national context, the current status of NRA and the self-assessment results to date.

The IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Japan in January 2016.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The NRA Liaison Officer for the IRRS mission was confirmed as Mr Masahiro Aoki.

NRA provided IAEA with the advance reference material (ARM) for the review on 11 November 2015. In preparation for the mission, the IAEA team members reviewed the Japan's advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources, were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 10 January 2016 in NRA, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific

issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the IRRS team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer was present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 11 January 2016, with the participation of NRA commissioners, representatives from management and staff. Opening remarks were made by Mr Shunichi Tanaka, NRA Chairman, Mr Jamet, IRRS Team Leader and Mr Caruso, IRRS Team Coordinator. Mr Aoki gave an overview of the Japan context, NRA activities and the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Japan and the NRA with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

The IRRS team performed its review according to the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday, 22 January 2016. The opening remarks at the exit meeting were presented by Mr Tanaka and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Jamet. Closing remarks were made by Mr Juan Carlos Lentijo, IAEA Deputy Director General, Department of Nuclear Safety and Security.

A joint IAEA and NRA press conference took place at the end of the mission.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Japan has a comprehensive legislative and regulatory framework for the peaceful use of nuclear energy and protection against ionizing radiation. The most important safety principles are enshrined in the Atomic Energy Basic Act. The Atomic Energy Basic Act states in Article 2, paragraph 2 that, by ensuring the safe use of nuclear energy, such energy shall be utilized with the objectives of contributing to the protection of people's lives, health, and properties, maintaining environmental conservation, and protecting Japan's national security, based on established international standards.

In addition, the NRA Establishment Act, the Reactor Regulation Act, the Radiation Hazards Prevention Act and other relevant acts provide for regulatory policy and implementation methods aimed at promoting safety during all stages associated with the use of radioactive material, i.e., from cradle to grave, as well as the use of nuclear power, i.e., from construction to decommissioning of nuclear facilities.

The Japanese government has established a national Strategic Energy Plan, developed by the Agency for Natural Resources and Energy (ANRE), under Japan's Ministry of Economy, Trade and Industry (METI). METI's "Long-term Energy Supply and Demand Outlook" has a horizon out to 2030 and it states the power-source composition for total generated electricity by 2030 and its goal is for nuclear energy to account for 20% to 22% of the power generation. The government has stated that nuclear power and usage must be developed with safety as a priority, with continued focus on ensuring emergency preparedness. This indicates the long-term nature of the nuclear industry in Japan.

While the Strategic Energy Plan provides national direction for the future of Japan's nuclear programme, there is no overarching governmental policy for nuclear safety besides the general policies and strategies enshrined in the aforementioned Acts. However, the Japanese government has established specific policies and strategies for specific issues warranting attention. Some of those issued in the last few years, include:

- The Basic Policy on the Reform of an Organization in charge of Nuclear Safety Regulation;
- The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority;
- The Strategy to Make Japan the Safest Country in the World: To secure public safety the government will continue to implement measures to combat terroristic activities;
- The Basic Policy for Emergency Decontamination Work.

The implementation of policies and strategies take place according to a two-stage planning process. The NRA Commission issues the mid-term goals for NRA every 5 years to establish a basic direction for nuclear safety regulation. In 2015, the Commission issued the current NRA mid-term goals which focus on the following topics:

- To restore public trust in the nation's nuclear regulation;
- To ensure strict and appropriate regulation for nuclear facilities;
- To be vigilant about the decommissioning of Fukushima-Daiichi NPP;
- To develop technical infrastructure and human resources for nuclear safety;
- To enhance nuclear security and to ensure implementation of safeguards;
- To enhance nuclear emergency preparedness and radiation monitoring.

The implementation of the NRA mid-term goals is the objective of the annual plans of the NRA. The reporting on the achievements and activities of NRA to the Diet takes place on a yearly basis.

The IRRS team found that the strategy established by the Japanese government sets out the priorities needed for the further development of the legal framework and thus implements a graded approach.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legislative and regulatory framework in Japan for nuclear and radiation safety is based on a five-level system:

- Basic Acts: at the top level define the basic legal framework and policy for the safe use and regulatory oversight of nuclear energy, and disaster control measures. Basic Acts need to be approved by the Parliament.
- Acts: implement the framework defined by the basic acts and form the main legal provisions for the development and utilization of nuclear energy and the bases for safety regulation, authorisations and inspection of nuclear facilities. Acts need to be approved by the Parliament
- Cabinet Orders: Particulars entrusted by the Act. Cabinet Orders are issued by the Cabinet and do not need to be approved by the Parliament.
- Ministerial Ordinances: prescribe details as entrusted by the Act. The NRA can issue Ministerial Ordinances in accordance with Article 26 of the NRA Establishment Act. Some of these Ordinances are also referred to as NRA Standards.
- NRA Regulatory Guides: Further particulars or interpretation of the Ministerial Ordinances, acceptable methods, conditions etc.

In the area of nuclear safety the two following Basic Acts are of importance:

- The **Atomic Energy Basic Act** is the most important piece of legislation. It defines the basic principles of nuclear energy use and safety, and the scope of the subsequent specific Acts.
- The **Basic Act on Disaster Control Measures**, covering all the types of disaster, defines the framework for emergency preparedness and response.

The most important specific Acts in the nuclear field are:

- The **NRA Establishment Act** stipulates NRA as a nuclear regulator, and provides details on its authority and responsibilities.
- The **Reactor Regulation Act** provides for regulations on all nuclear facilities and activities in order to protect the population and the environment from the harmful effects of radioactivity and makes provision for regulations over controlled nuclear materials, as well as securing the use of nuclear energy for the peaceful use.
- The **Radiation Hazards Prevention Act** imposes regulations on the use, selling, rental, waste management, and other handling of radioisotopes, use of radiation generating apparatuses, and waste management and other handling of objects contaminated by radioisotopes or radiation emitted from radiation generating apparatuses (hereinafter referred to as " radioactive contaminants").
- The **Nuclear Emergency Act** stipulates the responsibility of nuclear operators, the procedure for declaring a nuclear emergency, the establishment of Nuclear Emergency Response Headquarters, and implementation of emergency response or other measures related to addressing nuclear emergency.

- Acts relevant to the management and disposal of waste (see Chapter 1.7).

The Reactor Regulation Act is enacted by a series of NRA Ordinances covering commercial power reactors, power reactors at the research and development stage, research reactors, the nuclear facilities at the Fukushima Daiichi site, and fuel cycle and waste facilities.

In order to incorporate lessons learnt from the TEPCO Fukushima Daiichi accident, NRA established several "Study Teams" with cooperation of the Japan Nuclear Energy Safety Organization (JNES), Japan Atomic Energy Agency (JAEA) and other academic experts. The Study Teams developed new regulatory requirements based on the lessons learned from that accident, the latest technical knowledge, overseas regulatory trends including the IAEA safety standards and best practices found in other international organizations.

The major amendments subsequently introduced in the revised regulations include inter alia:

- The establishment of a new independent regulatory body with enhanced powers.
- The increase of the openness and transparency of regulatory activities.
- The implementation of important measures in the area of emergency preparedness, including the involvement of top-level politicians in emergency exercises.
- The integration of all regulations on power reactors into the Reactor Regulation Act.
- The enhancing of the regulatory requirements for existing and new plants, notably the strengthening of measures against natural hazards and severe accidents.
- The introduction of a back-fitting rule requesting that existing nuclear facilities shall be in compliance with the newest regulatory requirements.
- The introduction of an approval system for extension of operation periods of nuclear power plants.

The IRRS team concludes that the Japanese legal framework provides the required basis for regulation of nuclear and radiation safety within the mandate covered by NRA. The legislative changes and the expediency by which they have been implemented are recognized as a positive step underpinning and promoting nuclear safety, and are commended by the IRRS team. The newly introduced back-fitting rule, that requires the application of the same safety requirements for new as well as for existing nuclear facilities, is one such example of positive change.

With the legislative changes, the licensees have to comply with the requirements of the new legislation before they can restart their facilities. The IRRS team noted that some NPPs have received and several NPPs might receive in the near future the NRA's approval for compliance with the new regulatory requirements.

Facilities in operation combined with the restart programme after an extended shutdown will create additional and new oversight tasks for NRA. Being a young organisation, NRA should continue its efforts to implement the new Japanese regulatory framework with a view to strengthening operational safety. Specific attention should be given to ensuring operational safety at those restarting nuclear facilities that have been shut down for an extended period of time.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legislative changes and the timeliness with which they have been implemented are recognized as positive steps underpinning and promoting nuclear safety, and are commended by the IRRS team.*	
(1)	**BASIS: GSR part 1 Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR part 3 Requirement 2 states that: "***The government shall establish and maintain a legal and regulatory framework for protection and safety and shall establish an effectively independent regulatory body with specified responsibilities and functions".*
GP1	**Good Practice: The prompt establishment of a legal and governmental framework supporting a new independent and transparent regulatory body with increased powers.**
GP2	**Good Practice: NRA's prompt and effective incorporation of the lessons learnt from the TEPCO Fukushima Daiichi accident in the areas of natural hazards, severe accident management, emergency preparedness and backfitting of existing facilities, into the new regulatory framework.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

As a consequence of the TEPCO Fukushima Daiichi accident, Japan has fundamentally revised its regulatory system and established NRA as a new independent regulatory body with enhanced competencies in 2012. In 2014, JNES merged with NRA. Under the NRA Establishment Act, NRA now has sole responsibility for regulating nuclear safety, nuclear security and safeguards based on international commitments, and regulating radiation monitoring and the use of radioactive isotopes that were formerly handled by a range of administrative bodies.

The NRA is an external bureau of the Ministry of the Environment and therefore clearly separated from METI who holds jurisdiction over the use of nuclear energy. The NRA has clear authority and competence over safety regulation, in accordance with the provisions of the Reactor Regulation Act and the Radiation Hazards Prevention Act. It engages in independent decision-making concerning regulatory activities, such as permits, approvals, and inspections, including nuclear reactor construction permits, without any involvement by the authorities tasked with promoting nuclear energy.

The Chairman and Commissioners of NRA are appointed by the Prime Minister, with the consent of the Diet. The NRA Chairman appoints the staff of the Secretariat of NRA. With the objective of ensuring the independence and neutrality of regulation, Article 6, paragraph (2) of the Supplementary Provisions of the Act for Establishment of the Nuclear Regulation Authority stipulates that, following a five-year period of transitional measures after the entry into force of the Act, staff members of the Secretariat of NRA may not be transferred to any government organization that has jurisdiction over affairs concerning the promotion of the use of nuclear energy (the so-called "no-return rule").

The activities of NRA are financed by the national budget, with budget proposals being submitted to the Ministry of Finance by NRA. The budget proposals undergo appraisal by the financial authorities, according to the fiscal situation of the government as a whole. Authorities tasked with promoting nuclear energy are not involved in the approval process of the NRA budget.

The IRRS team recognised the improvements made by the Japanese government in terms of separating NRA from promoting ministries, and providing it with the necessary means to act independently from external interests. The openness and transparency by which NRA acts, and some of the regulatory actions considered by the IRRS team, also suggests that NRA acts with a high level of integrity, i.e. that NRA in those aspects has demonstrated effective (de facto) independence.

The IRRS team understands that, following the TEPCO Fukushima Daiichi accident NRA oriented its strategy to give first priority to the improvement of the nuclear safety regulation. However, in order to implement the newest international requirements and research results in the radiation protection field, further improvements have to be implemented (see Recommendation R3).

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Atomic Energy Basic Act, the Reactor Regulation Act and the Radiation Hazards Prevention Act assign safety responsibilities to licensees for all activities involving manufacturing, using, storing, transporting or reprocessing nuclear material and isotopes. The safety responsibility of the licensees is defined principally through legislation and licensing, continued regulatory oversight, and enforcement throughout all stages in the lifetime of a facility. This means that NRA is able to ensure that the licensees assume their safety responsibility.

After the TEPCO Fukushima Daiichi accident, the Reactor Regulation Act was amended to better reflect the prime responsibility for safety of the licensees. The newly introduced Articles 43-3-29 and 57-9 require that licensees of nuclear power plant shall periodically re-evaluate the safety of their facility and to improve the safety, to enhance education on operational safety, and to take any other necessary measures for preventing disasters. Similar requirements exist for fuel cycle facilities and fuel reprocessing facilities.

In addition Article 6, paragraph (9), of the Supplementary Provisions of the NRA Establishment Act explicitly states that the "Nuclear operators shall be deeply aware that they have the primary responsibility for ensuring the safety of their nuclear facilities and settling any accident, and shall endeavour to further formulate voluntary measures…".

Although Japan has extensive and detailed regulation, the law does not stipulate that compliance with regulations and requirements established or adopted by the regulatory body relieves the licensees of their responsibility for safety. The regulations are for the most part stated in general terms, and guidance documents leave the regulated parties room to propose alternative ways to comply with the regulations.

The responsibility for safety remains with the licensee, even if it chooses to call upon third parties. None of the acts allows the delegation of licensees' safety responsibilities to other parties. Licensees are responsible for verifying that products and services supplied to them by third parties comply with applicable law.

Under the provisions of the Act on Compensation for Nuclear Damage, which provides for liability payments in the event of a major nuclear accident, it is clear that the industry bears the liability.

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

In the legal and regulatory framework of Japan, NRA is responsible for nuclear safety regulation. Nevertheless, the involvement of different governmental organizations is inevitable in the regulatory process for nuclear facilities.

The following authorities have responsibilities related to use of nuclear energy and radiation protection:

- **Cabinet Office:** The Office for the Nuclear Emergency Preparedness in the Cabinet Office functions as the secretariat of the Nuclear Emergency Preparedness Commission and the Nuclear Emergency Response Headquarters, and coordinates the nuclear emergency preparedness and responses among competent government offices, local governments, etc. during normal periods and emergencies.
- **Atomic Energy Commission:** Responsible for coordination of policy and activities of relevant governmental organizations for nuclear energy use. The Atomic Energy Commission is under the Cabinet Office and composed of three Commissioners appointed by the Prime Minister with the Diet's consent.
- **Ministry of Health, Labour and Welfare (MHLW):** Responsible for the medical application of radioisotopes. Also responsible for occupational safety and health, including radiation protection.
- **Ministry of Education, Culture, Sports, Science and Technology (MEXT):** Responsible for nuclear research policies related to science and technology including promotion of research and development on

nuclear energy, human resource development of nuclear researchers and engineers, enhancement of their qualities, supervision of the Japan Atomic Energy Agency, and national liability for nuclear accidents.

- **Ministry of Economy, Trade and Industry (METI):** Responsible for nuclear energy policies including the development of nuclear power and nuclear fuel cycle facilities, ensuring a stable and efficient supply of nuclear source materials and nuclear fuel materials, and promotion of radioactive waste disposal generating from the use of nuclear energy.
- Other **Ministries** have duties within their mandate in the areas of transport safety, monitoring of radioactivity in the environment and the Security of nuclear facilities.

There is extensive coordination by NRA with the Office for the Nuclear Emergency Preparedness. The department heads of the Office regularly attend the management meetings of NRA.

However, the situation is different in other areas. The following examples where coordination of authorities could be improved have been identified by the IRRS team:

- NRA neither coordinates nor exchanges inspection findings with other authorities performing inspections at licensed facilities in areas that influence nuclear or radiation safety.
- The NRA outsources certain inspection activities to Registered Inspection Bodies but does not exercise sufficient regulatory oversight to ensure the quality of their work and confidence in their assessments.
- MHLW, MEXT, MOE and NRA all have responsibilities on radiation safety, but there is no coordination on radiation safety research.

The IRRS team confirmed that the existing arrangements among various authorities in several cases do not ensure the timely exchange of information regarding authorisations, inspections and enforcement actions to provide for coordinated and effective regulatory oversight as well as for the harmonization of the regulations under their respective responsibilities.

The NRA can provide the head of the relevant administrative organ with recommendations on matters for ensuring safety in the use of nuclear energy and request them to make a report concerning the measures that they have taken based on said recommendations.

There is one recent example of such a recommendation. As a result of a series of safety-related compliance issues and enforcement actions associated with the operation of the Monju Sodium Fast Reactor, NRA used this authority to recommend MEXT the replacement of JAEA by another operator. MEXT may also opt to revise the state of Monju fundamentally in order to reduce clearly the safety risks.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing arrangements in several fields, namely in the areas of inspection, radiation protection research and the new regulations for emergency workers, do not sufficiently ensure the timely exchange of information regarding authorisations, inspections, oversight of outsourced inspection bodies and enforcement actions to provide coordinated and effective regulatory oversight as well as for the harmonization of the regulations under their respective responsibilities.*	
(1)	**BASIS: GSR, Part 1 Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
R1	**Recommendation: The government should ensure that the Japanese regulatory authorities having responsibilities relevant to nuclear and radiation safety develop and implement an**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	effective, collaborative process for the exchange of information regarding policies, authorisations, inspections and enforcement actions to provide coordinated and effective regulatory oversight that should also ensure a harmonized regulatory framework under their respective responsibilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NRA does not coordinate nor exchange information about inspections with other regulatory bodies performing inspections at licensed facilities in areas that are influencing the nuclear or radiation safety like radiation protection or fire protection.* *NRA outsources certain inspection activities to Registered Inspection Bodies but does not exercise sufficient regulatory oversight to ensure the quality of their work and confidence in their assessments.*	
(1)	**BASIS: GSR Part 1 Requirement 29 Paragraph 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* *- Liaison with the relevant organization for joint inspections, where necessary."*
(2)	**BASIS: GSR Part 1 Requirement 20 Paragraph 4.19 states that** "*Technical and other expert professional advice or services may be provided in several ways by experts external to the regulatory body. The regulatory body may decide to establish a dedicated support organization, in which case clear limits shall be set for the degree of control and direction by the regulatory body over the work of the support organization. Other forms of external support would require a formal contract between the regulatory body and the provider of advice or services".*
S1	**Suggestion: NRA should consider improving its liaison with the relevant organizations for joint inspections and oversight of outsourced inspections.**

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The measures concerning safety control and management of disused or orphan radioactive sources are stipulated in the Radiation Hazards Prevention Act and its Ordinances. The responsibility for disused or orphan sources rests with the owner of the site or facility where the source was found. On request of NRA, the source has to be collected by an authorized operator and disposed as radioactive waste at an authorized facility.

In cases where the owner of a disused or orphan radioactive source cannot be identified, NRA coordinates relevant ministries and agencies and other organizations to ensure the safe disposal of the source.

The Radiation Hazards Prevention Act regulates the handling and the use of inter alia radioisotopes in order to prevent radiation hazards due to such activities and to ensure public safety. The Radiation Hazards Prevention Act regulates the handling and the use of inter alia radioisotopes, not including nuclear source material and nuclear fuel material, in order to prevent radiation hazards due to such activities and to ensure public safety. The scope of the Act covers artificial as well as naturally occurring radioactive material (NORM). The use of nuclear source material and nuclear fuel material, including NORM, is regulated under the Reactor Regulation Act.

The situation in Fukushima prefecture can be considered as an existing exposure situation as defined by the ICRP recommendations. Based on the Disaster Prevention Basic Act the government has established the Disaster Countermeasure Plan. The comprehensive and multi-layered measures to support the evacuees are based on this Plan. It should be noted that the handling of exposures of the general public and the associated policies with regard to evacuation, and lifting of evacuation orders, is *not* within the scope of this IRRS mission.

1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL

The Reactor Regulation Act and the Radiation Hazards Prevention Act provide regulations for the safe decommissioning of facilities and for the safe management of radioactive waste and spent fuel.

Decommissioning

The Reactor Regulation Act stipulates the requirements for decommissioning according to each facility and activity specified in the Reactor Regulation Act. Before starting decommissioning, the licensees shall prepare a Decommissioning Plan and modify their Operational Safety Programme in order to implement the Decommissioning Plan. These plan and programme have to be approved by NRA. The criteria for approval of Decommissioning Plans are specified in Article 119 of the NRA Ordinance Concerning the Installation and Operation of Commercial Power Reactors.

After completion of decommissioning the licensee has to submit an application to NRA for the Completion of Decommissioning Confirmation (CDC). The issuing of the CDC by NRA means that the establishment permit of the nuclear facility rescinds. The CDC and the ensuing release from regulatory control are based on the criteria specified in Article 121 of the NRA Ordinance Concerning the Installation and Operation of Commercial Power Reactors. However, this Ordinance does not include clearly defined criteria for the allowable residual radioactivity of the soil and on remaining buildings on the sites of the decommissioned facilities as identified in the NRA self-assessment (see Recommendation R8).

Radioactive Waste and Spent Fuel

The Reactor Regulation Act regulates all the stages for all nuclear facilities including the interim storage of spent fuel, radioactive waste disposal and reprocessing of spent fuel.

While there is currently no single consolidated document that addresses the IAEA requirements related to radioactive waste management policy and strategy, it was noted that Japan has considered some of the key elements within the existing legislative framework and policy statements issued by the ministries METI and MEXT. The two ministries METI and MEXT are responsible for developing policies for radioactive waste arising from commercial nuclear facilities and research institutions, universities, medical institutions, and private organizations. Japan has a stated policy that promotes reprocessing of spent nuclear fuel. In practice Japan has undertaken reprocessing of spent fuel both locally and at facilities in the United Kingdom and France. The use of plutonium in light water reactors is also actively pursued. The option of reprocessing is used as a means of reducing the overall volumes of high level waste that will require eventual disposal.

The Final Disposal Act provides the basic framework for undertaking the final disposal of high level radioactive wastes generated from spent fuel reprocessing. The Act for Deposit and Administration of Reserve Funds for Reprocessing of Spent Fuel from Nuclear Power Generation requires the operators of commercial power reactors to deposit the funds for spent fuel reprocessing in a fund administration corporation. The objective of the Act is to ensure the proper implementation of spent fuel reprocessing, disposal of radioactive wastes generated from reprocessing, and disassembling of reprocessing facilities.

A geological disposal facility is planned to be sited and constructed in the future. To this end a waste management agency, namely the Nuclear Waste Management Organization (NUMO) has been established under METI and this entity is tasked to develop the concept.

The funds for the disposal of high level radioactive waste of commercial power reactors are ensured by the licensees of those nuclear facilities, through the Final Disposal Act. METI reviews the level of funding and informs utilities of their obligations for further funding.

1.8. COMPETENCE FOR SAFETY

Licensed staff

To ensure the competence of licensees, the Reactor Regulation Act requires licensees to have the technical competence necessary to install systems, structures and components and to operate them, and, if required, to take measures to prevent and mitigate severe accidents. Specific review criteria for these capabilities are provided for in the NRA standards, such as the Review Standards for the sufficient Technical Capability of Power Reactor Establishers of Commercial Power Reactors to Implement Measures Necessary for Preventing the Occurrence and Expansion of Severe Accidents.

According to Article 43-3-24 of the Reactor Regulation Act, the licensees have to establish an Operational Safety Programme that specifies the education on operational safety for operational staff, and the continuous planning, implementation, evaluation, and improvement of operational safety activities including education and training. The NRA reviews the Operational Safety Programmes and can request modifications if needed. The compliance of the licensees with their Operational Safety Programmes is regularly inspected by NRA.

The supervisor responsible for the technical and safety aspects of a nuclear facility is appointed by the licensee and needs a license certificate as "Chief engineer of reactors" or "Chief engineer of nuclear fuel" or "Radiation Protection Supervisor" depending on the type of the facility by NRA. The supervisor position is designated as "Chief engineer of reactors" or "Chief engineer of nuclear fuel" or "Radiation Protection Supervisor" depending on the type of the facility.

The qualification examination consists of a written and an additional oral examination for some qualifications, both organised by NRA or Registered Examination Body. The certificate for "Chief engineer of reactors" and "Chief engineer of nuclear fuel" are issued by NRA to persons who have passed state examinations. As for "Radiation Protection Supervisor", its certificate is issued by NRA after passing mandatory course organised by Registered Certification Training Body and the written examination by Registered Examination Body. There are no legal requirements regarding educational background, experience, training or refresher training of the qualified examinee in general.

Regulatory body

NRA has been established as an external governmental organization, according to Article 3, paragraph (2), of the National Government Organization Act and has the similar status as a ministry. The staff members of NRA are civil servants and are categorised as administrative staff (technical staff and admin. staff) and researchers. NRA staff follow the position exchange practice of the Japanese administration. This practice requires that the members of the general management of NRA have to change their position every 2 to 3 years. More details on NRA's organizational structure and resources are provided in Chapter 3 of this report.

The IRRS team was informed that because of the new status of NRA the majority of these position changes take place within NRA itself and therefore do not lead to know-how drain. Since the establishment of NRA the rate at which the staff is leaving NRA has reduced, but still amounted to 16.6% in the year 2015. In addition it has to be mentioned that researchers and inspectors have less stringent position exchange requirements than the general management staff and are therefore less challenged by the abovementioned position exchange practice. Of note, the rate at which the technical staff are leaving NRA amounted to 7.0% in 2015.

With regard to the competency of the NRA staff, NRA has recently specified the required competences for each rank and position. The NRA Establishment Act requires that training programmes, including facilities to improve their professional skills, be established and that finance for human resource development be secured. The practical implementation of these legal requirements is one of the top priorities of NRA's mid-term planning and is also part of the NRA's self-assessment Action Plan.

NRA actually established its own training infrastructure, namely the Human Resource Development Centre and the Nuclear Safety Training Facility and has developed different training programmes, such as training for new employees and training for acquiring qualifications including basic training for nuclear safety inspectors. A full scope simulator is under preparation and will be available from March 2016.

The Nuclear Safety Training Centre of the Human Resource Development Centre in Hitachinaka city is equipped with a model of a nuclear power station and cutaway models of components of NPPs and equipment to train the conducting non-destructive inspections. In order to enhance the basic understanding of reactor operation a simple simulator is available.

The IRRS team recognised that the development and maintenance of the technical competence of the NRA staff is one of the priorities identified in NRA's self-assessment Action Plan and has been included as one of the five NRA's mid-term plan goals. Appropriate training infrastructure is currently being established. Although the situation regarding loss of competence because of the position exchange practice of the Japanese administration has been improved, the rate at which the technical staff are leaving NRA is still high (see Recommendation R5 and Suggestion S2).

R&D and Academic Institutions

The academic institutions are a source of specialists to the nuclear sector and in Japan the Government is responsible for funding of basic university training in this area. The nuclear safety research and the regulatory research are carried out by NRA, the Japan Atomic Energy Agency (JAEA) and the National Institute of Radiological Sciences (NIRS), respectively.

Since the integration of the former Japan Nuclear Energy Safety Organization (JNES), NRA has established a dedicated Regulatory Standard and Research Department serving as an internal TSO. Its research is focused on development of safety standards and regulatory requirements and has the following priorities:

- Regulatory challenges associated with decommissioning of Fukushima Daiichi NPP
- Measures against natural hazards inducing common cause failures which may result in severe accidents
- Enhancement of scientific and technical knowledge concerning measures against severe accidents
- Development of technical infrastructure to support the above activities.

JAEA and NIRS function as external TSOs for NRA. JAEA has of a dedicated group for nuclear safety research. NIRS covers the research related to radiation safety and radiation medicine.

Within the framework of its self-assessment Action Plan, NRA indicated that it intends to increase the financial contribution for JAEA's nuclear safety research and to strengthen the cooperation between NRA and JAEA in research fields. It is planned to intensify the deployment of NRA staff to the nuclear safety research group of JAEA in order to develop and maintain technical competence of the regulatory body.

The IRRS team was informed that the research and education activities related to radiation safety have tended to decrease and that there are no plans for NRA to address this situation (see Recommendation R3).

1.9. PROVISION OF TECHNICAL SERVICES

The Japanese government has a limited number of legal provisions for technical services related to personal dosimetry, environmental monitoring and the calibration of equipment.

There is no general authorization or approval process for technical services in Japan. However, licensees include the procurement managements of the technical services in their Operational Safety Programmes. The NRA reviews

these Operational Safety Programmes and can request modifications if needed. The compliance of the licensees with their Operational Safety Programmes is regularly inspected by NRA.

The technical services for nuclear facilities, including the central dose register, are mainly provided by private enterprises or government agencies such as the JAEA, which is a TSO of NRA.

There is a requirement for yearly calibration of workplace measuring equipment and, devices but not for measuring equipment for monitoring for public radiation protection.

In summary the IRRS team has concluded that the responsibilities of licensees regarding the technical services are regulated in compliance with the relevant IAEA requirements; however there are no legal requirements for providers of technical services in the areas of nuclear safety and radiation protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The service providers for occupational and public monitoring for radiation protection are not subject to an approval or authorization process by the NRA and there are no requirements on the necessary technical quality of the services provided.*	
(1)	**BASIS: GSR Part 3 requirement 25 para. 3.99 states that:** *Employers, as well as self-employed persons, and registrants and licensees shall be responsible for making arrangements for assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that arrangements are made with authorized or approved dosimetry service providers that operate under a quality management system.*
(2)	**BASIS: GSR Part 3 requirement 32 para. 3.135 states that:** *"The regulatory body shall be responsible, as appropriate, for: … (i) Verifying compliance with the requirements of these Standards in respect of public exposure in planned exposure situations …"*
(3)	**BASIS: GSR Part 1 requirement 13 para. 2.41 states that:** *"Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.*
(4)	**BASIS: GSR Part 3 requirement 14 para. 3.37 and 3.38 state that:** *"3.37. The Regulatory Body shall establish requirements that monitoring and measurements be performed to verify compliance with the requirements for protection and safety. … 3.38. Registrants and licensees and employers shall ensure that: … (a) Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of these Standards; (b) Suitable equipment is provided and procedures for verification are implemented; (c) Equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards; …"*
R2	**Recommendation: The Government should empower the regulatory body [1] to establish requirements for authorization or approval processes for service providers for monitoring of occupational and public exposures, and environmental monitoring in general, and verify that these requirements are met by licensees.**

[1] An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory *process*, including issuing *authorizations*, and thereby regulating the *safety* of *nuclear installations*, *radiation safety*, the *safety* of *radioactive waste management* and *safety* in the *transport* of *radioactive* material (IAEA Safety Glossary, 2016 Edition).

1.10. SUMMARY

The national policy and strategy for safety of Japan is mainly set out in laws, in particular in the Atomic Energy Basic Act, supported by a comprehensive framework for safety.

Japan has fundamentally revised its regulatory system. The establishment of a framework supporting a new independent and transparent regulatory body with increased powers, as well as the prompt and effective incorporation of the lessons learnt from the TEPCO Fukushima Daiichi accident in the areas of natural hazards, severe accident management, emergency preparedness and backfitting of existing facilities, into the Japanese legal framework is considered to be a good practice.

The IRRS team has also identified areas where further improvements can be made:

- The government and NRA should continue their efforts to implement the new Japanese regulatory framework to strengthen operational safety taking into account the potential restart of a number of nuclear installations. Specific attention should be given to ensuring operational safety at those nuclear installations that have been shut down for an extended period of time.
- The existing arrangements in several fields, namely in the areas of inspection, radiation protection research and the new regulations for emergency workers, do not sufficiently ensure the effective coordination between involved authorities and should be improved,
- The service providers for occupational and public monitoring for radiation protection should be subject to an approval or authorization process by the regulatory body.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Conventions, treaties and codes of conduct

Japan is a contracting party to all the conventions on nuclear safety under IAEA auspices: the Convention on Nuclear Safety, the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the Convention on the Physical Protection of Nuclear Material and the Nuclear Non-Proliferation Treaty.

In addition to the legally-binding international treaties and conventions, the Japanese government has officially committed to the IAEA to implement the Code of Conduct on the Safety and Security of Radioactive Sources, the Supplementary Guidance on the Import and Export of Radioactive Sources, and the Code of Conduct on the Safety of Research Reactors in the national legislation.

Multilateral and bilateral activities

Japan is member of the International Nuclear Regulators' Association (INRA) and participates in the activities of the Asian Nuclear Safety Network (ANSN), Regulatory Cooperation Forum (RCF) of the IAEA for the enhancement of nuclear safety. Japanese delegations participate in the Commission on Safety Standards (CSS) of the IAEA and the five relevant subcommittees and in the seven standing committees of the OECD/NEA, in the Multinational Design Evaluation Programme (MDEP) and in international joint research projects under the auspices of OECD/NEA.

NRA has signed information exchange arrangements under the government-to-government agreements for cooperation in the peaceful uses of nuclear energy with the regulatory bodies of United States, France, and the United Kingdom, and information exchange memoranda with its counterparts of Spain, Germany, Sweden, Canada, Finland, Russian Federation, Lithuania, Turkey, and Vietnam. The NRA also participates in the Top Regulators' Meeting on Nuclear Safety, a tri-lateral information exchange framework among Japan, China, and the Republic of Korea.

International peer reviews

In the year 2007 Japan invited its first IRRS mission; however, this mission was not followed up. The first Operational Safety Review Team Mission (OSART) of the IAEA reviewed the Takahama nuclear power plant in the year 1988. Since then Japan invited 5 further OSART-Missions.

Japan is also encouraging its own nuclear experts to participate in the international review missions. However, NRA recognizes the limitation of its contribution, since their staffs has not been able to provide sufficient feedback to other countries' regulatory activities. Within the frame of its Action Plan NRA intends to increase its resources attributed to international peer reviews and to train its technical staff in order to be able to constructively participate in international peer reviews (see also Chapter 3).

International assistance programmes

It is part of NRA's policy to support nuclear regulatory bodies, especially from embarking countries. More specifically the Human Resource Development Centre of NRA provides a wide range of training programmes including basic training and training in safety review techniques. Up to now staff members of the Vietnamese and Turkish authorities have been trained in Human Resource Development Centre. Additional seminars have been organised in Vietnam and Turkey. A further training programme is planned for Lithuania.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Based on the NRA Ordinance Concerning the Installation and Operation of Commercial Power Reactors NRA has established an Operational Experience Feedback (OEF) programme. Both the licensees and NRA undertake OEF.

National OEF

After an accident or incident has occurred, the licensee is required to immediately report it to NRA. A follow-up report has to be delivered within 10 days followed by an evaluation report on the causes and counter measures to prevent the same accidents or incidents. In response to the report from a licensee, NRA publicizes the details of the reported events, NRA's responses and the provisional INES rating of the event.

The licensees are also required to revise the Operational Safety Programmes to ensure the implementation of the preventive measures in relevant facilities, if needed.

International OEF

In addition to the above mentioned national information, NRA collects information on operational experience from a range of sources worldwide, including the IRS data base of IAEA and OECD/NEA, FINAS report of the IAEA, U.S. NRC's Bulletins, Generic Letters, Information Notice, Regulatory Issue Summaries, Licensee Event Report (LER) etc. The information collected covers all nuclear facilities, including commercial reactors, nuclear reactor at a stage of research and development, research reactors, and reprocessing facilities.

The analysis of the information at NRA consists of four screening and analysis steps. In the first step the national or international information is screened in order to identify technical and regulatory aspects that are of potential importance for Japan. This screening is refined in the second step by an in-house working group of the secretariat of NRA. Issues that may require technical or regulatory measures are then analysed in detail by the Technical Information Committee. This Committee, composed of senior management of NRA, prepares a report on actions and counter measures to prevent the same accidents or incidents.

The report of the Technical Information Committee is finally reviewed by the Reactor Safety Examination Committee or the Nuclear Fuel Safety Examination Committee in order to receive additional advice regarding the improvement of the regulation. Any matters identified by this process, that are deemed to require regulatory action are classified as "technical information requiring action", and are accordingly reflected in regulatory activities. Final decision on the required activities is made by the Commission.

Similar processes take place on behalf of the licensees, based on the technical information and review mission findings provided by the IAEA.

Dissemination of lessons learned and their use

NRA has established regulatory requirements in order to ensure that the lessons learned from operating and regulatory experience are shared between all the licensees. In addition, the OEF results are regularly discussed at meetings organized by the Secretariat of NRA, JAEA, and the Japan Nuclear Safety Institute (JANSI).

Internationally, NRA staff is participating in international meetings relevant to the feedback of operational experience, such as the IRS meetings organized jointly by the IAEA and the OECD/NEA and the meeting of the Working Group on Operating Experience (WGOE) of CNRA (Committee on Nuclear Regulatory Activities) of the OECD/NEA.

On the whole, the IRRS team found that the key elements of IAEA Safety Guide NS-G-2.11 have been implemented.

2.3. SUMMARY

The IRRS team concluded that Japan and NRA fulfil their international obligations. They participate in the relevant international arrangements and have implemented a system for the feedback of operational experience.

Although nuclear experts from Japan already participate in international review missions, NRA plans to increase its resources attributed to international peer reviews and to train its technical staff in order to be able to actively participate in the missions.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

The Act for Establishment of NRA, promulgated on 27 June 2012, established NRA as a new regulatory body in Japan to oversee nuclear and radiation safety with the objectives of protecting people, the environment and maintaining Japan's national security. NRA is still a young organization although many of its staff members had been employed by the previous regulator. NRA has experienced major organisational growth and changes during its first three years of existence, and is still developing its management system, organisational culture and broader capability. This together with a significant workload caused by the implementation of new regulations and the need to review applications to examine their conformity under new safety standards of the nuclear power plants after TEPCO Fukushima Daiichi accident represent a major challenge for NRA.

Tasks and authorities of the NRA are defined mainly in the Act on the Establishment of the NRA, the Reactor Regulation Act, the Radiation Hazards Prevention Act and in the Nuclear Emergency Preparedness Act. NRA is tasked with regulating safety, security and safeguards with regard to the use of nuclear energy and the use of radiation (with certain exceptions such as transport of radioactive materials, and medical use of radiation and the setting of dose limits, which is under the responsibility of the Ministry of Land, Infrastructure and Transport, MLIT and the Ministry of Health, Labour and Welfare, MHLW, respectively) and is required to conduct environmental monitoring in co-operation with local authorities. NRA has authority to establish NRA Ordinances to implement laws and cabinet orders within its assigned duties. NRA also has authority to issue licenses and approvals for the nuclear facilities and radiation activities as well as to conduct inspections to verify compliance with regulatory requirements. In cases of non-compliance, the legislation provides the NRA with enforcement powers and tools that enable it to require corrective measures from the operators to address the non-compliance and restore safety.

Due to the current situation following the TEPCO Fukushima Daiichi accident the NRA oriented its strategy to give priority to the improvement of nuclear safety. As a consequence, NRA is focusing its efforts towards nuclear safety regulations, research and review of applications of the nuclear power plants under new safety standards. While this is important and understandable, the IRRS team is concerned that NRA may not allocate sufficient priority and resources to its responsibilities in respect of other facilities and activities, and radiation protection. For instance, in its Commission meeting on 13 January 2016, priorities for fiscal year 2016 were discussed. A question was raised whether radiation protection resources and research activities had been inadequately addressed in the priorities for 2016. The decision of the Commission was to discuss priorities for radiation protection resources and research when planning the activities for the fiscal year 2017. The IRRS team highlights that, the NRA has to ensure it has sufficient capacity in terms of number of qualified and experienced staff in radiation protection in order to adequately fulfil its responsibilities. This should be considered when implementing measures to increase the qualification of NRA staff (see Recommendation R5).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Due to the current situation following the TEPCO Fukushima Daiichi accident the NRA has oriented its strategy to give first priority to the improvement of nuclear safety regulation, research and review of applications of the nuclear power plants under NRA standards. While this is important and understandable, the IRRS team is concerned that the NRA, while supported by NIRS, may not be allocating sufficient priority and resources to its responsibilities in the radiation protection area.*	
(1)	**BASIS: GSR Part 1 Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 Requirement 20, para. 4.22 states that** *"The obtaining of advice and assistance does not relieve the regulatory body of its assigned responsibilities. The regulatory body*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	shall have an adequate core competence to make informed decisions. In making decisions, the regulatory body shall have the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants."
R3	**Recommendation: NRA should put greater priority and allocate more resources on its oversight of the implementation of radiation protection measures by licensees as well as its participation in the development of international standards in radiation protection and related research activities in collaboration with NIRS.**

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

The head of NRA is the Chairman of its Commission, which is made up of five members appointed by the Prime Minister with the consent of the Diet. The Secretariat of NRA consists of three departments as well as an administration. NRA has 22 regional offices at locations near nuclear sites. The three departments are:

- The **Regulatory Standard and Research Department**, which formulates standards and guidelines, and conducts safety research in a variety of areas, including reactor systems, severe accidents, nuclear fuel and waste, seismicity and tsunamis;
- The **Radiation Protection Department**, which is responsible among other things for establishing an EPR system and implementing initial emergency response, establishing physical protection of nuclear materials, organizing radiation monitoring activities, implementing regulation of the use of radioisotopes, and implementing safeguards in accordance with international agreements;
- The **Nuclear Regulation Department**, which consists of one coordination Division and seven Divisions implementing regulation over specific nuclear facilities and activities, inspections of nuclear reactors, research reactors, decommissioning, nuclear fuel facilities, transport and storage and disposal of radioactive waste, and establishing measures against earthquakes and tsunamis

The organizational structure of NRA reflects its main tasks. The majority of NRA's professional staff is allocated to regulatory functions related to the safety of nuclear facilities to undertake review and assessment, inspections and regulations and safety research.

Based on the observations made during the IRRS mission across the different modules reviewed, it is not obvious that the structure of NRA and the management of its resources ensure that NRA performs its functions as efficiently and effectively as possible. It appears that the departments and divisions work in an isolated manner, which promotes a silos approach, although their tasks' have several similarities. For instance, the department responsible for Nuclear Regulation has separate divisions and processes for inspections, review and assessment on BWR and PWR. It might be worthwhile for NRA to consider if this organizational arrangement is effective and efficient. In addition, the manner which NRA is currently developing its management system processes without establishing cross-cutting core processes, particularly for authorization, review and assessment, inspection and enforcement, creates the possibility for inconsistency in regulation and supports the IRRS team's observation on isolation.

The NRA has developed a mid-term strategy for 2015-2019, which sets priorities and goals for NRA to allocate its resources. NRA can decide on the goals and priorities, and the use of resources without consent from other organisations. On the other hand, NRA does not collect information from licensees and other interested parties when planning for the next fiscal year. This would improve NRA's co-operation with other ministries and agencies as well as create opportunities to allocate its resources needed for the oversight of authorised parties more accurately and with a graded approach.

The fulfilment of NRA's annual goals is monitored semi-annually, and priorities are evaluated quarterly by management. NRA does not have a way to track how resources are used in different regulated areas. For instance it is not possible to know how many hours or days have been spent on e.g. inspection activities at nuclear reactors or on radioisotopes, or on review and assessment of nuclear reactors, fuel cycle facilities or research reactors. This, together with the initial status of the development and implementation of the management system (see chapter 4), does not enable the NRA to measure the efficiency of its processes and determine if its resources are used both efficiently and commensurate with the risks associated with regulated facilities and activities

The IRRS team considers that the current organisational structure of the NRA, its way of planning the annual activities and lack of measures to assess organizational performance and use of resources is not optimal for the NRA to discharge its responsibilities and perform its functions efficiently and effectively and in a manner commensurate with the radiation risks associated with facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current organisational structure of the NRA, its way of planning the annual activities and lack of measures to assess organizational performance and use of resources is not optimal for the NRA to discharge its responsibilities and perform its functions efficiently and effectively in accordance with a graded approach.*	
(1)	**BASIS: GSR Part 1 Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
R4	**Recommendation: NRA should evaluate the effectiveness of its current organisational structure, implement appropriate cross cutting processes, strengthen the collection of information from interested parties when planning its annual activities and develop tools to measure its performance and use of resources.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The Act for Establishment of NRA provides the legal basis for the independence of NRA. It describes NRA's governmental position and regulatory duties, as well as its regulatory powers, and defines no other responsibilities or duties to the NRA that would be in conflict with its regulatory control. Financial resources of NRA are currently adequate and allocated from the government budget. Budgeting of NRA is decided by the Ministry of Finance based NRA's budgeting proposal. Up to now NRA budget has been approved as suggested. As concluded in Chapter 1.3, the provisions in the legislation and in policy decisions allow for the effective independence of NRA.

One of the necessary elements in achieving effective independence is the competence of the staff to make decisions. As described in Chapter 3.1, NRA has identified a shortage of qualified staff and has proposed measures to fill these gaps (see Chapter 3.3) to ensure adequate capacity and independence in decision making.

Management routine oversight and regular discussions between the management and staff ensure that staff remains independent. New NRA staff receives training on the core values and principles that highlight the independent decision-making and priority to safety. Training on the safety culture statement, which endorses the same priorities, will follow. If a new person is recruited from the regulated industry, he or she is not allowed to take part in the oversight of the activities of his or her previous organization. NRA has a process, although not formalized, to address differing views within NRA.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The number of full time staff at the NRA is currently 920. In addition, there are 330 part time employees. The number of staff at the NRA has been increasing significantly over the past two years, mostly due to the merging of

the former technical support organisation JNES with NRA in 2014. NRA staff members are civil servants consisting of inspectors, reviewers, researchers and administrative staff, with more than 80 % having a technical background. There are career paths for changing jobs.

As a result of the self-assessment, NRA has identified that it does not have a sufficient number of qualified staff for performing the assigned responsibilities. This conclusion originates from generic conclusions of the TEPCO Fukushima Daiichi accident lessons learned. As mentioned previously, NRA is facing a heavy work load caused by the increased amount of review and assessment work due to the establishment and implementation of new regulations on nuclear power plants combined with the applications under the new safety standards. It is also expected that verification of compliance with the new requirements will result in an additional demand for inspections. As a consequence, NRA has identified a need for additional resources in the area of review and assessment (e.g. expertise in severe accidents and extreme external events), inspection activities as well as in the security of radioactive sources. NRA has also identified a lack of competent people to participate in international activities and co-operation.

NRA has developed competence profiles and qualification criteria for different positions in each department and is evaluating how inspectors fulfil the criteria. The evaluation of reviewers and researchers will follow later. The IRRS team observed that NRA has not identified human and organizational factors (HOF), safety culture, and management system as part of the competency profiles; even though these areas are essential in assessing licensees'/applicants' safety submissions. The NRA should ensure that relevant competencies and their criteria are covered in the competence management programme and that they are adequately communicated in the organisation. With regards to competencies on human and organizational factors (HOF), safety culture and management system, the NRA should ensure, as appropriate, that these are addressed in the regulatory inspections of licensees' operational safety programmes.

In order to meet the competence profiles NRA has established training programmes, which are currently being implemented for new entrants as well as for mid-career entrants. According to NRA, IAEA guidance has been followed to develop both competence management and training programmes. The IRRS team identified needs to ensure that training of the staff, in particular for inspectors and reviewers (see Chapters 6 and 7), is implemented and is adequate both in duration and content, including retraining.

NRA has identified several actions in its Action Plan to develop adequate amount of qualified resources. NRA has already adopted a "basic policy for human resource development" and a "Model career path for NRA personnel". Implementation of the policy has begun by developing processes for both competence and knowledge management. However, processes are not yet fully implemented or formalised within the management system. Measures in the Action Plan include recruiting experienced people outside the NRA as well as further education and training of NRA's staff. Practical measures to achieve required competencies are training, on the job training, job rotation inside the NRA, and increased and focused co-operation with universities, research organisations and international and overseas organisations. With regards to safety research, NRA aims at enhancing fundamental research and strengthening co-operation between the NRA and JAEA to contribute more to human resource development.

As a result of the self-assessment, NRA has identified that it needs to develop its working conditions to attract people to apply for NRA positions and to encourage them stay at NRA in order to build and maintain its expertise. NRA has identified ways to enhance attractiveness e.g. by providing overseas training/education, expanding opportunities to exchange personnel with other organisations and improving welfare programmes. The IRRS team identified concerns regarding the ability of NRA to retain and recruit suitable numbers of staff to enable it to fulfil its regulatory responsibilities. In addition to the measures planned by NRA it should consider pursuing strategic options for attracting new and retaining its current technical expertise. Such a strategy should seek to improve the attractiveness of NRA as an employer of choice and the roles that its staff undertake by providing them with more

responsibilities, the ability to directly influence safety performance of licensees, options to regulate in all various sectors of the industry, developing legislative requirements that impact national policy, and having a clear career path to senior levels within the NRA. Other options include improved remuneration e.g. healthcare, pension, leave, educational opportunities, welfare support etc.

The IRRS team acknowledges that the NRA, as a result of self-assessment, has identified a lack of sufficient number of qualified staff to perform the assigned responsibilities, and that NRA has started or is planning to initiate adequate corrective actions to ensure it has a sufficient number of qualified staff. The IRRS team highlights that in addition to formal qualification, the experience of the experts is important for the NRA to successfully fulfil its responsibilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NRA has identified, as part of its self-assessment, that it does not have a sufficient number of qualified staff for performing the assigned responsibilities, and that NRA has started or is planning to initiate adequate corrective actions to ensure it has sufficient number of qualified staff.*	
(1)	**BASIS: GSR Part 1 Requirement 18, para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff…"*
(2)	**BASIS: GSR Part 1 Requirement 18, para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management …"*
R5	**Recommendation: NRA should further develop and implement the activities related to the evaluation of competencies, execution of training programmes, on the job training, internal job rotation, and strengthening safety research, co-operation with technical support organisations (JAEA), universities, research organisations and international and overseas organisations, to ensure it has both qualified and experienced staff to fulfil its regulatory responsibilities in nuclear and radiation safety.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team identified concerns regarding the attractiveness of NRA to recruit and retain suitable numbers of staff to enable it to fulfil its regulatory mandate and responsibilities.*	
(1)	**BASIS: GSR Part 1 Requirement 11, para. 2.3 v 6 states that** *"Shall make provisions for adequate arrangements for the regulatory body and its support organisations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety".*
(2)	**BASIS: GS-G-1.1 para. 4.6 states that** *"In addition to working in an appropriate legal framework and employing sufficient staff with suitable qualifications and expertise, the effectiveness of the regulatory body will depend also on the status of its staff in comparison with that of the staffs of both the operator and other organizations involved. Members of the regulatory body staff should therefore be appointed at such grades and with such salaries and conditions of service as would facilitate their regulatory relationships and reinforce their authority".*
S2	**Suggestion: NRA should consider developing a strategy for attracting new and retaining its current technical expertise through seeking to improve the attractiveness of NRA as an employer of choice and the roles that its staff undertake by providing them with more responsibilities, the ability to directly influence safety performance of licensees, options to regulate in all various sectors of the industry, ability to develop legislative requirements that impact national policy, and having a clear career path to senior levels within the NRA.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

Legislation provides possibilities for the NRA to establish advisory bodies and to liaise with technical support organisations. NRA has established a Reactor Safety Examination Committee to examine and discuss matters concerning the safety of reactors and a Nuclear Fuel Safety Examination Committee to examine and discuss matters concerning the safety of nuclear fuel material. The committees work on the matters requested by NRA. A Radiation Council has been established based on the Act on Technical Standards for Prevention of Radiation Hazard to examine technical standards for radiation hazard prevention. This Council reports back to the NRA but also other ministries and agencies, based on their consultations. In addition to committees, the NRA can establish expert groups to provide advice. One expert group has been established in the area of Emergency Preparedness and Response.

Establishment of the committees and criteria for their members are based on the legislation. Practical matters on the management of the committees are given in the Cabinet Orders as well as management rules established by the committees. Committees can establish working groups. Advice provided by the committees or expert groups do not relieve the NRA from its responsibilities. Meetings of the committees are public. During the interviews between the counterparts a need for committees on waste safety as well as on security was discussed.

To support the NRA in its activities and decision making, the NRA complements its own resources by utilising technical support organizations. The main technical support organizations of the NRA are Nuclear Safety Research Centre of JAEA and NIRS. JAEA conducts nuclear safety research and provides input to e.g. regulations, and NIRS conducts studies and research to support NRA activities in the area of radiation protection related to e.g. emergency situations.

NIRS and JAEA are both organisations under MEXT. They are also both authorised parties to NRA due to their regulated facilities and activities and a possibility for conflict of interest has been identified. JAEA has made specific arrangements to minimize the possibility for conflict of interest by separating regulated and research activities as well as establishing a committee to oversee the activities. NIRS has also established a Regulations Support Committee to oversee the possibility for conflict of interest in NIRS activities. However, in NIRS activities, it is not possible to separate the use of nuclear and radioactive materials from all research activities and therefore similar separation of activities as established within JAEA is not feasible.

Research topics are determined annually by the NRA taking into account information collected from related organizations. Planned and ongoing research areas include topics related to TEPCO Fukushima Daiichi accident (different types of waste generated, management of fuel debris to avoid criticality), internal and external events to cause common cause failure (fragility of structures and components, tsunami hazard, volcanic effects, electric arcs/fires), nuclear fuel cycle (shielding analyses, ageing management for reprocessing plants), intermediate level waste generated by decommissioning for final disposal, EPR and RP (improving the knowledge to operate EAL, OILs), Safeguards, Clearance for radioactive isotopes, NPP ageing (Irradiation embrittlement of Reactor Pressure Vessel, concrete degradation, cables).

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

NRA's liaison with the authorized parties is outlined in its "Policy on Ensuring the Operational Transparency of the NRA". The main goal of the policy is to ensure transparency in communicating with authorised and other interested parties to reduce public doubt and distrust, as well as to enhance the neutrality and independence. NRA intends to foster communication with licensees while ensuring high levels of transparency in accordance with this policy.

Meetings between the top management of NRA and of nuclear power plant utilities are organised regularly to discuss safety improvements and improvements to regulatory activities. Meetings are also organised at non-

managerial levels between NRA and regulated entities to discuss matters such as implementation of regulations and review status of applications.

Following a review of the submission from licensees/applicants NRA discusses their findings with the applicant, using one of two forms of meeting; open meetings where public can attend and published on Internet and semi-open meetings between NRA and applicant/licensee. Regulatory decisions can only be made during open meetings. No regulatory decisions can be made in semi-open meetings.

The agendas and recordings or minutes of these meetings serve as the record of the meeting, and are made public as part of the enhanced transparency initiative of the NRA. The IRRS team was advised of a significant number of meetings between NRA and licensees over the last few years. Opinion of the licensees was varied; some of them highlighted their concern regarding the effectiveness of this arrangement in communicating issues between the two organizations and promoting their resolution.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team was advised of a significant number of meetings between NRA and licensees over the last few years. Opinion of the licensees was varied; some of them highlighted their concern regarding the effectiveness of this arrangement in communicating issues between the two organizations and promoting their resolution.*	
(1)	**BASIS: GSR Part 1 Requirement 22, para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based".*
(2)	**BASIS: SSG-12 para 2.30 states that** *"The regulatory body should establish a formal management system for dealing with licence applications, both initial applications and subsequent applications. The system should set out arrangements for requesting further information from the licensee, for carrying out review and assessment of the licensee's application and for carrying out inspections, as appropriate and necessary. The system should define responsibilities within the regulatory body for making the decision on whether to accept the application. The applicant or licensee should be informed of the decision in an appropriate manner, in accordance with the legal framework. All documentation relevant to the issuing of a licence or authorization should be recorded and kept for the lifetime of the installation or activity, and for a specified period beyond such lifetime, in accordance with legal requirements."*
S3	**Suggestion: NRA should consider reviewing the effectiveness of the mechanisms to communicate the outcomes of the regulatory review and assessment, further regulatory expectations and current issues to licenses/ applicants.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

NRA's regulatory activities and decisions have to be in accordance with the different Acts, Ordinances and Directives. At the moment stability and consistency of NRA's regulatory control relies mostly on the prescriptive nature of the legislation. The stability and consistency of the regulatory processes and decisions can be ensured after implementation of the management system (see Recommendation R6).

Changes to the legislation follow a process to which interested parties can also participate by providing comments. Changes are communicated back to the interested parties. NRA's decisions are documented and justified in review

memoranda. Decisions and related documents are published unless they are of confidential nature (security or proprietary information).

3.7. SAFETY RELATED RECORDS

Provisions for establishing and maintaining adequate and retrievable records relating to the safety of facilities and activities are set out in the legislation. Information related to nuclear safety of the facilities and activities has to be submitted to NRA for review and assessment in different stages of the lifetime of the facility. Information produced and submitted is managed within a database. Similarly for the radioactive sources, applications and notifications are kept as administrative documents.

The Reactor Regulation Act and the Radiation Hazards Prevention Act require licensees to record necessary matters and keep these records within the facility. The NRA verifies the creation and retention of these records through inspections as needed.

While the NRA has records and registers for safety related activities, it does not have a formal process described in its management system for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities. Examples on ineffective use of the records in authorization and inspection processes were given in Chapters 5 and 7.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

NRA operates in an open manner following the policy on ensuring the transparency and openness of the NRA (see Good Practices GP1 and GP2). NRA makes decisions in open meetings and materials related to the meetings are published with the exception related to security and proprietary information. Public and other stakeholder comments are solicited when revising regulatory requirements or other relevant regulatory documents e.g. policies. Media has the possibility to ask about nuclear and radiation safety matters from the NRA Chairman at its weekly press conferences, and twice a week from NRA's Secretariat. However, NRA's interactions and communications e.g. with other ministries and other governmental agencies as well as with the local people in the vicinities of the nuclear facilities appears to be conducted upon request.

NRA makes information on incidents, accidents and abnormal occurrences in facilities and activities and other information, available to authorized parties, governmental bodies, national and international organizations, and the public, as appropriate. The general practice is that if an operator submits an incident report to the NRA, NRA issues a press release. NRA currently has the capability and authority to promptly communicate and issue press releases without consent of outside during emergencies to provide information on safety significance of the accident. Other means to provide information are e.g. NRA's website and social media.

NRA had not established specific regulatory requirements for the licensees to inform the public about the possible radiation risks associated with the operation of a facility or the conduct of an activity. However, utilities publish information on the risks associated with the nuclear power plants, and events at their nuclear power plants in order to address expectations by the public, media and local governments. For instance, licensees of nuclear power plants have published probabilistic risk assessment results on the external and internal threats. New regulatory requirements introduced in 2013 require licensees to publish the results of periodic safety assessments of continuous improvement.

3.9. SUMMARY

In general, the responsibilities and functions of NRA comply with the IAEA safety standards. NRA is still a young regulatory body and has experienced major organisational growth and changes over the three years of its existence. It is in the early stage of developing its human resources, management system and in particular of its organisational culture. This, together with a heavy workload, caused by establishment of new regulations, and review of

applications of the nuclear power plants under new safety standards after TEPCO Fukushima Daiichi accident, constitute a significant challenge for NRA.

Following the TEPCO Fukushima Daiichi accident NRA has oriented its strategy to give first priority to the improvement of nuclear safety. While this is important and understandable, the IRRS team recommended the NRA to give greater priority to radiation protection matters.

To ensure that NRA fulfils its statutory obligations effectively, consistently and allocates its resources commensurate with safety, the IRRS team recommended that the NRA should implement cross-cutting core processes, strengthen the collection of information from its stakeholders when planning its annual activities, develop tools to measure its performance, and to evaluate the effectiveness of its organisational structure.

In the area of human resources the NRA has identified that it needs more qualified and experienced staff for performing its assigned responsibilities and developed several measures to meet the needs in the future. The IRRS team recommended the NRA to take further actions to develop and implement the planned activities as well as introducing measures to enhance the attractiveness of NRA.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The NRA issued its Management Rules in 2014, which apply to all work performed by NRA and document the requirements to be addressed by NRA for establishment of its Management System (MS), taking into consideration the relevant IAEA and ISO standards. The MS has been in application since April 2015. NRA has developed a Policy Statement on Nuclear Safety and a Statement of Nuclear Safety Culture, which are to be considered in the development of its MS. NRA consulted with its staff during the development process of the Statement of Nuclear Safety Culture, which was subsequently approved by the Commission.

The NRA Management Rules are supported by 12 "Relevant Rules", which provide additional information in specific areas (e.g. management rules implementation manuals, organization, training, transparency, internal audit, non-conformances, corrective and preventive actions, etc.). The content of these rules does not address the elements of a MS, which are usually described in the MS manual.

The NRA still has to address a number of issues related to the MS, including defining the hierarchical structure of MS documentation, developing an overall process map, a list of management, core and supporting processes and identification of process interfaces. The completion of these activities will directly support achieving consistency of regulatory processes across organizational boundaries and streamlining the development of MS documentation, including process descriptions.

The documentation of the MS includes 220 Operational Manuals. A manual, containing a description of the management system, structure of the organization, functional responsibilities and accountabilities and a description of NRA's processes has not been developed yet. The Operation Manual Development Rule contains details on how the manuals should be developed.

Approximately 40% of the total number of Operational Manuals is still under development. A documented analysis of the operational manuals needed to cover all activities conducted by NRA has not been conducted, so the list of Operational Manuals might not be completed. The IRRS team noted that some processes, including NRA's process for the management of organizational changes, the implementation of activities for promoting, enhancing and assessing safety culture, the management of records, the conduct of management system reviews, collecting and addressing expectations from interested parties, etc. are missing from the list. The Operational Manuals appear to address topics at various levels, some of them dealing with core regulatory processes (e.g. Guideline to write NRA Technical Report or Inspection Manual), while other are more working instructions (e.g. use of taxi tickets, etc.). In addition, some areas appear to be duplication, due to the existence of similar procedures. The development of the MS taking a top-down approach should allow for identification and elimination of such instances and should contribute to making it more user-friendly.

In order to ensure that the MS supports adequately the enhancement of safety culture in NRA, the organization should define specific actions to be taken and monitor their implementation. The IRRS team was informed that each department is required to take into consideration the Statement on Safety Culture in developing their annual plans. After establishment of NRA, staff went through three basic seminars on safety culture, to have staff recognize the need to promote safety culture in NRA. The objective was to provide regulatory staff with basic overview: a) on safety culture related issues based on IAEA INSAG documents; b) on situation in dealing with safety culture issues in some countries e.g. USA, UK or Germany; and c) on approaches of Japanese industry to safety culture enhancement and comment matter about safety culture from accident investigation committees of Fukushima-Daiichi NPP accident. Currently none of NRA's employees took safety culture awareness training except newly recruited staff, but such training will be offered by the HR Development Centre. NRA did not conduct safety culture surveys of its staff. Establishment of a safety culture baseline in NRA should allow for

evaluating its evolution and enhancements over time. The IRRS team informed NRA about the existence of IAEA safety culture self-assessment methodology for the regulatory bodies and encouraged them to develop specific actions for ensuring the key aspects of safety culture are shared within the organization and applied in the regulatory work. This is important because NRA is a relatively new organization, which is aiming to create an organizational culture for employees coming from two different backgrounds ("administrators" and "researchers"), which are reflected in their employees' status.

While NRA applies the principles of graded approach in some of its activities, there is no documented guidance on how MS requirements will be applied, in a graded manner to the conduct of regulatory activities and in the development of supporting MS documentation. The lack of guidance may lead to discrepancies in the implementation of regulatory activities (e.g. harmonization of review and assessment and inspection among various types of facilities and activities, et.), as well as of the level of effort associated with their conduct. In addition, this might have an impact on the MS documentation which is under development/ will be developed and associated verification and approval activities.

The NRA has identified, in its self-assessment and action plan, that the establishment of its MS is an area requiring further development. The IRRS team discussed with NRA representatives some of the future actions to be taken and provided examples on how management system was developed by various regulatory bodies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The NRA has identified in its self-assessment that the establishment of its management system is an area for improvement. Organization of management system documentation does not provide for ensuring appropriate consistency of regulatory approaches. Not all NRA management, regulatory and supporting processes are documented (e.g. preparation of training and retraining programmes, etc.). There are also processes missing, including the management of organizational changes, the implementation of activities for promoting, enhancing and assessing safety culture, the management of records, conduct of management system reviews, collecting and addressing expectations from interested parties, etc. Application of graded approach in the conduct of regulatory activities and in the development of supporting MS documentation is not consistently applied.*	
(1)	**BASIS: GSR Part 1 Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GS-R-3 para. 2.4 states that** *"The organization shall be able to demonstrate the effective fulfilment of its management system requirements".*
(3)	**BASIS: GS-R- 3 para. 2.6. states that** *„The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:* • *The significance and complexity of each product or activity;* • *The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;* • *The possible consequences if a product fails or an activity is carried out incorrectly.*
(4)	**BASIS: GS-R- 3 para. 2.8. states that** *„The documentation of the management system shall include … a description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved …"*
(5)	**BASIS: GS-R- 3 para. 6.1 states *that*** *„The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement".*
R6	**Recommendation: NRA should complete, document and fully implement its integrated management system for all regulatory and supporting processes needed to deliver its mandate. Grading of the application of management system should be applied consistently and generic**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	processes should be fully developed such as control of documents, products, records and management of change. The effectiveness of the NRA management system should be monitored and measured in a comprehensive way to identify opportunities for improvement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Specific measures to promote and sustain high level of safety culture in regulatory activities, in support of the recently issued Statement on Safety Culture have not been defined and implemented.*	
(1)	**BASIS: GS-R-3 para. 2.5 states that** *"The management system shall be used to promote and support a strong safety culture by:* • *Ensuring a common understanding of the key aspects of safety culture within the organization;* • *Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the* • *organization;* • *Reinforcing a learning and questioning attitude at all levels of the organization;* *Providing the means by which the organization continually seeks to develop and improve its safety culture.*
S4	**Suggestion: NRA should consider introducing specific measures such as awareness training or surveys to promote and sustain high level of safety culture in the conduct of its activities.**

4.2. MANAGEMENT RESPONSIBILITY

The overall responsibility for the MS is assigned to the Commission. A Management System Promotion Office was created under the Policy Planning and Coordination Division and the Promotion Office's manager has a direct reporting line to the Secretary General, who ensures the link with NRA Commission. The IRRS team was informed that this office's responsibilities would be expanded to enhance the internal audit function. This subject was also discussed at the Commission's meeting that took place on 13th January, 2016. The promotion of NRA's core values included the distribution to all NRA's staff of cards containing these statements.

The IRRS team considers that, in order to adequately support the further development of the MS, regular and pro-active NRA senior management commitment, including from the Commission members is needed. Such engagement will allow for identifying and streamlining the regulatory processes which impact various facilities and activities.

NRA creates mid-term and annual plans, which do not include communication with interested parties. Communication with industry and operating organizations might be useful in the planning process for evaluating the workload by identifying upcoming major requests from licensees. This could allow NRA to be better prepared for responding in a timely manner and allocating its resources accordingly (see Recommendation R4).

While the NRA annual plan contains targets related to inspection activities, no numeric values/ quantitative targets and/or description of activities for regulatory reviews are reflected in the plan. The IRRS team noted that performance targets would be assessed based on the individual targets. Performance targets for NRA's staff were established, as part of the annual planning process and there completion is assessed through self-assessment and first-line managers' review.

The IRRS team also noted that there are no specific plans for MS related activities for the next fiscal year (starting March 2016) at the moment. Such activities will be identified after the conduct of the review against the strategic plan of operations. Taking into consideration the extent of MS related work still to be completed, the IRRS team considers that a comprehensive plan should be developed and its implementation should be monitored and reported to NRA's senior management.

The MS should include mechanisms to take into consideration stakeholders' expectations and this should be reflected in the development of specific processes for collecting and analysing such information. The information collected from interested parties provides input for the continuous improvement of the MS. The NRA does not have such a formal process for collecting and addressing expectations from interested parties and did not conduct any survey on this topic (see Recommendation R6).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NRA plans to complete development of its management system in several years time frame. Even though development of management system is recognised as one of the NRA priorities, the work is not organised under a specific project, but only under sequence of general NRA annual plans, with no specific mid and long-term objectives and targets and long term resources planning.*	
(1)	**BASIS: GS-R- 3 para. 3.1 states that** *"The 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. 3.8 states that** *„The senior management shall establish goals, strategies, plans and objectives that are consistent with the policies of the organization".*
(3)	**BASIS: GS-R- 3 para. 3.11 states that** *"The senior management shall ensure that the implementation of the plans is regularly reviewed against these objectives and that actions are taken to address deviations from the plans where necessary".*
S5	**Suggestion: NRA Commissioners should consider taking a strategic approach to the implementation of the management system demonstrating their commitment to the project by initiating a specific multi-year management system development plan and by reviewing its implementation on periodic basis**.

4.3. RESOURCE MANAGEMENT

The NRA MS documentation does not contain a process description for resource management on a long-term basis (See Recommendation R6).

The MS Promotion Office is led by one manager, has two full-time and one part-time staff members and it will be expected to receive an additional three staff. The NRA should further monitor and assess if the resources dedicated to the establishment, maintenance and improvement of the MS continue to be adequate (see Recommendation R4).

4.4. PROCESS IMPLEMENTATION

NRA developed an Operation Manual Development Rule, which is used for the development of Operational Manuals. Taking into account that these 220 manuals contains/will contain information at various level of complexity (see Chapter 4.1), it might be very difficult to use the Development Rule for ensuring consistency of the documents.

NRA has not developed a MS manual and supporting documentations for all its processes. The elements necessary to be addressed by each process (e.g. requirements, risks, interactions, inputs, process flow, outputs, records, measurement criteria, etc.) will have to be specified in a MS document when the NRA hierarchical structure (e.g. procedures, work instructions, etc.) of the MS will be clarified.

Taking into account the current status of the MS, in which not all processes have been identified and documented, the assignment of responsibilities and authorities for each NRA process will have to be finally clarified at a later stage.

The process owners have not been identified at an organizational level for core regulatory processes (e.g. for inspection covering all facilities regulated by NRA). The current process owners are mostly divisional managers, so it may be difficult to propose and implement changes affecting other facilities, outside their responsibility (see Recommendation R6).

Requirements related to the management of safety records are identified in MS documentation. NRA has not yet documented a process for specifying how records linked to the NRA MS and its processes will be controlled, including retention times and the media to be used for ensuring that the records are readable and available. There is only general government level rule that do not reflect NRA specifics in this area. Records control is one of the generic management system processes and should be clearly defined in order to support other regulatory processes, ensuring consistency in decision-making and preservation of knowledge (see Recommendation R6).

Since its establishment, NRA went through two organizational changes. These changes were approved by the Commission, because this level of approval was indicated in the Document Control Rules. The IRRS team noted that NRA has not yet developed a documented process for evaluating and classifying the changes according to their importance for safety and for monitoring their implementation (see Recommendation R6).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation*: NRA has not developed a comprehensive description of its management system in a single document such as manual. In addition, there are more than 200 processes described inside the management system with flat hierarchy and without unified format. In many cases the similar processes such as inspection of different facilities and activities are developed in discretion of individual departments with no formal arrangement to ensure consistency.*	
(1)	**BASIS: GS-R- 3 para. 2.8. states that** *"The documentation of the management system shall include the following:* • *…* • *A description of the management system;* • *…* • *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* • *A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.*
(2)	**BASIS: GS-R- 3 para. 2.9. states that** *„The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use.*
S6	**Suggestion: NRA should consider developing a hierarchical structure for the management system that is easy to use and which supports effective and consistent implementation of regulatory activities. Specific descriptions of each process should be developed in a unified format including requirements, risks, interactions, inputs, process flow, outputs, records and measurement criteria.**

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The NRA MS has been recently introduced and is not fully implemented, so there is only a limited amount of information for assessing its effectiveness.

The MS Promotion Office has conducted three internal audits and it will be formally assigned this responsibility in the near future. NRA is planning to conduct five internal audits in fiscal year 2015.

NRA staff conducts self-assessments on a regular basis and the results are recorded.

The first NRA MS review is planned for March 2016. However, NRA does not have a documented process description on how MS reviews will be conducted.

The IRRS team noted that NRA is planning to develop a database for recording the results of the internal audits and the management of resulting corrective actions. The IRRS team proposed to include the results from all forms of assessments in the database, in order to have comprehensive information to be used, for example, as an input in the MS review.

NRA currently has a suggestion box for collecting input from staff, and a limited number of inputs (10) have been received. The IRRS team considers that more promotional activities should be conducted in order to enhance staff's participation in the MS improvement process.

A complete set of activities needed for measurement, assessment and improvement of the overall effectiveness of the management system are still to be implemented, and the results of all forms of assessments should be assessed and addressed to allow for efficient and effective discharge of NRA mandate (see Recommendation R6 and Suggestion S5).

4.6. SUMMARY

NRA has taken a number of steps towards the establishment of a MS, including the issuance of NRA Management Rules, a Policy Statement on Nuclear Safety and a Statement of Nuclear Safety Culture and creation of the Management System Promotion Office.

NRA still has to address a number of issues in order to finalise its management system, including defining the hierarchical structure of MS documentation, developing a management system manual, an overall process map, a list of management, core and supporting processes, identification of process interfaces and development of the supporting documentation for all processes. The completion of these activities will directly support achieving consistency of regulatory processes across organizational boundaries and streamlining the development of MS documentation.

In order to ensure that the MS supports adequately the enhancement of safety culture in NRA, the organization should define specific actions to be taken and monitor their implementation. These should include items such as awareness training and surveys of personnel.

To ensure full completion and implementation of integrated management system NRA Commissioners should consider taking a strategic approach to the implementation of the management system demonstrating their commitment to the project by initiating a specific multi-year management system development plan and by reviewing its implementation on periodic basis.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Reactor Regulation Act and the Radiation Hazards Prevention Act require the applicants to submit to NRA documents demonstrating the safety of regulated facilities or activities in order to support their applications for authorization. These documents differ depending on the type of facility or activity, based on a graded approach.

For a nuclear facility, the Reactor Regulation Act prescribes the permits, approvals required for construction and operation of the facility. It gives authority to NRA to grant permit or approval, to revoke permits and to suspend the operation of facilities. The major licensing steps established by this act are:

- Establishment Permit. The permit application covers siting, basic design of the facility and applicant competence,
- Approval of Construction Plan (prior to start of construction work),
- Approval of Operational Safety Programme (prior to starting facility operation). The Operational Safety Programmes address such matters as limiting conditions for operation, maintenance, in-service inspection, and testing of the facility, measures to deal with accidents (including severe accidents), requirement to report major safety problems to the regulatory body, and requirement to gain operational experience (for example operational safety reviews or methods for root cause analysis) and share it with other licensees as necessary,
- Approval of extension (beyond 40 years) of operation periods of NPP,
- Approval of decommissioning plan (prior to start of decommissioning),
- Confirmation of completion of decommissioning (see Chapter 1.7).

In addition to setting a timeframe for reviewing each type of application, the legislation also defines the key criteria to be met in order that an authorization can be granted and establishes the processes to address plant or operational safety programmes modifications, either through prior notification to or approval by NRA. Except for minor modifications, all modifications require NRA prior approval.

Licensee's submission includes information on technical aspects, safety assessment (covering design basis accidents and severe accidents), organizational aspects (including technical competence and quality assurance) and financial resources. Information required is described in various legally binding documents, mainly Cabinet Orders and NRA ordinances, taking into account the graded approach. Other publicly available documents, issued by NRA, may also provide additional details. In its self-assessment, NRA recognized that quality assurance programmes should be included in the application for the establishment permit and that an initial decommissioning plan should be developed at the time of establishment and be updated periodically during the lifetime of operations.

The licensee is required to submit an Operational Safety Programme for NRA approval before fuel loading that presents a summary of important safety measures. This is later used by NRA to confirm that the facility is being operated as intended and within safety limits, changes to the content of the Operational Safety Programme require submission of application for changes and authorisation by NRA. In addition to plant parameters, the Operational Safety Programme details the licensee's operating structure and the operational safety training arrangements.

Changes in the operational safety programme also require approval by NRA. Prior to authorising facility operation, NRA conducts a Pre-service Inspection of the facility to confirm that the construction of the facility satisfies the design intent.

Major authorizations, such as issuance of an Establishment Permit, are taken by NRA Commissioners during formal meetings, open to the public. NRA staff prepares a memorandum, usually quite short, with background information, conclusion of NRA review and suggested NRA decision. The meeting, normally chaired by NRA Chairman, starts with a short presentation by NRA staff based on the written memorandum. NRA commissioners may raise comments and ask questions to NRA staff. As a result of the discussion, NRA Commissioners may endorse the suggested decision or postpone the decision to a future meeting, so that NRA staff can further elaborate on the topic to take into account the Commissioners' comments.

The IRRS team noted that NRA guidelines allow some approval to be delegated to the Secretary General of NRA or other senior staff for less significant modifications.

Once NRA has concluded its review and made a conclusion on the application, NRA publicizes its decision on its official website and notifies it to the applicant. It is not NRA's practice to attach conditions to an installation permit or an approval (no license condition has been issued since NRA was established) as NRA's working method is to have the applicant update its submissions to NRA satisfaction. Therefore, authorizations usually take the form of very short (1 page) letters. Nevertheless, the Reactor Regulation Act allows for conditions to be attached to an Establishment Permit and allows NRA to order a licensee to modify Operational Safety Programmes. This act does not include equivalent provisions for the approval by NRA of construction plans or, for NPPs, approval of operation beyond 40 years. This may result in NRA declining an application and thus forcing the applicant to send a new/amended submission. This may create additional delays, which could have been avoided if a condition had been included in the approval.

NRA also issues certificates for specific positions within the licensee' organization such as "Chief Engineer of Reactor", "Chief Engineer of Nuclear Fuel" or "Radiation protection Supervisor". In addition to the licensing processes for facilities and specific positions in the licensee's organization, Japanese regulations also require approval by NRA of welding methods (for welding organizations, not for nuclear installation licensees) for some types of nuclear facilities. NRA may also issue Model Certification in relation to specified components for efficient authorization.

Finally, with regards to licensing processes, the damaged Fukushima Daiichi plant comes under specific provisions to ensure appropriate regulatory oversight and control. It is envisaged that the special management arrangement for Fukushima Daiichi Plant will continue for some time to come, the NRA designated the plant as a "Specified Nuclear Power Facility" on 7 November 2012, in accordance with the Reactor Regulation Act, in order to ensure appropriate measures can be adopted to suit the particular circumstances.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

In Japan, four authorizations are needed before a new reactor can be commissioned:

- an Establishment Permit which includes a review of the basic design and safety evaluation in relation to the siting of a reactor facility;
- Approval of Construction Plan which entails a review of the detailed design of the plant;
- Approval of Fuel Assembly Design, which entails a review of the design of the fuel assembly to be used in the reactor; and
- Approval of Operational Safety programmes.

The Reactor Regulation Act and associated NRA ordinances (NRA Ordinance on Commercial Reactors, NRA Ordinance on Technical Standards, NRA Ordinance on Quality Control Methods…) establish the corresponding regulatory requirements and regulatory processes.

NRA also conducts Pre-service Inspections and Fuel Assembly Inspections to check that reactor facilities have been constructed and fabricated in accordance with the approved plans.

Reactor Establishment permit

In deciding on the siting of reactor facilities, applicants or licensees are required to conduct adequate studies of external events that could occur at the proposed location and to take these into account in its design. The impact on society and the environment of a proposed reactor facility is evaluated as part of the procedure for granting a Reactor Establishment Permit. Moreover, similar to other large-scale industrial facilities, there is an obligation to conduct an environmental impact assessment.

The safety reviews for obtaining an Establishment Permit are carried out by NRA. Before granting such a permit, NRA has to:

- ensure that the applicant possesses the technical and personnel ability to build such a facility, operate it safely and efficiently and prevent severe accidents.
- consult the Atomic Energy Commission of Japan, in order to obtain the confirmation that there is no risk that the facility will be used for other than peaceful purposes.

No expiry date is set for a Reactor Establishment Permit. However, a 40-year operation limit is stipulated in the updated Reactor Regulation Act; this limit may be extended, after NRA approval, for a maximum of 20 additional years.

Approval of construction plan and fuel assembly design

After being granted with an Establishment Permit, licensees must obtain approval from NRA for their construction plan before commencing construction. The submission should include:

- a description of the reactor unit and facilities for the handling and storage of nuclear fuel material, the reactor cooling system, the instrument and control system, facilities for disposal of radioactive waste, radiation management and reactor containment facilities;
- a safety evaluation based on the detailed design for the plant. This will cover, for example, earthquake-resistance and strength, as well as safety-related design features specific to the equipment for which the application is being submitted;
- the quality control methods and inspection systems, which have to comply with the NRA Commercial Reactor Quality Management Standard Ordinance.

NRA approval must be sought for the design of the fuel assembly to be loaded into the reactor. When applying for approval for the design of the fuel assembly, applicants must attach a document covering, among other things, features of the fuel assembly such as its structure; heat, radiation and corrosion resistance; and provisions for quality assurance.

Operation license

Before commencing reactor operation, a licensee must:

- submit Operational Safety Programmes and obtain NRA approval. The Licensee shall from now-on comply to these programmes;
- undergo a Pre-service Inspection by NRA.

Measures to ensure the safety of nuclear reactors in case of design basis accidents, fire, internal flooding, severe accident or large scale destruction as well as operational limits and conditions (OLC) are to be addressed in

Operational Safety Programmes. Quality assurance provisions and management system aspects, including for external goods or services procurement, management of operational safety documents and records, education and training courses in safety activities have also to be included. Concerning ageing management, licensees with reactors of 30 years or older are required to include in their Operational Safety Programmes provisions for maintenance covering the ten upcoming years which are based on an evaluation of the ageing of equipment important to safety.

The fuel assembly to be loaded into the reactor must successfully pass a Fuel Assembly Inspection by NRA.

Periodic safety review and periodic safety assessment of continuous improvement

Following each periodic facility inspection, licensees are now required to conduct, a "periodic safety assessment of continuous improvement", and a more in-depth analysis is required every 5 years when revisiting the safety assessment that takes into account the latest (national and foreign) scientific and technical knowledge. The first submission of licensee' report is likely to occur mid-2017. NRA has developed a Guideline which details the expected content of licensee report. Although detailed on specific topics, such as seismic assessment or probabilistic assessment, equipment condition, ageing management and referring IAEA SSG-25 in the Guideline, some factors of IAEA SSG-25 like equipment qualification are not explicitly mentioned; the licensee is required to submit a periodic safety assessment report instead of an updated safety analysis report. If more challenging natural hazards or other significant issues have been identified the licensee is required to submit application for modifying establishment permit, if necessary (see Recommendation R11).

The license shall, as a result of its investigations, identify measures, called "voluntary measures", he intends to implement beyond the minimal ones necessary to comply with regulatory requirements.

Operation beyond 40 years

The Reactor Regulation Act prescribes an operating time of 40 years that can be expanded up to 20 more years with an approval by NRA. To support the application to extend the operation period of a facility, applicants must perform a "special inspection" to assess current status of the plant in detail, especially to detect any degradation, carry out a technical evaluation of any degradation and describe their maintenance and management policy during the extension period.

The IRRS team noted that the ageing management of NPPs has to be addressed by licensees and scrutinized by NRA under three regulatory processes, which may be concurrent: change in Operational Safety Programmes for plants operating beyond 30 years, report documenting the Periodic Safety Assessment of Continuous Improvement, approval of operation beyond 40 years. NRA recognizes overlaps but indicates that review of ageing matters beyond 30 years of operation and beyond 40 years of operation is performed by the same group within NRA. This group may however not be involved for the Periodic Safety Assessment of Continuous Improvement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Ageing management at NPP is to be addressed by licensees and examined by NRA under three regulatory processes which may be concurrent: change in Operational Safety Programmes for plants operating beyond 30 years, report documenting the Periodic Safety Assessment of Continuous Improvement submitted after every periodic facility inspection, approval of operation beyond 40 years. NRA recognizes overlaps although some differences in the purpose of the licensing process do exist.*	
(1)	**BASIS: SSG-12 para. 2.6 states that** *"The licensing process should be established in a systemic way to facilitate efficient progression of regulatory activities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S7	**Suggestion: NRA should consider enhancing the interfaces and overall coherence of the existing three regulatory processes related to NPP ageing management.**

Management of modification

The Commercial Reactors Ordinance requires licensees to take necessary measures (e.g. development of a plan for maintenance and management, its implementation) for facility modification and NRA confirms these licensees' measures in the approval of operational safety programmes. The Reactor Regulation Act requires licensees either to obtain NRA's permit for the modification of an establishment, or to notify such modifications to NRA in cases where such modifications will evidently not affect the conformity to the regulatory requirement. This act requires licensees either to obtain NRA's approval for a construction plan or to notify NRA of such a plan, before starting constructions. In case of notification of plant modification, the licensee should notify NRA of change30 days before the day that the change will be made.

NRA Authorization prior to restart of NPPs which were shutdown following the TEPCO Fukushima Daiichi accident in accordance with new regulatory requirements

After the TEPCO Fukushima Daiichi accident, all Japanese NPPs were shutdown, allowing for definition and implementation of measures to prevent, and should it occur, mitigate a severe accident and to enhance facilities protection against natural hazards. The Reactor Regulation Act was also amended based on the lessons learned from that accident and major new requirements were introduced, for example to:

- Strengthen measures against natural hazards which may lead to common cause failures (e.g. tsunami, earthquake, etc.);
- Strengthening measures to prevent and mitigate severe accidents.

With the goal to restart operation of NPPs, 19 applications have been submitted to NRA since mid-2013 and NRA completed the review of a few of them. Accordingly, 5 reactors (Sendai 1 and 2, Ikata 3, Takahama 3 and 4) were granted amended Establishment Permits and some of them got approval of Construction Plan and Operational Safety Programmes. This situation causes a unique challenge to NRA, both because of the importance of the NRA decision for safety and of the necessity to conduct parallel licensing procedures with numerous applications.

Concerning the on-going reviews of application for compliance with the new regulatory requirements for reactors, many interested parties would appreciate a clearer timeline, so that the date when NRA decision – either positive or negative – will become clearer to everybody.

In relation to the content of the safety analysis report supporting the application to compliance with the new regulatory requirements, the IRRS team noted that extensive information on the feasibility of local actions in severe accident conditions was provided. For example, detailed justifications of the routes to be followed and time needed to perform such actions are included.

5.3. AUTHORIZATION OF RESEARCH REACTORS

Currently no research reactor is operating in Japan, most of them since March 2011. Fourteen of them are under extended shutdown and eight under decommissioning.

The major licensing steps established by the Reactor Regulation Act, are established in Chapter 5.1: Establishment Permit, Approval of Construction Plan, Approval of Operational Safety Programme, and Approval of Decommissioning Plan.

The processes for the different authorizations, including Operational Safety Programmes Modifications, are also described in Chapter 5.1, is similar to NPPs, Chapter 5.2 but based on a graded approach.

The Reactor Regulation Act and the associated NRA ordinances and guides for RRs (NRA Ordinance Concerning the Installation and Operation of Research and Test Reactors, The Standard Review Plan on Approval of Operational Safety Programme of Research and Test Reactors, The Regulatory Guide on the NRA Ordinance on Standards for the Location Structure and Equipment of Research and Test Reactors, etc.) establish the corresponding regulatory safety requirements.

No expiry date is set for a Reactor Establishment Permit. However, the NRA may rescind the permission or order suspension of the operation of research reactor if it does not conform to the NRA Ordinance on Technical Standards for Research Reactors. Licensees are now required to conduct, every 10 years, a "Periodic Safety Assessment", considering the latest scientific and technical knowledge.

Until now the public did not participate in the authorization process. Its participation is under NRA consideration in the case of authorization prior to restart of operation of any research reactor.

With the goal to restart operation of RRs, applications have been submitted to NRA since mid-2014 and NRA is in the process of review them.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

The main fuel cycle facilities in Japan scope enrichment, fuel fabrication and spent fuel reprocessing, with an interim spent fuel storage facility currently under construction. Japan's Reactor Regulation Act and its supporting legislative framework require all such fuel cycle facilities to undergo an authorization process, which ensures that any prospective operator has to request approval from NRA prior to commencing each key stage of a facilities lifecycle. The Articles to the Act clearly set out a staged approach to Authorization of such facilities, which recognizes the unique requirements; initially this requires the "approval of the designation or permit of the activity" to the identified applicant for designated site and facility.

The licensee must obtain the approval of NRA with respect to the design and construction of the fuel cycle facility, and Ordinances state the need to detail the relevant processes, associated structures and equipment involved, justify their performance and the associated major limits of operation, and to also give proper consideration to severe accidents. There is evidence of a graded approach, the content of an application varies according to the type of fuel cycle facility, and each associated Ordinance requires different Articles to be complied with, which determine the scope of the justification required. NRA has not attached conditions to any licences issued for fuel cycle facilities.

With respect to the interim storage facilities for spent fuel, evidence was observed where NRA had issued an authorisation with limited conditions applying a limited number of the articles of the ordinance. This is an example of limited authorisation for the design of storage casks, restricting the scope of the activities that the licensee could undertake until such time that it was able to satisfactorily demonstrate compliance with the remaining articles. At the time of permitting the entire activity, licensees have to demonstrate compliance with the remaining articles.

It was evident that NRA is seeking to ensure that JNFL submits an appropriate justification in support of its application for the reprocessing facilities at Rokkasho, However, the initial submission for this facility based on new regulatory requirements was submitted over 2 years ago and has still to be approved and this is discussed further under review and assessment below. Currently 8 supplementary submissions have been provided by JNFL to satisfy the requirements of NRA. The IRRS team noted that the backfitting approach being adopted by NRA that requires licensees to implement required improvements to existing facilities to satisfy new legislative requirements has yet to be achieved for the 2 reprocessing facilities in Japan.

As highlighted previously, Commissioners of NRA determine whether a fuel cycle facility application should be approved and authorised. The Fuel Cycle Facilities Divisions provides advance information to the Commissioners and actively seek to address any concerns they raise regarding the case for approval, so that authorisations are finally agreed without individual objection. NRA grants a large number of approvals throughout the lifetime of a facility and with the start-up of Rokkasho reprocessing facility, the work load is significant. However, NRA does not have a formal mechanism for recording the applications to maintain an up to date record of a facilities status and not all fuel cycle facilities have been re-authorised by NRA under the new legislation. The absence of a system to record the status of applications and an up-to-date record of the facility is addressed by the Recommendation R6 against the Management System.

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The Reactor Regulation Act and associated cabinet orders, ordinances and guidelines provide the legislative framework for regulation of facilities managing radioactive waste from within the nuclear fuel cycle.

The Radiation Hazards Prevention Act and associated cabinet order, and ordinances provide the legislative framework for regulation of facilities managing radioactive waste from the applications of radioisotopes other than nuclear fuels and nuclear materials.

Under both frameworks prior authorisation is required from the regulatory body (NRA). The prospective applicant is required to make an application to the regulator and such application must be supported by safety documentation providing details prescribed by the regulator.

A graded approach to authorisation is evident, In the case of non-nuclear facilities, the application process is more form based.

- A more detailed process of approval (licence) is granted in the case of facilities authorised under the Reactor Regulation Act. Under the Reactor Regulation Act separate ordinances have been developed addressing activities related to: Interim storage and treatment of radioactive waste;
- Disposal of Category 1 radioactive waste (waste requiring disposal in a geological repository);
- Disposal of Category 2 radioactive waste (waste that may be disposed in near surface trenches or repository other than a geological repository);
- Off-site transport of nuclear fuel materials.

At present the only disposal facilities approved entail near surface burial of low level radioactive waste in trenches or pits. While intermediate depth disposal is envisaged for some category 2 radioactive waste no facilities of this nature have been authorised currently.

The authorisation is granted in a staged manner addressing siting and design, construction (except for category 2 disposal facilities) operation, closure (in the case of category 1 disposal facilities), decommissioning. The approval process requires evaluation and approval by the regulatory body of:

- site-related factors and their impact on safety;
- the applicant's technical capability and financial basis to appropriately carry out the proposed activity;
- facility design specific criteria concerning technical capability and the prevention of radiological disaster;
- operational safety programmes;
- decommissioning plans (prior to start of decommissioning).

It was noted by the IRRS team that the authorisation process entails a number of individual approvals granted to each facility. There was however no clear evidence that the regulator has a formalised system for the tracking of all approval granted (see Recommendation R6).

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

NRA is the Competent Authority for the authorisation of the use of ionising radiation in the form of sealed sources, unsealed sources and radiation generating apparatus with some notable exceptions. In particular, radiopharmaceuticals and radiation generators in medical facilities using energies below 1 MeV such as in diagnostic radiology are authorised by the MHLW, radio pharmaceuticals and radiation generators used in veterinary practices are authorised by MAFF and the transport of radioactive material outside the facility is authorised by the MLIT.

The Radiation Hazards Prevention Act, the Cabinet Order for Enforcement of that Act and the associated NRA Ordinance in combination provide the detailed requirements for a series of notification and authorisation processes. The authorisations are for: Specified Permitted Users, Permitted Users, Permitted Waste Management Operators, Registered Users, Registered Users of Approved Devices with Certification Label and Registered Dealers/Lessors.

Applicants to NRA are required, as part of the application processes, to provide such information as: detailed plans for the facility, the procedures to be used with the sources and the measures to be taken to prevent radiation hazards. NRA has the power to attach conditions to each authorisation but only uses this in exceptional circumstances and typically at the request of the applicant and relies on the detailed requirements in the legislation. While NRA does not routinely issue authorisations in stages, staging is sometimes performed at the request of the applicant particularly in relation to complex facilities. Once an application has been approved by NRA, the applicant is granted with a permit for use. However, applicants that fall into the category of Specified Permitted User or Permitted Waste Management Operator have also to undergo and pass a facility inspection by NRA or by a Registered Inspection Body in order to commence an operation. In practice such inspections are carried out by a Registered Inspection Body and take place after NRA has authorised the facility. The purpose of the inspection is to check that arrangements at the facility are in conformance with the regulatory requirements. The Registered Inspection Body issues a certificate of conformance directly to the authorised entity without conveying the results of the inspection to NRA. NRA receives an inspection report for the facility before the end of the following month.

This an NRA Commission decision that requires NRA to process applications and issue permits within 90 days. All authorisations issued by NRA are open ended (i.e. no expiry date) and applicants incur a once off financial charge. In general the various forms of authorisation reflect the complexity and potential hazard of the use of ionising radiation and constitute a graded approach to authorisation.

Japan implements the Code of Conduct through the establishment of NRA as the Regulatory body and through the detailed requirements set out in the Radiation Hazards Prevention Act. NRA manages an interactive electronic source tracking system that provides for the cradle to grave tracking of sources and has an electronic document management system for the management of authorisations and inspections. The Custom Authorities have installed radiation detection systems at thirteen ports and notify NRA in the event of the discovery of a source. For provisions on orphan source management see Chapter 1.6.

However, NRA does not issue any guidance for applicants and has no documented procedures for the authorisation process and relies only on the detailed requirements encoded in the legislation (see Recommendation R6). With the exception of Permitted Waste Management Operators there are no requirements to make provision for the end of life of the facility, disposal, return of sources to the supplier or associated financial provisions in the authorisation process. While there are many bodies with responsibility for authorisation, there are no practical coordination arrangements in place. While an operator may be authorised by NRA it can only commence operations when it

receives a certificate of compliance from the Registered Inspection Body. In practice NRA's authorisation is essentially a hold point in the authorisation process, as the information gathered by the Registered Inspection Body is pertinent to the safety assessment prior to operation. The IRRS team considers that the information gathered by the Registered Inspection Body needs to be incorporated into the review and assessment by NRA prior to the full authorisation. In addition, there is inadequate regulatory oversight of the Registered Inspection Body by NRA and there is no service level agreement or policy framework in place between the two entities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While an operator may be authorised by NRA, it can only commence operations when it receives a certificate of compliance from the Registered Inspection Body. In practice NRA's authorisation in relation to radiation sources is essentially a hold point in the authorisation process, as the information gathered by the Registered Inspection Body is pertinent to the safety assessment prior to operation. Therefore, relevant safety information gathered prior to the commencement of operations during a facility inspection is not formally reviewed by NRA prior to full authorisation.*	
(1)	**BASIS: GSR Part 1 Requirement 25 states that** *"The regulatory body shall review and assess relevant information……. to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization…"*
R7	**Recommendation: NRA should incorporate the findings of the facility inspection into the review and assessment and the authorization process for radiation sources.**

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

For radiation facilities, the authorised operator is obliged to produce a decommissioning plan that details the decommissioning activities to be undertaken. There is no legal obligation for NRA to approve such plans however NRA is mandated to provide the authorised operator with additional guidance in the event that the regulator is not satisfied with the plan. At the end of the decommissioning activities the operator is required to submit a report to NRA detailing the actions completed. NRA may require the operator to undertake additional actions. There is no evidence that NRA issues a formal closeout releasing the operator from further responsibility.

The IRRS team considers that based on the graded approach the process followed by NRA may be appropriate however a formal response from the regulator confirming the release from further responsibility should be given by NRA for radiation facilities.

In the case of nuclear facilities authorised under the Reactor Regulation Act, the operator is obligated to submit an application for decommissioning to the regulatory body. This application must be supported by a detailed decommissioning plan that must be approved by the regulatory body prior to the start of decommissioning.

The decommissioning application is further supported by a safety assessment for the decommissioning activities.

As part of the self-assessment that was conducted in preparation for the IRRS mission NRA identified that while it has demonstrated close compliance to the IAEA standards, NRA has no requirements related to the development of an initial decommissioning plan early in the life of the plant and submission of such to the regulatory body for review, consistent with the requirements of GSR Part 6 Requirement 10. This has been included in the action plan developed by NRA.

The IRRS team confirmed that for facilities regulated under the Radiation Hazards Prevention Act a set of clearance criteria consistent with the values in GSR Part 3 has been developed. In the case of facilities regulated

under the Reactor Regulation Act a smaller set of clearance values (33 nuclides) has been developed for NPPs. NRA may consider having only a single consolidated list of clearance values that are applied to all facilities.

Furthermore the IRRS team identified that NRA has no clearly defined criteria for the release of sites at the end of decommissioning, consistent with GSR Part 6 requirements 5 and 15. Lack of criteria results in the NRA not being able to complete the process of termination of authorization as mentioned in the NRA self-assessment and Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In the case of non-nuclear facilities authorised under the radiation hazards prevention act the regulator does not provide a formal confirmation to the operator regarding completion of decommissioning and release from further responsibility.* *In its self-assessment, NRA recognized there is no requirement related to the consideration of decommissioning during the design, construction, commissioning and operation of the facility.* *As part of the Self Assessment, NRA identified that it has no clearly defined criteria for the release of sites at the end of decommissioning, consistent with GSR Part 6 requirements 5 and 15. Lack of criteria results in the NRA not being able to complete the process of termination of authorization.*	
(1)	**BASIS: GSR Part 6 Requirement 5, states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met.*
(2)	**BASIS: GSR Part 6 Requirement 5, para 3.3 states that** *"The responsibilities of the regulatory body shall include: ...* *Establishing requirements and criteria for termination of the authorization for decommissioning and especially when facilities and/or sites are released with restrictions on their future use;*
(3)	**BASIS: GSR Part 6 Requirement 15, para 9.2 states that** *The regulatory body shall review the final decommissioning report and shall evaluate the end state to ensure that all regulatory requirements and end state criteria, as specified in the final decommissioning plan and in the authorization for decommissioning, have been met. On the basis of this review and evaluation, the regulatory body shall decide on the termination of the authorization for decommissioning and on the release of the facility and/or the site from regulatory control.*
(4)	**BASIS: GSR Part 6 Requirement 15, states that** *"On the completion of decommissioning actions, the licensee shall demonstrate that the end state criteria as specified in the final decommissioning plan and any additional regulatory requirements have been met. The regulatory body shall verify compliance with the end state criteria and shall decide on termination of the authorization for decommissioning.*
R8	**Recommendation: NRA should establish requirements relating to consideration of**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	decommissioning during all life stages of nuclear and radiation facilities and criteria for the release of sites at the end of decommissioning.

5.8. SUMMARY

The Reactor Regulation Act and the Radiation Hazards Prevention Act provide the legal framework requiring licensees to conduct safety assessment for each authorization stage of regulated facilities and activities, and under which NRA conducts its review and assessment on the licensees' applications before authorization. This legal framework is well developed with consideration of a graded approach. However some improvements are necessary in relation to the regulatory processes to address ageing management at NPPs, decommissioning of nuclear facilities and radiation source facilities.

The authorization process is often followed by an inspection process which, in practice, constitutes a hold point before a facility can be operated. Interface between these processes could sometimes be improved.

Following the TEPCO Fukushima Daiichi accident, NRA developed updated regulations to improve evaluation and protection against extreme natural hazards and to improve prevention and mitigation of severe accident. As a result of the back fitting rule introduced in the updated Rector Regulation Act, licensees are required to have NRA authorization prior to restarting each reactor.

This currently creates a heavy workload for NRA as numerous applications have been filed and most of them are still under processing. Authorization (or interdiction) to operate reactors beyond 40 years will also create in the future a challenge for NRA and attention needs to be paid on interface with the Periodic Safety Assessment of Continuous Improvement.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

Concise and clear in-house principles have been established by NRA with regard to review and assessment. Among NRA five "guiding principles for activities":

- principle "(1) Independent Decision Making" includes the following statement "*We shall make decisions independently, based on the latest scientific and technological information, free from any outside pressure or bias*";
- principle "(3) Open and Transparent Organization" includes the following statements: "*We shall ensure transparency and appropriate information disclosure on regulations, including the decision making process. We shall be open to all opinions and advice from Japan and the international community and avoid both self-isolation and self-righteousness*".

NRA Policy on Ensuring the Operational Transparency of NRA also stipulates that the basic policy of the organization includes "*to adhere to the principle of decision-making based on written documents*". In addition, item "2. Decision-making taking into account the risks" in NRA Statement on nuclear safety culture states that "*Decision shall be made in an independent and objective manner taking due account of the risks. Anyone who makes a decision is responsible for explaining logically the rationale of the decision while clarifying its own roles, responsibilities, and authority*" and item "7. Rigorous and prudent decisions and agile actions" states that "*In response to any challenges to ensuring safety, all the staff shall make conservative decisions for safety taking into account even the worst-case scenario*".

NRA performs reviews and assessments for each of the stages of the lifetime of a nuclear facility.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

To establish the review team/unit to process an application, considering human resources available, NRA management takes into account the experience of staff (e.g., those who have already performed similar reviews or who are familiar with the facilities…).

In conducting a review, if NRA identifies needs for clarifications or additional information, NRA request applicants to provide supplementary information. Interviews (face to face) and meetings are used by NRA to express such needs. Schedule for the review and progress in reviewing may also be discussed during the meetings.

Within NRA, the progress of reviews is reported at executives' meetings, departmental meetings, etc.

In NRA management system, there is no governing procedure for performing review and assessment, such as describing how review teams are set up, how they exchange information, report on progress, or how they document opened or closed points (see Recommendation R6).

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

NRA in-house resources

NRA inherited staff from NISA and, since March 2014, from JNES. JNES staff formed the majority of the NRA Regulatory Standard and Research Department, which is providing expertise, on its request, to NRA Nuclear Regulation Department for review and assessment or inspection. NRA may also recruit mid-career workers from the private sector and who have substantial experience or expertise related to nuclear power, but this is not often the case. Training for new employees and training for acquiring basic knowledge and improving expertise (for example specialized training on probabilistic risk assessment) are largely under development. Moreover, there are no documented expected competences for qualifying as a reviewer (see Recommendation R5). Personnel are gaining

experience by conducting numerous reviews and assessments of safety licensees' evaluations, currently mostly in relation to the implementation at sites of the new safety requirements developed after the TEPCO Fukushima Daiichi accident. With regard to these new safety requirements, one lecture was delivered to reviewers to familiarize them with the changes introduced.

NRA resources are oriented at conducting the review of the numerous applications received to the compliance with the new regulatory requirements. This focus does not enable NRA to update its internal review guidelines or to update existing ones.

In its self-assessment, NRA identified the need for additional competent staff to perform the numerous on-going and upcoming reviews.

Reactor Safety Examination Committee and Nuclear Fuel Safety Examination Committee are currently not involved in licensing review (they may however be involved in the development of regulations or regulatory guidance).

Review of operational experience feedback

In addition to performing inspection on compliance of licenses with their Operational Safety Programmes, which have to address "*related to sharing of technical information on operational safety among licensees when such knowledge is gained by a licensee that conducted maintenance or inspection*", "*matters related to disclosure of information regarding non-compliance*" as well as "*methods for root cause analysis, systems for conducting such analysis*", NRA also performs review of events reported, under criteria established by NRA Ordinance, by licensees. The IRRS team noted that such reported events are not so numerous, as reminded in the table below and NRA underlined that, prior to the shutdown of Fukushima Daiichi accident, more reports were submitted (~30 in a year).

Number of events reported by Japan nuclear facility operators			
April 2012 - March 2013	April 2013 - March 2014	April 2014 - March 2015	April 2015 - to date
9	10	8	5

Operating experience review process is summarized in Chapter 2.2 of this report. The IRRS team questioned NRA on actual output of this process:

- An internal information memorandum that summarizes international events is issued each week;
- For the past 3 years, the event that resulted in an actual change of regulatory requirements is the US Byron 2 event. The event, which occurred in January 2012, lead to a change in regulatory requirement approved in June 2015 and specific information to the on-site inspectors. Another event – the fire at Onagawa 1 following 2011 Tohoku Earthquake – was discussed in the Reactor Safety Examination Committee but this did not result in an advice to change in requirements. The former NISA issued instruction to all NPP licensees for appropriate improvements with a limited scope, and the NRA is now revisiting this issue.
- It was unclear for the IRRS team how lessons learned from other events are incorporated into NRA internal review guidance and inspections programme to ensure Japanese licensee have taken appropriate action. No actual example of modified review or inspection guidelines was presented to the IRRS team. They are however discussed at monthly meeting between JANSI and NRA; they may also be directly discussed between licensees as a result of the provisions of their respective Operational Safety Programmes.

In addition to events which are mandatory to report, the NPP licensees also shares with JANSI and, on a voluntary basis, with NRA "minor" events. NRA finds such information useful for operating experience feedback and discusses it at its meetings with JANSI.

The IRRS team stresses that the restart of some reactors creates now a significant change, compared to the situation for the past 4 years when all reactors were shutdown, with regard to the potential for national operational experience feedback, whether directly identified by the licensees or resulting from NRA inspections or reviews. This will constitute a challenge for NRA as the past years have been primarily devoted to developing new regulatory requirements for the design of nuclear facilities and reviewing design and operational changes to comply with these requirements. The IRRS team believes it would be beneficial for NRA to be fully aware of regulatory and practical provisions implemented by foreign regulators which faced similar situation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NRA is collecting operating experience of national nuclear facilities beyond the reporting requirements defined in the laws and regulations. Few events are reported to NRA on a mandatory basis, by licensees. NRA reviews selected international events and "minor" events provided by licensees on a voluntary basis. Except for one international event, the IRRS team did not get evidence of actual changes (in regulation and regulatory practices) resulting from the lessons learned from events reviewed.*	
(1)	**BASIS: GSR Part 1 para 3.4 states that** *"The regulatory body shall establish and maintain a means for receiving information from other States and from authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience."*
(2)	**BASIS: GSR Part 1 para 3.5 states that** *"To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks. Such measures could comprise promulgating new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities."*
(3)	**BASIS: SSG-12 para. 2.36 states that** *"Throughout the licensing process, the regulatory body should ensure that the licensee has an established feedback system for learning from experience (regarding engineering, human and organizational aspects). Review, assessment and inspections performed by the regulatory body to confirm the existence and the application of such experience feedback should also be considered. …"*
S8	**Suggestion: NRA should consider reviewing its current operating experience feedback process to:** • **determine whether its criteria allow the reporting of enough safety significant events;** • **ensure lessons learned from these events, including return to service from extended shutdowns, are taken into account by the licensees and actually result in appropriate and timely measures at the facilities.**

Calculation capabilities

NRA operates its own computer codes that enable NRA to carry out independent calculation, for example related to NPP transient analysis.

Licensees' organizational changes

The Commercial Reactors Ordinance contains requirements for quality assurance, education on operational safety, but does not specify any requirements regarding licensees' organizational changes although changes to a licensees' organizational structure may have an impact on safety. The Operational Safety Programme does not address in details the structure of licensees' organization and how changes will be managed.

The IRRS team noted that NRA did not conduct reviews of the licensees' process for managing their organizational changes and there is no specific procedure/guide describing how NRA is assessing licensees' organizational changes (see Recommendation R6), while the commercial reactor ordinance (Article 92-1-4) requires licensees to include the organizational structure in there operational safety programme.

In Chapter 3.3 it is suggested that NRA should consider recruiting people who have competencies in the areas of human and organizational factors and management system. The above-mentioned finding supports the view of the IRRS team that human factor related aspects are not widely recognized in NRA's oversight functions. The process of change should be defined and they should be identified, classified and controlled according to their significance for safety.

Technical support organizations (TSO)

NRA can seek technical assistance from both JAEA and NIRS. But, for the licensing of NPP, NRA does not use any external TSO.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The regulatory regime in Japan is prescriptive in nature, considering the level of detail of the legislation, Cabinet Order, NRA Ordinance and NRA regulatory guidance document.

For example, for nuclear power plants, detailed regulatory requirements on commercial power reactors are stipulated in the Reactor Establishment Permit Ordinance which is used in licensing for Establishment Permit, and the Technical Standards Ordinance which is used in the approval of Construction Plans. These requirements set the basis for review and assessment of licensees' applications.

Reactor Establishment Permit review goals

NRA Ordinance on Standards for the Location, etc. establishes the review criteria relating to Reactor Installation Permits; it also presents design requirements in regard to external events. Other key aspects to be reviewed include technical capability and financial basis of the applicant, technical capability for taking measures to prevent occurrence and progression of a severe accident, limited purpose for peaceful use, other technical capability for operating safely the reactors, compliance of location, structure and equipment with relevant NRA Ordinances.

The adequacy of the basic design of a nuclear power plants is now reviewed for anticipated operational occurrence, design basis accidents, accidents that may lead to severe accidents or severe accidents, both in reactor and in spent fuel pool.

Construction plan review goals, operational safety programme review goals

NRA review goals are to determine whether the construction plan and the operational safety programmes are both:

- complying, in their content, with the regulatory requirements and consistent with NRA guidance;
- consistent with the submission justifying the Establishment Permit.

Periodic safety assessment of continuous improvement review goals

NRA needs to evaluate whether the licensee's methods of investigation, analysis, and comprehensive evaluation comply with the one specified in the regulations and consistent with NRA guidance. According to NRA understanding of the law, this is not to be considered as a "review" per say.

Operation beyond 40 years of operation

NRA review is to assess whether the plant equipment current status, the foreseen status of equipment status at the end of the extension period as a result of ageing and the maintenance policy are adequate to ensure safety.

Internal guidance for review and assessment

The principal purpose of this systematic plan is to assure the quality and uniformity of staff safety reviews and is also to make information about regulatory matters widely available so to improve communication with stakeholders and increasing understanding of the regulator's review process.

Licensing step	NRA review guidance
Reactor Establishment Permit	There are standard review plans (SRP) and other public guidelines for the review of applications. SRP for PWR has been recently updated (November 2015) as part of the process to review application for compliance with new regulatory requirements (amendment of Establishment Permit). As applications prior to restarting BWR were submitted recently, the development of an updated BWR SRP is ongoing. NRA staff stresses that, regulatory requirements more than often technology neutral and that the PWR SRP is already a good basis. Some guides have been published mid-2013 (Guideline for Evaluation of Effectiveness of Measures to Prevent Core Damage Containment Vessel Function Failure of Commercial Power Reactors, Guideline for Evaluation of Effectiveness for Measures to Prevent Fuel Damage in Spent Fuel Storage Pool of Commercial Power Reactors, Guideline for Evaluation of Effectiveness of Measures to Prevent Fuel Damage of Commercial Power Reactors during Shutdown), but most guides regarding design basis accidents are quite old and sometimes of high level (Review Guide for reviewing safety assessment of Light Water Nuclear Power Reactor Facilities (1990)). NRA has acknowledged the need to enhance review guidance in its self-assessment and initiated an action plan to further enhance its review guidelines.
Construction plan	The Commercial Reactor Technical Standard Guide (June 2013) gives interpretation of the corresponding NRA Ordinance and is used for the review. It consist of a table, the left column being the article of the ordinance, the right column its interpretation.
Approval of Operational safety programme	NRA has developed a Standard Review Plan on Commercial Reactors Operational Safety Programme Standards. On several item, the review aims at checking if an appropriate explicit commitment has been made by the licensee or whether a policy or plan has been developed. For some topics related to the NPPs licensing, such as quality assurance or maintenance, complying with a Japanese industrial standard (e.g. standard JEAC 4111-2009 for quality assurance or JEAC4209-2007 for maintenance and inspections for NPPs) is an acceptable means to comply with regulatory requirements.
Report on periodic safety assessment of continuous improvement	No "review" guide is currently available within NRA. Some NRA staff recognized that having such internal guidance would be useful, including to help documenting, if any, the "review".
Approval of operation beyond	There are two guides related to the application for operation beyond 40 years.

40 years of operation	The first one is presenting NRA criteria for decision making. The second is addressing licensee's submission, especially the presentation of the results of the "special inspection", which has to be completed before applying for authorization. With regard to the evaluation of ageing related degradation, the scope is identical to the one set in NRA guidance for Operational Safety Programme for operation beyond 30 years.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Review is conducted through licensee's document review, interview between NRA staff and licensee, as well as "open meeting" between NRA and licensee:

- "Open meetings" are meetings chaired by NRA commissioners where NRA staff addresses the outstanding points and, when needed, requests the licensee to provide additional information or amend its initial submission. These meetings are open to public, they are also broadcasted on NRA website;
- Interviews are the routine mode of questions and answers. They occur nearly every day. Prior to closing the interview, a wrap-up where questions raised, answers or documents provided are confirmed. The meeting agenda and summary report, primarily based on the wrap-up outcome, are available on NRA website.

It is not NRA usual practice to send E-mail or formal letter to the licensee to raise questions or to identify shortcomings in the licensee submission. As a result of interviews and open meetings, the licensee will update its submission.

In addition, when NRA makes significant regulatory decisions such as the permission for amended establishment permit in accordance with new regulatory requirements NRA may participate in the briefing session to the local communities near the nuclear power and explains its regulatory decisions in details, based on the request from local governments.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

Concerning the review related to the key licensing steps, the IRRS team noted the following:

Establishment Permit	In reviewing Reactor Establishment Permits, the siting conditions and design of facilities are evaluated to confirm that the risk of radiological consequences for the public or the environment as a result of radioactive releases is 'acceptably' low.
Approval of construction plan and pre-service inspection	Inspection at sites are performed by headquarter staff who are cognizant of the construction plan review.
Approval of operational safety programmes	Operational safety programmes are reviewed based on the permitted establishment permit, including the limits and conditions of the operations.
Periodic safety assessment of continuous improvement	No "review" has been yet performed. Even if the periodic safety assessment of continuous improvement may result in an updated SAR, the licensee is not required to submit it to NRA unless the assessment identifies a need to amend the establishment permit. In NRA guidelines such amendment is currently found

	necessary if the periodic safety assessment identifies more severe conditions (e.g. natural hazards).
Approval of operation beyond 40 years	The review evaluates ageing management provisions as well as the long term maintenance policy of the licensee

NRA has developed guidance on the content of applicant's submission and on their review by NRA. However, not all licensing processes benefit from such guidance and the level of detail of guidance may allow wide interpretation. There is for example no guidance for the "review" of reports on Periodic Safety Assessment of Continuous Improvement. Furthermore, some existing guidance does have to be updated, for example to fully capture the consequences of recent IAEA Safety Standards. NRA review guidelines ("Standard Review Plan") do not give detail procedures to be followed in the review and assessment process and may not be considered as a systematic plan to provide assurance that all the topics significant to safety will be covered.

In its self-assessment, NRA recognized that NRA resources were oriented at conducting the review of the numerous applications received considering, the new regulatory requirements, not at developing or updating its internal review guidelines or to update existing ones the standard review plan and guides for the authorization for commercial nuclear power plants should be enhanced (see Recommendation R11).

Reviews currently performed to assess compliance of reactors with new regulatory requirements

Currently, in NRA Nuclear Regulation Department, staff is mainly reviewing application for compliance with new regulatory requirements. To process these applications, NRA established 2 teams to review earthquake and tsunamis aspects and 4 teams (3 teams for PWR and 1 team for BWR) to review the other aspects. About 100 persons are involved, with support from an additional 100 specialized staff from NRA Regulatory Standard and Research Department (mostly former JNES staff). They review the amendments to the Establishment Permit, the Construction Plan and the Operational Safety Programmes. This allows integration of the reviews performed by headquarters, the pre-service inspection remaining a separate action.

Each team has a team leader: half of them are senior reviewers. For the PWR and BWR teams, which comprises 15-20 people, staff is working within 4 sub-teams ({design basis, fire, flooding}, {severe accident, accident analysis}, {structures}, {quality management system, operating procedures}). Sub-team leads are senior reviewers; they participate in interviews with licensees. Team leaders are made aware of the key points discussed during interviews with licensee. To circulate information, in each team, a short team meeting takes place every day. However, exchange of information across teams is not as much developed and relies largely on upper management; NRA recognizes increased communication between teams would be beneficial.

Reviewers from NRA headquarter do occasionally come to sites and participate in inspection activities. In relation to the restart of NPP, their on-site observations are largely oriented at confirming information collected in licensee submission or during interviews/open-meeting and having a better understanding of the actual means installed/available as a result of the new safety requirements. For Takahama Unit 3/4 restart, the first operational safety inspection, with account taken of the new safety requirements, took place during 3 weeks in October 2015. In the team of thirty of so inspectors, several reviewers were incorporated.

More frequent site visit might be beneficial for improved understanding of licensee's provisions and concerns, if any, as well as further common (i.e. license and NRA) understanding of safety significance of a particular situation.

Progress on review is reported every two months to NRA Commissioners, in addition to information they would get during "open meeting". The review itself is documented in two separate documents:

- One, mostly for NRA staff internal use, is the standard review plan (the left column list the applicable regulatory requirements; the right column the conclusion of NRA staff on compliance) ;
- One, a summary assessment report, endorsed by NRA Commissioners. The one related to the amendment of Sendai 1/2 Establishment permit is about 400 pages long.

Both documents, which present conclusions on conformity with regulatory requirements, thus the basis for issuing the authorization, are made available on NRA website.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The process of review and assessment by NRA for research reactors is similar to the ones for nuclear power plants and fuel cycle facilities.

To apply for the Establishment Permit of a research reactor, the applicant shall submit documents similar to those for the safety analysis report (SAR), which are stated in IAEA NS-R-4 with an exception. According to NS-R-4 requirement 3.6, a SAR shall give a detailed description of the reactor site, the reactor, experimental devices, a safety case and all other facilities and activities with safety significance. The exception mentioned is that information on decommissioning is not given. A corrective action for this issue is proposed by NRA in the Action Plan. The licensee is not required to submit an update of the SAR except in the case of an application for modification of establishment permit. However, when they are updated without a modification of establishment permit, during the process of periodic safety review, the NRA will verify the updating process through the NRA's operational safety inspections. There is no formal process to review these updated documents by NRA.

Others related review and assessment activities are:

- According to the Ordinance on Standards for the Location, Structure and Equipment of Nuclear Research and Test Reactors, the research reactor shall be so designed that their safety functions will not be impaired by earthquake, tsunami and other important natural phenomena (i.e. tornadoes).
- Structures, systems and components (SSCs) bearing safety functions are classified into two categories "prevention system" and "mitigation system". SSCs are further classified into Class 1, Class 2, and Class 3 according to their safety functions and include "monitoring systems" for accident conditions. No explicitly mention is given to "software" safety classification, but software is not used for most of the RRs' protection system.

According to the Research Reactors Ordinance, a licensee shall perform a periodic safety review (PSR) every 10 years. The corresponding PSRs have been carried out by the licensee for all available reactors systematically without a guideline for their content. In the Action Plan NRA proposed to prepare a guide for the PSR content. Furthermore, the licensee shall perform technical review on aging before 30 years has elapsed from the start of operation, and then preparing implementation plans against aging with a periodicity, at least every 10 years.

NRA coordinates the examination of submissions of the applicant documents and there are meetings between specialist of both NRA and licensee to discuss in detail the information given in the documents. The NRA observations are communicated in a summary report at the end of each meeting.

There are no requirement related to the consideration of decommissioning of the research reactor facilities during the design, construction, commissioning and operation of the facility. A corrective action to this issue is proposed by NRA in the Action Plan.

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The process of review and assessment (examination) of fuel cycle facility submissions by NRA is similar to that for nuclear power plants, where either an open or closed review is completed. The route is decided by the Committee

based upon the facility application, but each culminates in NRA considering the submission for approval, once NRA's Fuel Cycle Facility Division has completed its examination and produced an assessment pack. There is discretion within NRA guidelines for the management and administration of documentation for the approval to be given at different levels, dependent on the content and safety significance.

The Fuel Cycle Facilities Division of NRA coordinates the examination of submissions and the key interactions with the licensee are in the form of meetings where technical specialists discuss the application in detail, at the end of each meeting a summary record is produced that is used to communicate NRA's position to the licensee. The status of this summary, and its effectiveness and suitability as a definitive record of the regulators position was unclear to the IRRS team. The effectiveness of the current arrangements needs to be reviewed and the need for a formal method to notify licensees so they are clear on the regulatory expectations and opened issues related to the examination of their application and subsequent authorization but the current approach to openness by NRA should continue. This is discussed further in Chapter 3.

For fuel cycle facilities, the examination scopes the full application and considers matters important to safety including cooling, criticality, and containment, as well as the organizational structure of the operator and named appointments in key roles, including the key safety role of the Chief Engineer. NRA guides define the range of hazards that need to be considered by the licensee's submissions for fuel cycle facilities and examined by the regulator. The IRRS team confirmed that the new requirements of fuel cycle facilities reflect the unique nature of these types of facilities. NRA's review for compliance with the new regulatory requirements for the fuel cycle facilities is ongoing and there is a significant amount of work to be completed by NRA before compliance with the new regulatory requirements can be authorized.

During the mission it was evident that NRA regularly requests the licensee to submit supplementary information in support of its application to allow NRA to complete its examination. The IRRS team sought assurances regarding the degree of analysis undertaken by applicants and during NRA's examination regarding human factors safety analysis, and the approach to safety culture within the operator. Although, there are basic requirements within the regulatory framework for the need to consider human factors, the IRRS team was unable to confirm that a systematic approach is applied as part of the application process, or by NRA, to understand the factors that affect human performance, and minimise the potential for human errors to contribute to or escalate faults. This observation potentially extends to other nuclear facilities, although this was not specifically investigated by the IRRS team.

A systematic approach is needed to identify human actions that can impact safety for all operating modes and all fault and accident conditions identified in the safety case, including severe accidents. A proportionate analysis should be carried out of tasks important to safety and used to justify the effective delivery of the safety functions to which they contribute. The analysis should evaluate the demands these tasks place upon personnel in terms of perception, decision making and action. It should also take into account the physical and psychological factors that could impact on human performance.

The analysis should be sufficiently detailed to provide a basis for developing user interfaces, procedures and job aids, as well as helping define operator roles and responsibilities, staffing levels, personnel competence and training needs, communication networks and work-space design. The workload of personnel required to undertake these actions and controls should be analyzed and demonstrated to be reasonably achievable.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A systematic approach was not evident as part of the application process, or by NRA, to understand the factors that affect human performance, and minimise the potential for human errors to contribute to or escalate faults.*	
(1)	**BASIS: GSR Part 1 Requirement 32, states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles requirements and associated criteria for safety upon which its regulatory judgements, decisions, and actions are based."*
(2)	**BASIS: GSR Part 4 Requirement 11, states that** *"The Human interactions with the facility or activity shall be addressed in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required in response to anticipated operational occurrences and accidents, ensure an adequate level of safety."*
S9	**Suggestion: NRA should consider reviewing the regulatory requirements for all nuclear facilities to ensure that submissions by licensees give full systematic consideration to human and organizational factors and human errors in the design of the plant, and the sufficiency of qualified and experienced NRA resource to assess this.**

The nature of the geology in Japan means that it is essential that NRA is able consider the adverse impact that natural hazards would have on siting of the facility and under the Reactor Regulation Act it can refuse the location of the facility if its examination of the early submission by the applicant or licensee on seismic, tsunami and volcanic inputs indicate that it is unsuitable, but no evidence of this being implemented was observed.

As part of the backfit approach JNFL, the licensee for the reprocessing facilities at Rokkasho, completed a severe accident analysis in accordance with the new legislative requirements. NRA's examination considered that the initial submissions made 2 years ago by JNFL were deficient. Revised submissions have been provided, necessary due to the initial lack of clarity in setting out regulatory expectations. NRA is currently undertaking its examination of the severe accident analyses submissions for the reprocessing facilities, which will have to be completed satisfactorily before the plants will be allowed to commence operations. JAEA, the licensee for Tokai, is still developing its application for compliance with the new regulatory requirements.

For fuel cycle facilities, the licensee is required by the Reactor Regulation Act to regularly undertake a comprehensive evaluation of the safety of said fuel cycle facilities. A regulatory Guide provides details of the Periodic Safety Assessment of Continuous Improvement and sets out the requirements for licensees to install equipment or apparatus contributing to the improvement of the safety of their facilities, enhancing education on operational safety, taking any other necessary measures for preventing accidents; taking into account the latest knowledge on safety. As part of its assessment, licensees have to investigate and evaluate the implementation and validity of their efforts for fulfilling these responsibilities, to ensure they focus effort on continuously improving the safety of their facilities. The assessment is required to be completed within 6-months of the Periodic Facility Inspection, which is undertaken annually; hence a comprehensive evaluation is required every year. In addition, there is a legal requirement that the effects of ageing be assessed and by the licensee 20-years after operations first commence, which is to be repeated at an interval of no greater than 10 years, and a plan developed from the analysis to implement appropriate maintenance.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The process for review and assessment of waste management facilities authorised under the Reactor regulation act is similar to that for nuclear power plants and fuel cycle facilities, but a graded approach is adopted with the level

of detail being commensurate with the hazard posed. The content of the safety documentation to be submitted is detailed in the ordinances specific to the type of facility in question. The applicable ordinances and guides detail the various safety evaluations that are required and these include as appropriate evaluation of containment structures, shielding, heat removal, fire and explosion, seismicity, tsunami, safety significant instrumentation, operational procedures. Included in the safety documentation is an operational safety assessment detailing the general operating rules and procedures and limiting conditions of operation.

The reviews of an initial application include review of the applicant's business plan and means to secure appropriate funding for the planned activity. The professional history of the main engineers is also evaluated by NRA. Approval is based on compliance to the criteria specified in the applicable ordnances and demonstration that the applicant has sufficient technical capability and financial means to conduct the proposed activities.

All authorized facilities are obliged to undertake a periodic safety review. The frequency of these reviews is ten years. Furthermore waste interim storage facilities are required to undertake an aging management review prior to twenty years of operation

Aging management review and severe accident evaluation is not required for the current near surface disposal facilities based on the low hazard posed.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

When an application for an authorization is submitted to NRA, the application is assigned to an officer to conduct the review and assessment. The officer checks that all of the documentation required in the legislation has been submitted and will request additional information if necessary and hold a meeting with the applicant where appropriate. Once the officer has completed the review and assessment of the application, a recommendation to grant or refuse an authorization is made to the Director of the Radiation Regulation Office and Safeguards Division or to the Director General of the Radiation Protection Department or the Director General of the Secretariat for more complex applications. The relevant director makes the final decision on the authorization. NRA Commission is then informed of such authorizations typically on a quarterly basis. The IRRS team was informed that additional review and assessment of facilities is only performed as part of an application by an operator to modify an existing authorization. NRA also considers review and assessment to be incorporated into the inspections that are carried out by NRA and the Registered Inspection Body. IRRS team was informed that an officer has a responsibility for periodically collating findings from inspections, categorizing them and sharing them within NRA.

NRA has not established criteria for the conduct of review and assessment beyond those provided in the regulations and relies exclusively on an examination of the documents supplied against the legislative requirements. NRA does not have any documented procedures for review and assessment (see Recommendation R4 and Suggestion S6).

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

NRA has developed guidance and ordinances specifying the content of detailed decommissioning plans and the submitted plan are reviewed against these criteria.

NRA currently does not have requirements relating to the consideration of decommissioning during design and construction of nuclear facilities. NRA did recognize this in its self-assessment and identify an action to address this shortcoming (see Recommendation R8).

In the case of radiation facilities NRA does undertake a review of decommissioning plans submitted but has no obligation approve such plans. However when NRA identifies deficiencies in the plans they are communicated to the licensee (see Recommendation R8).

6.8. SUMMARY

Review and assessment is directly related to verifying criteria established in the acts, regulations and guides. To cope with the numerous documents, NRA develops internal guidance to help perform and document the review, even if some areas would benefit from additional guidance (see Chapter 9). However, NRA faces the challenge of updating these documents to keep them consistent, both with national requirements and with IAEA Safety Standards. The current standard review plan and guides for the review of application for authorization of nuclear power plants are, with a few exception, quite old and they should be updated or further enhanced to fully take into account IAEA safety standards and new Japanese safety requirements (see Chapter 9). As reviews are currently underway for compliance with new regulatory requirements, the experience gained in this review will likely provide insight for these updates.

During its review process for nuclear facilities, NRA allows a high level of transparency by having meeting with licensees open to the public or by having meeting agenda and summary report available on NRA website. NRA also publishes the result of its reviews for these authorizations such as an evaluation report that document the basis for NRA's decision.

NRA should better interfacing review and assessment with inspections, as both processes are often imbricated to actually allow a facility (nuclear facility or radiation source facility) to operate.

For nuclear facilities, NRA faces the following challenges of:

- shifting from current design reviews, in relation to the implementation of the new safety requirements published after the TEPCO Fukushima Daiichi accident, to the reviews of matters related to the safety of a facility being again operating (if the design reviews conclude that new requirements have been adequately complied with);
- enhancing its operating experience feedback process and better addressing human and organizational factors.

7. INSPECTION

7.1. GENERIC ISSUES

The Reactor Regulation Act and the Radiation Hazards Prevention Act provide the legal framework for various types of regulatory inspections, (e.g. pre-service, welding, fuel assembly, periodic facility, operational safety, and on-site inspections for nuclear facilities as well as inspections for radiation sources and facilities), and under which these inspections are structured to confirm the compliance of facilities and activities to the relevant requirements.

7.1.1. INSPECTION PROGRAMME

The frequency, scope and content of most types of inspections are prescribed in detail by laws and subordinate legally binding Ordinances allowing little freedom to the NRA to revise the inspection programme to incorporate risk information or performance issues.

NRA performs several types of inspections:

Periodic safety management review: The licence holders have legal obligations to periodically check their safety related performance, which is in their terminology called *"licensee's inspections"*. The regulatory body has to check how licensees have performed their own inspections in the process called "*periodic safety management review"*. These inspections are performed by inspectors from the Head office.

Periodic facility inspections are performed by NRA inspectors to check the facility during outages. The license holders are legally obliged to formally apply for the NRA to perform such inspection and NRA cannot perform such inspection without the application. The IRRS team considers that the legal requirement for NRA to perform inspection only after the license holder applies for it is highly unusual. Facility inspections are performed by NRA staff coming from the Head Office.

Facility inspections for nuclear power plants last on average 3 months, but could be longer as in the case with the latest inspection of the recently restarted Sendai 1 unit.

Operational safety inspections are performed by NRA four times per year. Each of these operational safety inspection campaigns basically last for two weeks and has a strictly prescribed scope and content. Such inspections are performed also during certain predefined activities in the plant such as fuel loading. For these kinds of inspections NRA prepares plans in advance taking into account experiences from previous inspections and other information indicating areas where to focus the inspection.

Operational safety inspections are performed by resident inspectors from regional offices. In these regional offices, which are next to each nuclear site, typically there is one chief resident inspector, one resident inspector per unit on site and one severe accident advisor.

Specialized types of inspections like welding inspections or fuel assembly inspections are also performed by NRA. For example, the extent of welding inspections is determined by the type of facility and the details of the analysis provided by the licensee in its application. It is NRA's technical specialists who define the final details of the welding inspections and the type of testing to be done. The IRRS team considers that while this provides confidence in the integrity of system welds important to safety, it appears to place the burden and responsibility for confirming weld integrity on the regulatory body and not the licensee.

The IRRS team is concerned that such strongly specialized and prescribed inspections might diminish the prime responsibility of the licensee for safety, although the IRRS team was informed that this is not the case as NRA is mainly just witnessing what the licensee is doing during such inspections.

NRA does not perform joint inspections with other authorities, does not coordinate inspection plans nor exchange inspection findings with them. NRA inspectors are never accompanied by representatives of other organisations, but sometimes visit sites accompanied with staff members from other departments of NRA.

NRA does not have consolidated annual baseline inspection programme containing all types of inspections performed by NRA. The number, type and duration of inspections undertaken by NRA are significant however there does not appear to be an integrated approach to the planning and management of inspections. An integrated plan is necessary to support effective and efficient conduct of the inspection process and to allow for the relevant information to be shared among NRA staff at the Head Office and at regional offices.

In theory NRA inspectors can perform unannounced inspections, but in practice such inspections are not done.

Possibilities for inspectors to enter and inspect sites at any time are limited to the periods of above mentioned legally prescribed inspections. To avoid potential problems with the site access the NRA has entered agreements to facilitate the inspectors' free access to sites. During such visits, that are undertaken almost daily, resident inspectors do not perform inspections, but rather what is referred to as 'assessments'. The assessments are not legally prescribed and can be considered a type of informal oversight of the day to day operations on the plant. The inspectors may propose to their superiors the legally binding reactive on-site inspections to be carried out, if they discover issues that would justify inspection and enforcement measures during the assessment. Such reactive inspections then have to be authorized by the commission or the Director General of Nuclear Regulation Department in the case of deviation from the LCO, which the IRRS team finds to be an unusual practice.

The IRRS team noted that any findings from the assessment have first to trigger approval by Commission or senior management in NRA in order to perform a reactive inspection to deal with the issues arising and only after that can corrective actions be imposed on the licensee. IRRS team considers that this process should be revised to be more efficient and effective.

Legal framework for performing inspections

The unnecessary complexity of the legal framework with respect to inspections was also recognized during the IRRS mission to Japan in 2007. However, the IRRS team noted that the approach remains essentially the same 9 years later. During the preparations for the IRRS mission the NRA also recognized the unnecessary complexity of the legal framework for performing inspections and has already foreshadowed improvements towards simplification. Such improvements will require changes in the laws, which will likely take considerable time. The NRA' intention is to prescribe in law what kind of inspections the operator is obliged to do in order to verify compliance with safety requirements and to empower the regulatory body to develop the details of the inspection process for verification of compliance. At the time of the mission plans were still in the conceptual stage and drafting of new legislation had not started yet. It was explained to the IRRS team that a draft law will first be discussed with stakeholders and the public and then submitted to the governmental legal office. Only after that will the draft be sent for adoption by the parliament.

The IRRS team considers that the above intentions are needed and reasonable, and that simplification of the legal framework would contribute to the greater efficiency and effectiveness of the inspection processes. The law should provide general requirements for the licensees to define operating limits and conditions together with requirements to verify their conformance by suitable processes, which include review, assessment, surveillance, inspections or any other means for monitoring that the operations conform to operating limits and conditions. The objective of NRA inspections would then be to monitor (assess, inspect, oversee, review …) that those limits and conditions are fulfilled and that the licensee is performing their part of verification. Enough freedom should be left to NRA to decide, based on graded approach, what type of inspection activities would be best suited to the needs.

NRA has recently developed and started a programme for monitoring safety culture within licensed facilities. The understanding what safety culture is and what safety culture is meant to achieve is increasing among both regulatory staff and regulated entities. This is an area where the regulator and licensees can work together. However, embedded safety culture requires a profound change in attitudes and the concept of 'safety culture' does not translate easily into the Japanese language which in itself may be an obstacle to its implementation.

The NRA assesses licensee safety culture primarily through Operational Safety Inspections. Licensees are required to develop and periodically adjust a plan to foster a healthy safety culture. The licensee does this by performing a self-assessment of the previous period and factoring the performance into the plan for the next period. The NRA onsite inspectors are trained and guidance is provided on 14 specific traits of a healthy safety culture. The inspectors, as part of the Operational Safety Assessments, record their determinations against these traits during their in-plant walkdowns and observations of the daily corrective action programme meetings. One example of a trait is "questioning attitude". The inspectors' determinations or judgments against the traits are recorded and subsequently utilized to make recommendations regarding the licensee's plan to address safety culture.

The records of inspections are retained by NRA and the period of retention varies between 5 and 30 years depending on the type of the record. The records of the facility assessment by regional inspectors are retained for 6-months. It is possible that some of the inspection records being disposed of, particularly those destroyed after 5 years, would be of benefit beyond the five year limit particularly when considering plant modifications, safety case revisions or decommissioning proposals.

The records of inspections are stored in paper form in a central storage in Tokyo. No electronic data base system for archiving and retrieval of data exists with the exception of such system with data about radiation sources. Similarly is for operational safety inspections only that those records are since few years ago published on internet and thereby electronically saved and available also in the future.

The IRRS team noted that inspections of different types of facilities are performed by other divisions of NRA following different procedures though based on the same set of laws. There seems to be no coordination between divisions for these inspections.

7.2. INSPECTORS

New inspectors usually spend up to two years working under the close supervision of the senior inspector on the site. After that they receive 8 days training if they are to become resident inspectors performing operating safety inspections or 5 days if they are to become facility inspectors. On a voluntary basis they can undergo additional specialisation training that includes one week of simulator training. There is no regular retraining programme in place for inspectors.

NRA inspectors have in place an extensive set of procedures and guidance on how to perform inspections. (In the context of this report, "inspection" also includes those inspector observation activities currently performed under NRA "assessment" processes). The IRRS team noted that most of them are in the form of check lists leaving little freedom to inspectors for personal assessments or judgements. This might be the reason why NRA in the past did not feel a need to extend amount of initial training for inspectors. The IRRS team's observations in the field also indicated that inspectors are sharply focused on the specific activities being checked. For example, the IRRS team witnessed how inspectors in the control room of the NPP were just checking status of certain indicators on the control panel as it was prescribed in their checklist while paying no attention to numerous alarms and activities by operators that were going on at the same time in the control room. NRA is aware that a major change of inspection system would require improvements also in capacity and capability for performing credible inspections. The new inspection framework would require a new approach where the current checklist-type of inspections needs to be changed to an approach that is flexible and more analytical in order to achieve a holistic understanding of safety

issues. This change in approach is not only in the hands of NRA but also requires legislative changes. It is important to drive this change (and it is being done) but the outlook would have to be several years to reach the next level. Necessary legislative changes will take time.

There are currently about 180 inspectors for nuclear safety at the NRA. Inspections of different types of facilities are performed by different divisions of the regulatory body following different procedures although based on the same set of laws. There seems to be no coordination between divisions about that (see Recommendation R4).

NRA does not coordinate nor exchange information about inspections with other regulatory bodies performing inspections at licensed facilities in areas that are influencing the nuclear or radiation safety like radiation protection or fire protection. The NRA out sources certain inspection activities to Registered Inspection Bodies but does not exercise sufficient regulatory oversight to ensure the quality of their work and confidence in their assessments.

NRA archives inspection records only in paper form. There is no electronic data management system in place that would allow quick and efficient data sharing and retrieval. The retention period of inspection records is relatively short. The NRA only partially documents its inspection process in the area of radiation sources (see Recommendation R6).

The IRRS team has observed examples of inspections that were inefficient and repetitive. For example inspection of low level waste rubbles at Fukushima Daiichi site were performed by measuring radiation levels on all containers instead of just a sample of them. Additionally, the same rubbles were already previously inspected by the licensee.

The IRRS team was informed that the periodic facility inspections of nuclear facilities lasts in average 3 months, but could be extended up to 4 months. The IRRS team considers that this is unusually long period and that there is space for improvement in terms of efficiency and effectiveness (see Recommendation R4).

<table>
<tr><th colspan="2">RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</th></tr>
<tr><td colspan="2">Observation: There are several types of inspections taking place in Japanese nuclear facilities and activities. For most of them the frequency and content are prescribed in detail either by law or by subordinate, legally binding ordinances. There is little possibility for the NRA inspector to initiate unplanned or unannounced inspections. There is also limited possibility to perform targeted reactive inspections and thereby quickly react to emerging and developing situations.
There is duplication of inspection effort between NRA and Licensee. NRA, for example of fuel cycle facilities, currently undertakes inspection of all primary welding of nuclear facilities, whilst also confirming the qualification of welders undertaking the welding. This situation might jeopardise the primary safety responsibility of the licensee.
Inspectors have free access to facilities at any time during specific periods of the inspections prescribed in the law. For periods other than those access is granted only based on the agreement with licensees. There are no legal provisions assuring such access. NRA does not perform unplanned and unannounced inspections.
NRA makes inspections to verify the qualification, training and retraining of the nominated personnel, but do not cover processes used by the licensee to ensure the personnel conducting safety related functions are fit for duty.</td></tr>
<tr><td>(1)</td><td>BASIS: GSR Part 1 Requirement 2 paragraph 2.5 states “The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:
…
(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;
…”</td></tr>
<tr><td>(2)</td><td>BASIS: GSR Part 1 Requirement 27 states that “The regulatory body shall carry out inspections</td></tr>
</table>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."
(3)	**BASIS: GSR Part 1 Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
(4)	**BASIS: GSR Part 1 Requirement 29 Paragraph 4.50 States that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(5)	**BASIS: GSR Part 1 Requirement 29, para. 4.52 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach."*
(6)	**BASIS: GSR Part 1 Requirement 29 Paragraph 4.53 States** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* – *Structures, systems, components and materials important to safety;* – *Management systems;* – *Operational activities and procedures;* – *Records of operational activities and results of monitoring;* – *Liaison with contractors and other service providers;* – *Competence of staff;* – *Safety culture;* – *Liaison with the relevant organization for joint inspections, where necessary."*
(7)	**BASIS: GSR Part 3 Requirement 2 paragraph 2.14 states** *"The government shall ensure that adequate arrangements are in place for the protection of people and the environment, both now and in the future, against harmful effects of ionizing radiation, without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks. This shall include arrangements for the protection of people of present and future generations and populations remote from present facilities and activities."*
R9	**Recommendation: The government should improve and simplify the inspection framework to:** • **Increase NRA flexibility to provide for efficient, performance based, less prescriptive and risk informed regulation of nuclear and radiation safety;** • **Ensure NRA inspectors have formal rights for free access to all facilities and activities at any time;** • **Allow NRA decisions about reactive inspections to be made at the lowest possible level.** **Based on the revised inspection framework the NRA should develop and implement a programme of inspection of all facilities and activities specifying types and frequency of regulatory inspections (including scheduled inspections and unannounced inspections) in accordance with a graded approach.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The initial training provided to NRA inspectors is very limited in time. There is no retraining programme in place.*	
(1)	**BASIS: GSR Part 1 Requirement 18 Paragraph 4.13 states** *4.13. A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements".*
S10	**Suggestion: NRA should consider improving training and retraining of its inspectors in order to improve their competencies for inspections, associated assessments and decision making.**

7.3. INSPECTION OF RESEARCH REACTORS

The inspections of research reactors are performed in accordance with similar procedures (and periods) as for nuclear power plants. Inspections are done using the Guide for Operational Safety Inspections and the Facility Specific Inspection Manual.

A licensee must not start the operation of a research reactor before the completion of the NRA's Pre-Service inspection, with respect to its construction work and performance.

During the operation stage a licensee must specify operational safety programmes and obtain the approval from NRA. After approval, inspections to verify compliance of the operational safety programmes are performed by NRA.

In case of extended shut-downs periodic inspections are performed at regular intervals not exceeding one year. When research reactor is shut-down for a longer period than usual because of the construction of facilities for modifications the licensee is required to submit the quality assurance (QA) program during the corresponding period for it to NRA as part of the approval process for its design and construction related to the modification. After approval, inspections to verify compliance of QA activities are performed by NRA.

Currently there are 10 inspectors for Operational Safety Inspections of research reactors and 14 for the other inspections in NRA Headquarters. In addition there are regional inspectors. All the inspectors are certified by NRA according to their technical knowledge and specific training.

The IRRS team during the visit to JRR-3 has observed the daily inspection meeting. During inspection, the maintenance work and the records of the last weeks were checked by NRA inspectors, and a visit to the facility was made. The IRRS team was informed by the licensee that the JRR-3 is in condition to restart its operation in case NRA would authorize its compliance with the new regulatory requirements.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

The Reactor Regulation Act defines the same range of inspections for fuel cycle facilities as for nuclear power plants (Pre-Service, Periodic Facility, Operational Safety, and Welding Inspections).

Pre-Service Inspections are led by NRA headquarter inspectors, whose technical specialists develop the scope, content and acceptance criteria based on the licensee's application for authorisation to undertake the activity. The scope and content of a submission is determined by the type of activity. Pre-Service Inspection is related to the content of the submission prescribed in the Act and follows a graded approach, appropriately focusing on the most hazardous of the fuel cycle activities, with a commensurate period of time to complete them. They confirm the

adequacy of construction in line with the design intent and associated limits and conditions in the safety justification. Each individual inspection and test has to be signed off. Once all have been completed satisfactorily, the report and record is presented to the NRA commissioners, when they are satisfied, the facility can move into the Operational Phase.

During the Operational Phase, Periodic Facility Inspections are undertaken annually by NRA. The scope is based on the content of the original Pre-Service Inspection identified above, further informed by operational and regulatory experience. It can take NRA up to 4-months to complete. Inspectors again seek to confirm that the performance of the structures, systems and components will continue to meet the design intent.

Similar to other facilities, Operational Safety Inspections are undertaken 4 times a year (quarterly) for major fuel cycle facility, but dependant on the type of facility, the duration can vary between 3 and 10 days. During the site visit to Rokkasho by members of the IRRS team, it was identified that although a schedule is developed, which identifies the areas to be inspected, the schedule only defines the scope of the inspection and not the depth. Hence the extent and associated rigour of Operational Safety Inspections is not evident in the schedule, but details on how rigorous the inspection should be conducted is discussed and determined in internal meetings prior to the inspection, how this detail is recorded was not observed. In addition, the regional inspectors also undertake facility walk-downs, which are basic plant walk downs, in many cases they are undertaken on a daily basis. These were observed by members of the team during the mission and amount to basic housekeeping and plant status checks.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

Waste management facilities regulated under the radiation hazard prevention act

For radioactive waste management facilities regulated in terms of the Radiation Hazards Prevention Act, two types of periodical inspections are performed:

1. Mandatory inspections on a three to five year basis

These inspections are undertaken on behalf of NRA by two registered inspection bodies –

a. Nuclear safety Technology Centre (NUSTEC)

b. Radiation Management Institute (RAMI)

The Permitted Waste Management Operators are obliged to apply to the registered inspection bodies for inspection. The Radiation Hazards Prevention Act (Articles 12-9) requires application to NRA. However, the IRRS team was informed that in practice the applications are submitted to the registered inspection bodies acting on behalf of the NRA and not to the NRA. There is no direct involvement of NRA in the application for these mandatory facility inspections.

Following completion of the inspection, the registered inspection body provides a report to NRA on the inspection undertaken. In the event of identified non compliances the registered inspection body is required to provide a report to NRA immediately. The NRA then undertakes follow-up action with the authorised operator. Such follow-up may include a request for the operator to take corrective action or submit a revised application for change in the permission granted.

NRA does not have a process to verify that all authorised operators have applied for the mandatory inspection or that the inspections have been completed. The registered inspection bodies do however from time to time provide notification to the NRA on facilities that have not applied for inspection within the appropriate timeframe.

NRA does not have a process in place to verify that licensee submit applications for the mandatory facility inspection or confirming that these inspections are carried out by the registered inspection bodies. Similarly there is no evidence of a plan for the periodic inspections required of these facilities (see Suggestion S1).

2. Inspections undertaken by NRA staff once every ten years.

In the development of the annual inspection plan the NRA includes some inspections of authorised non-nuclear facilities. These facilities are required to be inspected by NRA at least once every ten years. Noting that NRA has been in existence since 2012, not all facilities have been inspected by NRA at present.

Waste management facilities under the Reactor Regulation Act

Inspections of waste management facilities are prescribed in the Reactor Regulation Act. Whilst the frequency and type of inspections (pre-service, welding, periodic facility, operational safety inspections) to be performed are prescribed in the law as being the same for all facilities, the depth of inspection is based on a graded approach considering the content of the facility safety documentation. Pre-Service inspection and periodic inspections include representatives from the NRA headquarters as well as representatives from the site/regional offices.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The NRA conducts compliance inspections of authorised users of radioisotopes and other radiation apparatus, in accordance with the Radiation Hazards Prevention Act, with its own inspectors. The Act also allows external inspection bodies, registered by NRA, to conduct inspections of Specified Permitted Users in order to confirm conformity to technical standards prior to initial use of radioisotopes and other radiation apparatus, and periodic inspections thereafter. Currently, there are two external Registered Inspection Bodies performing these tasks.

There are about 8,000 authorised operators of radiation sources and facilities of which 2 400 Permitted Users are subject to an On-Site Inspection by NRA inspectors once every ten years. The Registered Inspection Bodies conduct Periodic Inspections for 1 200 Specified Permitted Users every 3 to 5 years.

Although permitted by the Radiation Hazards Prevention Act, the NRA or the two Registered Inspection Bodies do not conduct unannounced inspections. The NRA prepares an annual plan for On-Site Inspections for authorised operators at the beginning of each fiscal year, which includes the number of inspections to be conducted, the facilities to be inspected and the primary issues to be addressed. The plan needs to be approved by the NRA Secretariat and communicated to the two Registered Inspection Bodies. The priority of On-Site Inspections in the annual plan is given to facilities that have not had an inspection for more than 3 years following its authorisation, or where more than 10 years have passed since the previous On-Site Inspection (excluding facilities of Specified Permitted Users and Permitted Waste Management Operators which are subject to Periodic Inspections and Periodic Confirmation by the Registered Inspection Bodies). The plan also includes On-Site Inspections at research facilities that have radiation generating apparatus with large output power. The NRA conducts roughly 200 On-Site Inspections per year.

Although one Registered Inspection Body conducts 240 periodic inspections per year, the other has only been recently registered and has conducted few actual inspections yet. They each submit a report every month to the NRA, which details the number of inspections they have conducted and the results of the inspections. While the NRA reviews and approves the inspection procedures of the Registered Inspection Bodies as part of the registration process, it does not periodically verify the quality of their work or verify the accuracy of their inspection results.

Every planned On-Site Inspection by the NRA is conducted by a team of at least 2 inspectors who use a checklist with itemized items that correspond to regulatory requirements. The inspection is predominantly a records examination, with interviews of the people concerned, in order to determine if the authorised users is complying with the relevant regulatory requirements. When inspectors find non-conformances of regulatory requirements, they report their findings to the authorised user at the end of the inspection and to their Director upon returning to the office. The Director will in turn report it to the NRA Commission and will issue an instruction to the authorised user to fix the problem. Implementation of corrective action by the authorised user is verified at the next inspection.

The NRA has not established procedures for the conduct of inspections. It relies exclusively on the inspector checklist which contains the legislative requirements and items from the licensee's operation programme under the license which are to be inspected, in addition to some procedural guidance for the inspectors. There is no systematic approach to training inspectors. Inspectors are only required to attend a two week course prior to the commencement of their duties (see Recommendation R5).

The IRRS team also noted that the NRA inspectors or the Registered Inspection Bodies do not conduct joint inspections with MHLW at medical facilities. IRRS team considers that conduct of joint inspections would be beneficial for ensuring overall safety.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

In the case of non-nuclear facilities, inspections of facilities undergoing decommissioning are only undertaken in the event that the decommissioning activities generate significant quantities of radioactive waste.

Facilities (nuclear power plants, research reactors as well as fuel cycle facilities) undergoing decommissioning are subjected to periodic inspections and operational safety inspections. However based on the progress with decommissioning the frequency of the operational safety inspection may be reduced to lower than the normal four times a year.

7.8. SUMMARY

The legal framework and established practice in Japan provide for comprehensive inspections in all licensed facilities. Types of inspections, their frequency and duration are prescribed in detail by legally binding documents. Inspectors are provided with detailed guidelines how to perform inspections. Inspections are in most cases oriented towards the verification of the performance of the equipment in the facility and less into the organisational and human behaviour related aspects of operation. The framework and practical arrangements for regulatory inspections are in principle in accordance with relevant IAEA safety requirements. However, the IRRS team concluded that the NRA inspection programme needs significant improvement in certain areas (see Recommendation R9).

In particular the legal framework for inspection is prescriptive in nature and allows very little freedom to NRA to decide on the scope, frequency and content of inspections taking into account risk significance of issues. NRA inspectors should be legally allowed to have free access to any site at any time. The decision process for initiating reactive inspections should be shortened. Inspectors should be provided with more training and retraining. Inspection practices of different divisions of NRA addressing different types of facilities should be harmonized. The document management system for keeping track of inspection findings and sharing information among other departments of NRA needs to be approved.

NRA has recognized the need for the simplification of the legal framework related to inspections, but has not yet initiated the required changes. The IRRS team supports the idea of the simplification of the legal framework with the aim to provide more power to NRA to plan and perform inspections in an efficient, performance based and risk informed way.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Reactor Regulation Act and the Radiation Hazards Prevention Act provide the legal framework for the NRA to implement an enforcement programme. Numerous Articles in the Acts provide NRA the authority to take actions to respond to non-compliances with regulatory requirements or conditions specified in the authorization. For example, for nuclear power plants NRA is authorized, when a violation of the operational safety programme is identified, to order a modification to the safety programme, rescission of a permit, or issue Orders to stop operations.

A graded approach is utilized in enforcement involving Operational Safety Inspections. "Implementation Guideline for Operational Safety Inspection for Commercial Power Reactor Facilities" contains guidance regarding assessment of the significance of a violation by considering the effects on nuclear safety. The type of violation is determined by a deterministic assessment of the degree of actual or possible influence on nuclear safety. Violations are characterized as Violation 1, Violation 2, Violation 3, or Monitoring in order of safety significance. For the first three types of violations, NRA responses are graded. For "Monitoring" violations, NRA monitors the licensee corrective actions and examines those in future inspections. Other than the Guideline referenced above and some specific guidance contained in the Acts, there is not a formally documented Enforcement Policy.

During Periodic Facility Inspections NRA suspends the ongoing inspection when a non-compliance is identified and will not complete that portion of the inspection until the licensee has addressed the issue satisfactorily. The licensee cannot resume power operations until the condition is fully resolved (and the Facility Inspection is subsequently completed.) There are no additional enforcement activities conducted for these circumstances.

NRA enforcement processes do not contain specific considerations for licensee-identified violations, but in such cases, the licensee is usually well advanced in corrective actions which enable timely NRA review and closure of the issue. Important policy aspects such as encouragement of licensees to identify and correct non-conformances and safety culture implications could be addressed in a formal enforcement policy.

NRA inspectors confirm that licensees have completed appropriate corrective actions to address violations. This includes review of licensee's extent of condition activities and root cause analysis. The intensity of these NRA verification activities are adjusted commensurate with the severity of the violation. There is, however, no systematic process in place for tracking licensee's corrective actions. This is left to individual inspectors to follow.

For significant violations, a detailed review of the licensee's root cause analysis is performed in the NRA headquarters. NRA does not yet have a formal document setting forth how to determine the graded response activities but is developing such a process to apply to future violations.

Articles in the Administrative Procedure Law provide for licensees to appeal violations.

Enforcement actions are integrated into assessment and enforcement, primarily through the periodic Operational Safety Inspections.

8.2. ENFORCEMENT IMPLEMENTATIONS

At power reactors, potential enforcement actions are promptly communicated to the licensee. Typically this is via verbal communications from the Chief Inspector to licensee management. While NRA HQ is informed of the issue, for low level violations (Monitoring) the issue is assessed by the inspectors and subsequently communicated in writing to licensee management. The NRA Commission is periodically provided a listing of all Monitoring violations. For issues impacting nuclear safety (Type 1, 2, or 3), NRA HQ and the Commissioners are promptly informed. Sanctions, including ordering changes or shut down and removal of authorization are determined by the Commission. The IRRS team noted that there is not a documented process for determining the level of sanctions.

Establishment of a formal process would contribute to transparency and predictability. The IRRS team considers that the enforcement process could be supplemented with media reports.

The Reactor Regulation Act has provisions for individual enforcement actions and NRA will consider issuance of violations to individuals when appropriate to hold them accountable for their actions. Cases of significant wrongdoing can lead to prosecution.

Due to the operational status of most commercial reactors since inception of the NRA, there has been limited experience in implementing enforcement activities.

NRA inspectors are not authorized to order actions to address present or imminent safety issues. Inspectors would pursue such issues through communications with the licensee and promptly contact NRA management for assistance if needed to address the matter.

At the NRA Headquarters such information would be brought as one of the issues to the next regular session of the NRA Commission when order for corrective actions would be decided. In very urgent cases an extraordinary session of the Commission could be summoned and the decision could be made if at least three members are present.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no clear written enforcement policy in place at the NRA. There is no documented process in place at NRA for determining the level of sanctions. NRA inspectors have no power to enforce corrective actions if there is an imminent likelihood of safety significant event. They are required to defer to NRA headquarters. This situation probably endures for inspectors at all licensed facilities in Japan.*	
(1)	**BASIS: GSR Part 1 Requirement 30 states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."*
(2)	**BASIS: GSR Part 1 Requirement 31 states that** *"In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties."*
(3)	**BASIS: GSR Part 1 Requirement 31, para. 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events."*
R10	**Recommendation: NRA should establish a documented enforcement policy with criteria and processes for determining graded sanctions or penalties for non-compliances, and a provision for processing orders to minimise the decision time for corrective actions if there is imminent likelihood of safety significant event.**

8.3. SUMMARY

NRA processes for enforcement are fragmented and some processes are not documented. While NRA has had limited experience with enforcement, it has demonstrated that it can and will take action to address significant licensee performance issues. However, predictability of the involved processes is not strong. NRA needs to establish a formal Enforcement Policy that sets forth processes clearly addressing items such as evaluation of the severity level of non-conformances, sanctions for different levels of non-conformances, processes for issuance of Orders, and expected actions of NRA inspectors if significant safety issues develop.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Atomic Energy Basic Act states that the utilization of Nuclear Energy shall be limited to peaceful purposes and requires that safety is ensured and performed taking into account established international standards for the purpose of contributing to protecting people's lives, health and property, preserving the environment, and assuring national security.

The NRA develops and publishes regulation and guides for various stages (e.g. design, construction, operation, decommissioning) for different types of facilities and activities, in the form of NRA ordinances and related guides. Regulations for nuclear safety of nuclear power plants at the level of ordinance are developed by the NRA. Other administrative agencies consult with the Radiation Council, which aims to harmonize the technical standards on radiation protection.

In developing regulations and guides for NPPs, the regulatory body takes into consideration comments from interested parties, latest knowledge and experience feedback. To incorporate opinions from stakeholders, the NRA asks for public comments on the content of regulations and guides and NRA may also ask for contributions from other government organizations. Through this process, the NRA can have opinions from licensees, and the NRA had opportunity to listen to licensees' opinions in the meeting open to the public for significant changes of the regulations. The NRA commissioners make the decision when a draft document will be made available for public comment, then, after reflecting public comments, also make the decision on issuing the regulations and guides. These meetings are broadcast live on the internet.

NRA develops regulations and guides and seeks to ensure IAEA Safety Standards are used as a basis for the development of its regulations; NRA participates in all the activities under the IAEA's Commission on Safety Standards (CSS) and, CNRA of the OECD/NEA. Research and development work and technological advances are also considered. However, NRA has not documented a systematic process for evaluating and reviewing the regulations and guides, including taking due account of the IAEA safety standards in a structured and methodical manner. NRA needs to document a systematic process for evaluating and reviewing regulations and guides, which should include the guidance on Periodic Safety Assessment of Continuous Improvement that has been highlighted as needing updating during the mission (see also Chapter 6).

The Safety Analysis Report should present sufficient information on the facility or activity that allows the authorization process to proceed efficiently. NRA does not issue detailed guidance on the format and content of documents to be submitted by the applicant in support of authorization applications. This issues related to guidance is also highlighted in Chapter 6.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *There is no documented and systematic process in place for regularly evaluating and reviewing regulations and guides to ensure they are updated. IAEA safety standards are considered but not in a structured manner. While the NRA has issued some guidance documents in support of its regulatory activities, these do not cover the full range of activities regulated for radiation sources and associated facilities.* *NRA has developed a Guideline for Periodic Safety Assessment of Continuous Improvement of Commercial Power Reactors which details the expected content of the report. Although that guide details specific topics, such as seismic assessment or probabilistic assessment, and refers to the IAEA SSG-25 in general, some factors like equipment qualification are not explicitly mentioned.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience "*
(2)	**BASIS: GSR Part 1 Para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending the regulations and guides"*
(3)	**BASIS: GSR Part 1 Requirement 32 states that:** *'The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.'*
(4)	**BASIS: GS G 1.5 Para 3.11 states that:** *'Irrespective of the degree to which the regulatory body has developed prescriptive regulations, the regulatory body is required to give consideration to supplementing its regulations with guidance documents…..'*
(5)	**BASIS: GSR Part 1 requirement 25 states that** *"The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization".*
(6)	**BASIS: GSR Part 4 para. 5.2 states that** *"The safety assessment in itself cannot achieve safety. Safety can only be achieved if the input assumptions are valid, the derived limits and conditions are implemented and maintained, and the assessment reflects the facility or activity as it actually is at any point in time. Updating of the safety assessment is also important in order to provide a baseline for the future evaluation of monitoring data and performance indicators and, for facilities for the storage and disposal of radioactive waste, to provide an appropriate record for reference with regard to future use of the site."*
(7)	**BASIS: SSG-25 para. 2.13 states that** *"The 14 safety factors recommended in this Safety Guide are listed in the following ….: Safety factors relating to the plant...."*
(8)	**BASIS: SSG-25 para. 2.18 states that** *"The steps of the review should be carried out in four phases, which may overlap or be further subdivided as appropriate:...."*
R11	**Recommendation: NRA should:** • **improve and document its process for regularly evaluating and reviewing regulations and guides and as the emerging need arises;** • **supplement the regulations with guidance documents where necessary; and** • **improve its guidance on Periodic Safety Assessment of Continuous Improvement.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The Atomic Energy Basic Act establishes the basic framework policy for ensuring the safe use of nuclear energy, and the following acts, among others, define specific measures in implementing that framework:

- The NRA Establishment Act
- The Reactor Regulation Act
- The Nuclear Emergency Act

The Reactor Regulation Act assigns responsibility for ensuring safety and improvement of safety to the licensees for all activities associated with nuclear power plants. This responsibility cannot be delegated to other parties. To support its regulation of Nuclear Power Plants, the NRA has developed requirements in the form of ordinances for commercial power reactors and specific guidance covering site characteristics, design, construction, commissioning, operation, decommissioning, and radiological protection.

Regulations require that prior to commencing the operation, an Operational Safety Programme must be submitted that includes the operational limits and conditions, maintenance, inspections, and tests of SSCs, which needs to be approved by the NRA. The licensee must comply with this approved Operational Safety Programme, and in case of a violation to this programme, the NRA may order the licensee to take corrective actions, or even to shut down the plant depending on the situation. In addition, before dismantling a NPP the licensee must also develop a Decommissioning Plan and get NRA approval.

NRA has developed guides to support the review of applications for an establishment permit. Examples are the Commercial Reactor Establishment Permit Guide, the Commercial Reactors Technical Standard Guide, the Commercial Reactors Operational Safety Program Standards or Guidelines for Fire Protection of Commercial Power Reactor Facilities, Guidelines for Volcanic Effect Assessment for Nuclear Power Plant, or Standard Review Plan for Technical Competence of Licensees in Taking Necessary Measures to Prevent and Mitigate Severe Accidents at Commercial Power Reactors. NRA reviews licensee's applications using regulatory guides to ensure that the design meets the relevant requirement, if the licensee decides to use different methodologies other than those highlighted in the guides, the NRA reviews the adequacy of the methodologies on case by case basis with the reference to the relevant regulatory guides.

In response to the TEPCO Fukushima Daiichi accident, NRA developed new regulatory requirements and emphasis was given to strict evaluation of natural hazards, the need to take measures to prevent and mitigate severe accidents, back-fitting system and new requirements for continuous improvement. This revision assigns the licensee the responsibility to act proactively in installing equipment, enhancing education of personnel or taking any other necessary measures for preventing disasters, taking into account the latest knowledge on safety at nuclear facilities. This prompt response is highlighted as a Good Practice (GP2) in Chapter 1. NRA has identified certain actions associated with Regulations and Guides in its self-assessment, which would be implemented under the appropriate action plan.

Periodic safety review (a part of periodic safety assessment of continuous improvement)

In response to the TEPCO Fukushima Daiichi accident the Reactor Regulation Act was revised in June 2012 and an evaluation system to enhance the safety of commercial power reactor facilities was introduced, replacing the former periodic safety reviews. Licensees are now required to conduct, at least every 5 years, a "periodic safety assessment of continuous improvement". The first submission of such safety assessment report should occur in mid-2017.

NRA Guideline for Periodic Safety Assessment of Continuous Improvement of Commercial Power Reactors details the expected content of such submission. It should include, for example, information on insights from probabilistic safety assessment and deterministic safety analysis, natural hazards analysis, equipment condition, ageing management provisions and identification of measures to improve safety, called "voluntary measures". Should a licensee not implement the voluntary measures he identified, the NRA would not be able to directly order the licensee to implement them. The NRA would have to act indirectly to ensure the required improvements are implemented, using the commitment in the approved Operational Safety Programme as a basis.

The update by the licensee of the SAR following the completion of the Periodic Assessment of Continuous Improvement to include the insight on safety assessment and safety measures is not mandatory. NRA may however

develop new regulatory requirements based on the insights gained and, through the implementation of the backfitting rule, the licensee will have to comply and, if needed, apply for an amended Establishment Permit.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The Reactors Regulation Act provide for regulations on the installation and operation of reactors, which includes the criteria for the permission of establishment of the research reactors.

The requirements for establishment of a license for a research reactor are specified in the Research Reactors Establishment Permit Ordinance, and are based on a graded approach according to the categorization and characteristics of the reactor. The categorization is based on the power and type of reactors and includes low-power reactors, critical assemblies, medium- and high-power reactors, sodium-cooled fast reactors, gas-cooled reactors. There are also specific requirements for research water-cooled reactors with thermal power in excess of 500kW, sodium-cooled fast reactors, gas-cooled reactor and reactors using experimental devices such as high pressure and temperature loops, cold neutron sources, hot neutron sources and also for the case of reactors used for testing hazardous materials.

Similarly to the nuclear power reactors a licensee shall develop, specify and obtain approval from NRA for an "Operational Safety Programme", specified on the Research Reactors Ordinances, and NRA inspects the compliance with the Operational Safety Programme. In addition, regulatory requirements highlight the need for the licensee to prepare a policy for quality assurance activities, and implement, evaluate, and continuously improve them.

In 2013 new requirements were established to prevent escalation on BDBA conditions for water-cooled research reactors with a thermal output of 500 kW or more, sodium-cooled fast reactors and gas-cooled reactors.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

As for NPPs, the Atomic Energy Basic Act establishes the basic framework policy for ensuring the safe use of nuclear fuel cycle facilities, and the subordinate legislation sets out the detailed regulatory framework. The framework contains a significant amount of documentation that defines the regulatory requirements and expectations for fuel cycle facilities, *with* specific ordinances and guides covering fuel fabrication and enrichment, spent fuel reprocessing and spent fuel storage facilities. These ordinances and guides cover each stage of the facility's lifecycle and define the content of the submissions that the licensee has to provide in its application to the regulatory body when seeking authorisation to undertake an activity.

In addition to the need to consider criticality, cooling, containment and shielding, the regulatory requirements for fuel cycle facilities do also focus on those areas that are important to these types of facilities including ventilation, hydrogen, geometry, material selection, chemical hazards, process control, instrumentation, etc. The requirements are written at a high level and no detailed standards set out how to meet the regulatory expectations. It is the responsibility of the licensee to identify the codes and standards that are applicable to the structures, systems and components for the fuel cycle facilities, demonstrate that they are suitable for each application and develop the associated application.

The guide on periodic assessment or continuous improvement safety review for fuel cycle facilities limits the consideration of external hazards to seismic and tsunami. This should be revised to ensure that all relevant external hazards are considered. The recommendation earlier in this Chapter is intended to ensure this is addressed by NRA. It was also identified that the regulations and guides do not require a Probabilistic Safety Assessment to be completed for fuel cycle facilities. The recommendation R11 for nuclear power plants is also appropriate to the fuel cycle facilities taking into account their specific features.

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

NRA has established a suite of regulatory requirements (ordinances) and guidance, to be used by applicants and licensed entities related to radioactive waste management facilities. These cover

- Interim storage and treatment of radioactive waste
- Disposal of Category 1 radioactive waste (waste requiring disposal in a geological repository)
- Disposal of Category 2 radioactive waste (waste that may be disposed in near surface trenches or repository other than a geological repository)
- Off-site transport of nuclear fuel materials.

The requirements and procedures of authorization for waste management facilities are basically the same as those for nuclear power plants, but the requirements in terms of contents and levels differ based on a graded approach. Under this legal framework, the licensee is primarily liable for all operational safety matters occurring during establishment and operation of its waste disposal facility until the completion of decommissioning of such facility.

NRA has also established standard review plans, to be used by NRA staff, for the review of operational safety programmes for said facilities.

As part of the advanced reference material and action plans prepared for the IRRS mission, the NRA has recognised the need to develop additional requirements and guidance related to intermediate depth disposal, since the number of decommissioned plants is expected to increase and certain waste will not be allowed for near surface disposal because of exceeding limit of radioactivity concentration designated for that disposal.

In view of the fact that there are no projects related to geological disposals of radioactive material in Japan foreseen in the short term, the NRA has not developed any regulatory criteria for the disposal of these wastes.

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Japan has a comprehensive suite of legislative provisions including Acts, Cabinet Orders, Ordinances and Notifications providing for the regulation of radiation sources and facilities. When the NRA establishes regulations concerning technical standards in relation to radiation, it consults with the Radiation Council which is a statutory body tasked with advising on the consistency of technical standards issued by competent authorities such as NRA, MHLW, MAFF and MLIT. NRA promotes its regulations to the extent that it communicates with authorised entities when there is a significant change, in discussions during inspections and when it provides speakers to industry seminars.

The regulations have a high degree of prescriptiveness and while NRA has issued administrative circulars responding to specific incidents, it has not issued any practice specific guidance documents to supplement the regulations in this area (see Recommendation R11).

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The requirements and guidance for decommissioning are included in the ordinances pertaining to the specific facility (NPP, Research Reactor, Fuel cycle, waste management, or radiation facility). For each facility type the operator is obliged to prepare a decommissioning plan and submit this for approval to NRA. The content of the decommissioning plan is prescribed in the respective ordinances. Following the completion of decommissioning activities the operator is obliged to submit a report detailing the decommissioning activities completed and ask NRA for confirmation of completed decommissioning measures.

The IRRS team observed that the regulation stipulates a very detailed and prescriptive way the information to be maintained and the storage period for the decommission phase.

9.8. SUMMARY

NRA develops and publishes regulation and guides for different types of nuclear facilities and activities covering various stages (e.g. design, construction, operation, decommissioning). NRA develops regulatory requirements (NRA ordinances) that are performance-based, and it develops standard review plans and other supplementary guides. In 2013 NRA developed new regulatory requirements incorporating lessons learned from TEPCO Fukushima Daiichi accident to require licensees to give consideration to natural hazards relevant to Japan, associated severe accidents and new requirements for continuous improvement of the plant safety. The IRRS team identified that the NRA has no requirement related to the consideration of decommissioning during the design, construction, commissioning and operation of the facility as mentioned in Chapter 5 of this report.

During the development of regulations and guides for NPPs, the regulatory body takes into consideration comments from interested parties, other government organizations, the public and feedback based on experience when applicable, and there is some consideration of the relevant IAEA safety standards.

Currently, there is not a documented process in place for regularly evaluating and reviewing regulations and guides, and revising as appropriate. IAEA safety guides are considered, this does not ensure full compliance. While the NRA has issued some guidance documents in support of its regulatory activities these do not cover some activities regulated as for radiation sources and associated facilities.

NRA has included requirements for continuous improvement of the plant safety assigning the licensee the responsibility to act proactively installing equipment however the guides for Periodic Assessment of Continuous Improvement do not require the consideration of all natural hazards.

In 2013 new requirements were established to prevent escalation on BDBA conditions for water-cooled research reactors with a thermal output of 500 kW or more, sodium-cooled fast reactors and gas-cooled reactors.

As part of the advanced reference material prepared for the IRRS mission by the NRA, several actions has been identified which would be implemented under the appropriate action plan.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1 GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

The regulatory framework in the area of emergency preparedness and response (EPR) is set out in the Atomic Energy Basic Act, Reactor Regulation Act, Radiation Hazards Prevention Act, Nuclear Emergency Act, Basic Act on Disaster Control Measures and in other legally binding documents. It is complemented by an NRA EPR Guide, which is formulated in accordance with the Nuclear Emergency Act and provides detailed guidance to be followed in order to meet the legal requirements.

NRA, in line with the NRA Establishment Act, is responsible for the regulatory aspects of emergency preparedness and response for NPPs.

The Nuclear Emergency Act requires NPP licensees to develop a "Nuclear operator's EPR plan" for each site, to annually update the plan and to consult with the national government and local governments when developing or modifying the plan. The plan should be submitted to NRA as part of the licensing process. NRA reviews the plan and may instruct utility to make changes, if necessary. Review is performed based on defined criteria, which allows for consistency in the review of plans from different utilities. Plans are reviewed annually. The Reactor Regulation Act requires licensees to test the operational safety programmes in an exercise utilizing a severe emergency scenario prior to starting operation of a NPP, and then perform such exercises annually.

The regulatory framework for EPR at NPPs was extensively revised and enhanced after the accident at the Fukushima Daiichi NPP. In 2015 NRA started a new type of inspections related to preparedness for response to severe accidents in the NPPs that plan to apply for compliance with new requirements. These inspections are based on a checklist which has not yet been formalized. NRA also observes and evaluates exercises organized by NPPs and requires that appropriate corrective actions are implemented in the on-site emergency plans based on the outcomes of the exercises.

NRA also regulates use of sealed sources, unsealed sources and radiation generators except those of low energy. Only limited aspects of EPR are addressed in the regulations related to these sources. Authorized operators are not required to establish EPR plans. Actions to be prepared concerning accidents with these sources are very limited and do not take into account hazards associated with them. Usually these actions represent a small part of the Radiation Hazard Prevention Programme that is submitted to NRA. There is no NRA guidance to perform review of these actions. There are also no requirements to conduct exercises. The need to address this issue was identified by NRA in its self-assessment (A23 in the Action Plan).

NRA does not regulate transport of sources, which is performed by the MLIT. EPR for transport accidents are regulated by MLIT, and NRA has a role to provide advice upon request.

NRA is designated as National Competent Authority under the Convention on Early Notification in Case of a Nuclear Accidents and Convention on Assistance in Case of a Nuclear Accident or Radiological Emergencies.

With regard to overall emergency response, NRA staff takes part in the activities of Nuclear Emergency Response Headquarters and its Secretariat, in the nuclear facility Emergency Response Centre and in other response entities.

The IRRS team identified a number of deficiencies with respect to emergency preparedness and response to radiological emergencies. Details of these observations are presented throughout the Chapter 10.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are very limited requirements for EPR in relation to sources of ionizing radiation regulated under the Radiation Hazards Prevention Act. Furthermore, several organizations are involved in regulating the use or transport of radiation sources. Authorized operators are not required to establish EPR plans and arrangements. There are no requirements to conduct training or exercises for radiological emergencies. There is no clear definition of roles and responsibilities of licensees and NRA in deciding on mitigatory actions on the scene. There is a lack of emergency response arrangements within NRA to address response role of NRA in radiological emergencies.*	
(1)	**BASIS: GS-R-2 para. 3.8 states that** "*The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. […]"*
(2)	**BASIS: GS-R-2 para. 5.14 states that** *"Each response organization "shall prepare a general plan or plans for coordinating and [performing their assigned functions…]. […]"*
(3)	*In addition, the following paragraphs provide basis for this recommendation:* ***GS-R-2, paras. 3.6, 3.10, 3.11, 3.15, 3.16, 4.1, 4.9, 4.19, 4.24, 4.37, 4.38, 4.51, 4.70, 4.83, 4.84, 5.2, 5.13***
R12	**Recommendation: NRA and other authorities having jurisdiction for radiation sources should develop a single set of requirements and guidance for EPR in relation to radiation sources including requirements related to emergency plans, arrangements for timely notification and response, and quality assurance programme using graded approach.**
S11	**Suggestion: NRA should consider strengthening its plans and procedures to consistently respond to emergencies related to radiation sources.**

Assessment of threats (Hazard assessment)

NRA has made generic threat (hazard) assessments for severe nuclear emergencies which form the basis for guidance on Emergency Planning Zones around different nuclear facilities. These are included in the NRA's EPR Guide.

As for the NPP operators, the IRRS team observed indications that assessments of threats (hazards) are being performed to some extent, as a basis for defining their site-specific Emergency Action Levels. There are regulatory requirements for authorized operators to systematically perform a threat (hazard) assessment to ensure that all practices and situations (on-site and off-site) that could necessitate an emergency intervention are identified. This is performed under the establishment permit and then reviewed every 5 years, as a part of "Periodic Safety Assessment of Continuous Improvement".

10.2 FUNCTIONAL REGULATORY REQUIREMENTS

Establishing emergency management and operations

The Nuclear Emergency Act as well as the Emergency Action Plan Order require nuclear operators to establish a nuclear disaster prevention organization, to appoint its manager and his/her alternates and to staff the organization adequately to perform functions related to prevention of emergency situations, as well as response to and recovery from an emergency. The staffing requirements need to consider the possibility multiple units' at the site being in accident conditions simultaneously. NRA has requirements for allocation of operator staff and seconded personnel for response activities, as well as requirements for staffing of the operator's emergency response center.

Compliance with these requirements is checked within the process of reviewing on-site emergency plan. Operators are required to notify off-site authorities about the on-site response organization to allow for coordination between on-site and off-site.

For authorised users of radiation sources regulated under the Radiation Hazards Prevention Act, NRA does not have requirements to establish and maintain an adequate emergency management structure to manage the on-site response and to coordinate the response with off-site response organizations (see Recommendation R13).

Identifying, notifying and activating

In the light of the lessons identified in the response to the TEPCO Fukushima Daiichi accident, the NRA decided to require implementation of Emergency Action Levels to help operators to promptly identify an emergency class (Alert, Site Area Emergency and General Emergency). The Emergency Action levels are associated with predefined response actions on the site and protective actions for the public. The emergency classification system is consistent with the IAEA Safety Standards. This change is currently only implemented for the NPPs and is intended to facilitate a prompt implementation of emergency response actions. Currently, the level of detail of the developed Emergency Action Levels may vary among different NPPs. There is no complete set of Emergency Action Levels developed for nuclear facilities other than NPPs (see Recommendation 13). The need to address this issue was identified by NRA in its self-assessment (A20 and A22 in the Action Plan).

The NRA EPR Guide requires that Emergency Action Levels specific to the characteristics of the power reactor and conditions of the site shall be established by the nuclear operators and provides guidelines for the Emergency Action Levels. While the concept of Emergency Action levels is presented in details in the NRA EPR Guide and the Japan Electric Association Guide, it has not been consistently applied in the higher level regulations (e.g. Nuclear Emergency Act or Reactor Regulation Act). The Acts still contain provisions which address the 5 μSv/h criterion and notifications under Articles 10 and 15.

The Japanese regulations require that notification of all relevant authorities, including NRA, is performed directly by the operator, which should also confirm the receipt of the message either by phone or through the automated system. The notification procedures are required to be part of the NPP emergency plan. There is also a time requirement for notification (15 minutes from identification of an event), which is tested through the NPP exercises and evaluated by NRA. While there is no single designated off-site notification point (as required by GS-R-2 para 4.22), the utilization of an automated system for confirmation of receipt of the information would most likely eliminate the need for operator to directly notify all relevant off-site authorities.

The Japanese regulations require that the operator identifies the emergency class using Emergency Action Levels and notifies local and national authorities. Based on the notification State[2] makes confirmation and declaration of the appropriate conditions, after which decisions are taken on activation of protective actions[3].

As for the operators other than NPPs, there are no NRA requirements for prompt identification of an emergency and determination of the appropriate level of response (GS-R-2, para 4.19) (see Recommendation 13).

Taking mitigatory actions

The Nuclear Emergency Act and the Reactor Regulation Act give responsibility and authority to operators of the NPPs to prepare for and to take necessary measures to prevent or to mitigate consequences in an emergency involving the facility or activity under their responsibility. The accident management procedures are also required to be part of Operational Safety Programme consistently with GS-R-2. For the other users the Radiation Hazards

[2] For the emergency classes of Site Area Emergency and General Emergency operator will promptly notify States (primarily Prime Minister and the NRA) after which State will immediately identify occurrence of the appropriate conditions and provide such information to the local government and general public without delay. State and local governments will implement protective actions.

[3] Further assessment of off-site arrangements in this regard is subject to other IAEA peer review (i.e. EPREV) and goes beyond IRRS mission

Prevention Act also requires the immediate measures to be taken by operators and for these measures to be part of the Radiation Hazards Prevention Programme.

The Radiation Hazards Prevention Act gives NRA the authority during an emergency to give orders to the operators regarding the necessary measures to be taken on the scene. As for emergencies at NPPs, the same authority has been assigned to NRA in the Reactor Regulation Act, which is explained in the NRA EPR plan and might be further detailed in the future revisions. The Nuclear Emergency Act was changed after the TEPCO Fukushima Daiichi accident by limiting authority with respect to the technical matters of mitigatory actions to NRA only.

The need for operators to identify what on-site support from the off-site emergency services may be warranted and the need to put in place coordinated operational arrangements to implement this support are part of existing regulations as required in GS-R-2 (para. 4.40). Arrangements are verified by the NRA and other authorities through the exercises. The Nuclear Emergency Act requires that coordination between the nuclear operators and organizations providing support to be part of their emergency plan.

The Radiation Hazards Prevention Act requires that licensees of use of sources, defined in the Act, take immediate actions in an emergency in cooperation with relevant emergency services.

Taking urgent protective action

The Nuclear Emergency Act and the Basic Plan for Disaster Preparedness clarify the role for taking urgent protective actions off-site as well as for the overall off-site emergency preparedness and response to be with the off-site authorities. In addition to introduction of the Emergency Action Levels, the NRA EPR Guide introduces the use of Operational Intervention Levels to support the prompt implementation of the off-site urgent protective actions based on monitoring results and redefines the Emergency Planning Zones, putting these concepts in general consistency with the IAEA Safety Standards[4].

The Radiation Hazards Prevention Act, the Reactor Regulation Act and the Nuclear Emergency Act require that operators take all necessary actions at the site, but do not have explicit requirements for operators to establish arrangements to warn personnel and other individuals on the site of an emergency, to evacuate non-essential personnel and other individuals from the site, or to provide first aid.

Providing information and issuing instructions

The Basic Plan for Disaster Preparedness recognizes sharing the role, at the preparedness stage, among the nuclear operator, NRA and other off-site authorities, including educational institutions, in providing information to the public living in the vicinity of nuclear facilities within the emergency planning zones on potential consequences in case of a nuclear accident, the actions to take and how these actions are to be taken. The IRRS team was informed that there are public information centres located in the vicinity of the NPPs, where public is able to come and get an information about the various matters related to NPPs. However, there is no verification mechanism by NRA to ensure that NPP operators take part in this process.

With regard to source operators, the Radiation Hazards Prevention Act requires that operators of radioactive sources issue warning to people in the vicinity in an emergency involving sources under their responsibility which is consistent with GS-R-2 (para. 4.38). Article 29 of the Radiation Hazards Prevention Ordinance contains a list of actions which should be performed by the operator. This is verified by the NRA during the inspection, however, no criteria or checklist is used for verification.

[4] Further assessment of off-site arrangements in this regard is subject to other IAEA peer reviews (i.e. EPREV) and goes beyond IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although a regulatory framework for EPR at NPPs was extensively revised and enhanced after the accident at Fukushima Daiichi NPP, there are still issues which remain to be addressed. There is a need for NRA to develop a complete set of Emergency Action Levels for nuclear facilities other than NPPs. There is also a need to develop a guidance to assist operators of nuclear facilities, in definition of conditions or parameters for prompt judgement of Emergency Action Levels. There is a need to verify implementation of requirements for provision of information, at the preparedness stage, by the operator to the public living in the emergency planning zones around NPPs.*	
(1)	**BASIS: GS-R-2 para. 4.19. states that** *"The operator of a facility or practice in threat category I, II, III or IV shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency, and determination of the appropriate level of response. This shall include a system for classifying all potential nuclear and radiological emergencies […]"*
(2)	**BASIS: GS-R-2 para. 4.54 states that** *"For facilities in threat category I or II arrangements shall be made, before and during operations, to provide information on response to a nuclear or radiological emergency to…. population groups … within the precautionary actions zone and the urgent protective action planning zone. […] and the effectiveness of this public information programme shall be periodically assessed."*
(3)	*In addition, the following paragraphs provide basis for this recommendation:* ***GS-R-2, paras. 4.23, 4.25,***
R13	**Recommendation: NRA should establish:** • **complete set of Emergency Action Levels for nuclear facilities other than NPPs and associated guidance to promptly define Emergency Action Levels for all nuclear operators;** • **verification process that licensees participate in provision of information to the public within emergency planning zones around nuclear facilities at the preparedness stage.**

Protecting emergency workers

Provisions for protection of emergency workers are given in the Radiation Hazards Prevention Act, the Reactor Regulation Act and Industrial Safety and Health Act covering various aspects such as: minimization of doses and application of different dose restrictions for emergency works other than dose limits for normal operation; monitoring and assessment of doses; provision of personnel protective equipment and monitoring equipment; implementing measures to prevent inadvertent ingestions (banning smoking, eating and drinking in the areas where they are undertaking emergency work); health surveillance and medical examinations; training; recording of doses; and sharing the information with emergency workers. In addition, the Reactor Regulation Act requires that nuclear operators formulate procedures addressing these aspects in order to protect emergency workers. NRA and MHLW both regulate arrangements for emergency workers designated from the plant radiation workers under the Commercial Reactor Ordinance and MHLW Ordinance. There is a requirement for the nuclear operator to identify and designate emergency workers at the preparedness stage. Other categories of emergency workers are under the jurisdiction of the other authorities including National Personnel Authority, local government personnel authority and Ministry of Defence.

The IRRS team was informed that NRA and MHLW are planning to issue revised regulations addressing several aspects of arrangements for emergency workers by 1 April 2016. These revised regulations will include the

following: predefined dose limit of effective dose of 250 mSv for emergency work for preventing or converging catastrophic events, provision for health surveillance and provisions for incurring further occupational exposure by radiation workers because of doses received in an emergency response. NRA and MHLW cooperate in regulating arrangements for onsite emergency workers from the utility.

These changes in regulations of NRA and MHLW would make the requirements, in general, consistent with GS-R-2. In addition, cooperation between different authorities regulating arrangements for emergency workers should be continued, taking into account changes entering into force on 1 April 2016. (see Suggestion S1 and Recommendation R1). The need to address this task was identified by NRA during self-assessment process (A21 in the Action Plan).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Since the TEPCO Fukushima Daiichi accident efforts were made to enhance requirements for emergency workers. NRA and MHLW are proposing changes covering different aspects of regulations for emergency workers. The changes, as foreseen from April 2016* need to be steadily implemented. Cooperation between different authorities regulating arrangements *for emergency workers should be continued, taking into account changes entering into force on 1 April 2016.*	
(1)	**BASIS: GS-R-2 para. 4.58. states that** *"Those called upon to respond at a facility in threat category I, II or III or within the precautionary action zone or the urgent protective action planning zone shall be designated as emergency workers. […] In addition, the radiation specialists …, radiation protection officers and radiological assessors … who may respond to emergencies involving practices or other hazards in threat category IV shall be considered emergency workers. […]"*
(2)	*In addition, the following paragraphs provide basis for this recommendation:* ***GS-R-2, paras. 4.62, 4.63***
S12	**Suggestion: The Government should consider ensuring that the relevant authorities establish consistent requirements for categories of emergency workers performing similar tasks**.

Assessing the initial phase

The NRA EPR Guide requires nuclear operators to assess the emergency situation and introduces Emergency Action Levels as a basis to judge the emergency class and the need for corresponding emergency response actions on-site and off-site (use of Emergency Action Levels is discussed above). In addition, the Basic Plan for Disaster Prevention gives responsibilities to operators for carrying out monitoring and assessment of the situation, for predicting the conditions and for sharing this information with off-site authorities. NRA verifies these activities during review of the emergency plans and at exercises.

Managing medical response

The NRA EPR Guide requires operators to make arrangements for medical response as required in para 4.78 of GS-R-2 and for establishing operational arrangements with local medical facilities and designated hospitals.

Other activities in emergency preparedness

There is no regulation under the NRA jurisdiction which would require operators to take measures to mitigate non-radiological consequences in particular in terms of managing stress and psychosocial impacts among emergency workers. These aspects are dealt by the MHLW and its relevant regulations.

Japanese regulatory framework in EPR addresses explicitly the recovery and need to prepare for and to recover after an emergency. However, this is primarily focused on the off-site recovery efforts and their coordination

without providing further guidance on how the recovery is to be taken and what conditions need to be met and without clarifying the need to put arrangements in place to transition from emergency phase operations to long term recovery operations (as required in para. 4.99 of GS-R-2). With regard to a site where an accident has happened, the Reactor Regulation Act (Art. 64-2) authorizes NRA to designate "specific nuclear facility" for a nuclear facility at which specific emergency measures were taken. In these circumstances, the NRA is authorised to require nuclear operators to prepare a plan for measures to be further taken within specific timeframes. Operators have the responsibility to implement this plan and NRA is given explicitly an authority to conduct inspections regarding the implementation of the plan.

The operators do not have any responsibility in planning and implementing agricultural countermeasures and long term protective actions such as relocation off-site.

10.3 REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authority

The assignment of authorities regarding relevant functions in EPR is discussed in 10.1 and 10.2 where relevant.

Organization

The on-site overall organization for managing EPR and its staffing are discussed in 10.2 (Establishing emergency management and operations). The Nuclear Emergency Act, the Reactor Regulation Act and the Radiation Hazards Prevention Act have specific provisions for qualification and training of personnel in general in relation to the performance of their duties which can be sufficiently applied to EPR. These are complemented with the provisions set forth in the Emergency Action Plan Ordinance and are further addressed in the Basic Plan for Disaster Preparedness.

The current regulations do not require operators other than nuclear operators to set up an emergency organization and to staff specific positions with qualified and trained staff as required in GS-R-2 (see Recommendation R13).

Coordination of emergency response

The relevant aspects of coordination of EPR of operators with off-site emergency services and response organizations are discussed in 10.2 and in 10.3 and it is addressed in the Nuclear Emergency Act and Emergency Action Plan Ordinance.

Plans and procedures

Nuclear Emergency Act and Commercial Reactors Ordinance require for commercial NPPs development of on-site emergency plans and procedures. NRA reviews on-site plans and Cabinet Office is reviewing those parts of the on-site plans which have implications for off-site arrangements e.g. notification and communication arrangements with off-site authorities. NRA has an internal guidance for reviewing on site plan to ensure consistent method in the review process for all NPPs. If deviations are found, NRA requires necessary changes. Furthermore NRA requires that on-site plans are coordinated with those of off-site authorities and are reviewed every year. However, there is no requirement for coordination of this plan with other plans on the site such as those for physical protection of the facility, for firefighting etc.

The requirements for developing procedures as necessary for the emergency response are given in the Emergency Action Plan Ordinance with clarification in the NRA Nuclear Operator's EPR Plan. For other facilities or activities involving ionizing radiation sources, no requirement for on-site plans exist (see Recommendation R13). This is not consistent with GS-R-2 (para. 5.19). Further discussion on the issue of verification of emergency plans established by nuclear operators is given in Chapter 10.1.

Nuclear or radiological EPR seems to follow the all hazards approach taking into account existing arrangements and responsibilities for managing conventional emergency consistently with GS-R-2. Current requirements also address the need to manage nuclear emergency coincident with natural disaster.

Logistical support and facilities

The Nuclear Emergency Act and Emergency Action Plan Ordinance require that equipment, communication means, materials and facilities needed to support the emergency response and for performance of functions of the on-site disaster prevention organization are to be installed by nuclear operators and elaborated in the on-site emergency plan consistently with GS-R-2. These equipment and facilities are required to be continuously maintained in proper order and regularly checked. The NRA Guide for Nuclear Operator's EPR plan clarifies the requirement for facilities, equipment and tools as well as redundant arrangements given in the Emergency Action Plan Ordinance. The NRA has also been given authority in this Act to perform specific inspection at the radiation measurement facility established by nuclear operators. NRA has authority to order nuclear operators additional measures to be implemented in relation to this radiation measurement facility. In this regard, an ordinance of the Cabinet Office sets provisions for these facilities to be able to withstand impacts from external natural hazards, to be provided with independent power supplies and to provide for the needs of workers utilizing these emergency centres consistently with GS-R-2. This would not be verified by the NRA but by other authority (Cabinet Office).

No provisions for logistical support and facilities for operators other than nuclear operators are stipulated in current regulations (see Recommendation R13).

Training, drills and exercises

The Reactor Regulation Act and the Radiation Hazards Prevention Act contain provisions, in general, for the technical competences of operators and for training of staff. These technical competences for nuclear operators are required to cover the management of severe accidents. Specific provisions for training in EPR exist in Emergency Action Plan Ordinance and in the Basic Plan for Disaster Preparedness.

Nuclear operators are required on the basis of Nuclear Emergency Act to conduct and evaluate drills and exercises, as well as to report their results to the NRA. Emergency exercises are the main means for NRA to verify adequacy and efficiency of the on-site emergency arrangements. Every year 1-2 exercises are organised at each nuclear site complemented by more than 10 annual on-site drills. The NRA representative performs evaluation using pre-defined criteria and guidance. In addition, the licensee carries out its own evaluation. Furthermore, headquarters of NRA participates in exercises by activating its own emergency centre, resulting in about 20 exercises annually for NRA. Based on exercise evaluation of on-site reports and NRA's response report a summary evaluation report is prepared and made publicly available.

NRA analyses the outcome of exercises and, when needed, directs the operator to take corrective actions. The effectiveness of those actions will be tested in the next exercise. Furthermore, on-site emergency plan is updated and sent to NRA for review within the regular annual review schedule.

NRA and all nuclear licence holders have an annual meeting to share experience and results of exercises. The meeting is available to the public through the web.

All NPPs have a programme for training their staff on nuclear safety which includes response to nuclear emergencies. The training is tailored to the roles of trainees in response to an emergency. Records of training are provided to NRA and are subject of verification during inspections. However, no longer term training programme exists to ensure that all parts of the on-site plans are systematically tested at regular intervals.

Licensees regulated under the Radiation Hazards Prevention Act are not required to establish exercise programmes or to conduct and evaluate exercises. This is not consistent with GS-R-2 (para. 5.33 and 5.34) (see Recommendation R13).

Quality assurance programme

Some specific elements for ensuring quality such as review of emergency plans, conduct of exercises and maintaining of equipment and facilities needed for the emergency response are also stipulated in various documents (e.g. Nuclear Emergency Act, Emergency Action Plan Ordinance and Basic Plan for Disaster Preparedness). For operators regulated under the Radiation Hazards Prevention Act, the current regulations do not require establishment of quality assurance programme as required in GS-R-2 (paras 5.37-5.39) (see Recommendation R13).

The Reactor Regulation Act requires that nuclear operators carry out regularly a self-evaluation of overall safety within their responsibility. This self-evaluation considers measures to prevent severe accidents as well as measures taken in response to them, should they occur.

10.4 ROLE OF REGULATORY BODY DURING RESPONSE

The roles of NRA in an emergency response are defined in the Nuclear Emergency Act, Reactor Regulation Act and Radiation Hazards Prevention Act and are further elaborated in the Basic Plan for Disaster Preparedness and NRA EPR Plan. They include: providing advice to operators as well as ordering specific measures to be taken on-site by operators (including dispatching its staff at the accident site); coordination with involved parties; evaluation of the situation and analysis of its impacts; providing information, advice and instructions to local governments and other off-site authorities (including dispatching an official with relevant expertise to local authorities upon their request); dispatching its staff to specific positions within Cabinet Office and National Emergency Response Headquarters (including the NRA chairman having the role of vice-director general of National Emergency Response Headquarters in an emergency); assisting the Prime Minister in deciding on emergency response measures; monitoring and planning the allocation/mobilization of resources (equipment and materials) in an emergency response (based on their database established at the preparedness stage for that purpose); provision of information to the public; coordinating the off-site monitoring, consolidation of monitoring results and sharing of them with all interested parties; managing the dose assessment; participating in the medical response to the emergency and managing the health screening among affected populations; and issuing notification to off-site authorities about an emergency after receipt of such notification by operators and assisting in the declaration of emergency class. The Nuclear Emergency Act gives provisions for NRA to carry out training and exercises in relation to its role in emergency response.

In addition, NRA has a role and responsibilities as a National Competent Authority for emergencies within the country under the Early Notification Convention and Assistance Convention. There is an internal manual (NRA Initial Response Manual) describing NRA's internal emergency response organisation and roles, as well as rosters of the on-call staff to respond to emergencies at NPP. The IRRS team was informed that plans and procedures for response to other types of emergencies are under development.

10.5 SUMMARY

There is a regulatory framework for EPR at NPPs, which was extensively revised and enhanced in line with the IAEA Safety Standards after the TEPCO Fukushima Daiichi accident. Generally the regulations for NPPs are consistent with IAEA Safety Standards in the area of EPR, and regulatory processes for verification of their adequate implementation on-site are in place. However, some aspects in the following areas need to be clarified, such as verification of the NPP operators' participation in the process of provision of information, at the preparedness stage, to the public living in the emergency planning zones, development of guidance for defining

Emergency Action Levels for operators of nuclear facilities other than NPPs and development of those levels for nuclear facilities other than NPPs.

Progress in enhancing the arrangements for emergency workers was noted by the IRRS team. Cooperation between different authorities regulating arrangements for emergency workers should be continued, taking into account changes entering into force on 1 April 2016.

Lack of requirements for EPR in relation to sources of ionizing radiation regulated under the Radiation Hazards Prevention Act should be addressed through cooperative efforts between all relevant authorities. This includes requirements related to emergency plans and establishment of arrangements for timely notification and response and quality assurance programme.

11. ADDITIONAL AREAS

11.1. OCCUPATIONAL RADIATION PROTECTION

LEGAL AND REGULATORY FRAMEWORK

General considerations

The NRA and MHLW are the primary regulatory bodies responsible for implementation of the requirements concerning occupational exposure. The legislative framework is defined by the following acts: the Atomic Energy Basic Act, the NRA Establishment Act, the Reactor Regulation Act, the Radiation Hazards Prevention Act, the Industrial Safety and Health Act, associated cabinet orders and ordinances.

The scope of the IRRS mission with respect to occupational radiation protection was the facilities and activities regulated by NRA. The NRA is responsible for the occupational radiation protection for workers in nuclear power plants, fuel cycle facilities, research reactors, interim storage and radioactive waste management facilities, facilities and activities involving radioactive sources (such as high activity irradiator facilities, radionuclide production facilities, sources in research laboratories and industrial radiography, tele therapy sources) and radiation sources such as linear accelerators. The NRA and the MHLW establish regulatory documents independently. The Radiation Council, a body connected to the NRA, participates in the final approval of the relevant acts and ordinances related to the radiation safety. Both the NRA and the MHLW establish dose limits, and the NRA approves licensees' limits and conditions of operations as a part of operational safety programme. There are many advantages in the establishment of a single standard or ordinance that represents the "Basic radiation protection standard". This standard would apply to all occupationally exposed workers, would include all items mentioned in GSR Part 3 and would be approved by both the NRA and the MHLW.

The MHLW has the legal right to perform occupational radiation protection inspections in the installations regulated and inspected by the NRA. The inspections of the two regulatory bodies are not coordinated and there is no formal communication between the NRA and MHLW as to findings in the inspections (See Recommendation R1).

Occupational (or public) radiation protection for existing exposure situations due to natural radiation, and these situations, (radon and cosmic radiation exposure for aircrew) are outside the scope of the IRRS mission.

Dose Limitation

The NRA action plan, developed in preparation for the IRRS mission, recognizes the need to reduce the annual dose limit to the lens of the eye to conform to GSR Part 3, however there is no plan for implementing the dose limit reduction. A limit of 2 mSv equivalent dose to the surface of the abdomen plus an internal committed effective dose of 1 mSv to a female worker during pregnancy is prescribed in the ordinances. The GSR Part 3 dose limitation focuses on the embryo or fetus, and establishes a 1 mSv limit. The GSR part 3 also states that the breast-fed infant should be afforded the same broad level of protection as is required for members of the public. The ordinances do not mention restrictions for mothers who are breast-feeding infants.

Optimization

NRA requires, in the Standard Review Plan of Approval of Operational Safety Programmes, that the licensees implement optimization in occupational radiation protection. Previous studies of annual collective doses in NPPs (ISOE database) show that from 1995 to 2014 for PWRs and BWRs worldwide, the annual collective dose per reactor fell by a factor 2 to 3 due to optimization (ALARA implementation) and continuous safety improvement actions. In Japan from 1995 to 2014, no significant reduction in the collective annual dose per reactor for PWRs or BWRs can be seen.

With regard a proposal to introduce the ICRP/IAEA concept of dose constraints into the legislation to serve as an optimization tool, the Radiation Council reports its view that the dose constraints are not necessary since the introduction of specific dose constraints for occupational exposure may hinder the flexible and optimized management of licensees' radiation protection measures. The previously mentioned Article 3.2 of the Ordinance on Prevention of Ionizing Radiation Hazards also precludes optimization. There are no regulatory mechanisms that allow the NRA to evaluate the effectiveness of optimization actions such as access to a national dose database or occupational radiation protection benchmarking between similar nuclear power plants. There are no guidelines for the Licensees to follow as to how to implement optimization and how to evaluate optimization initiatives (see Recommendation R3).

GENERAL RESPONSIBILITIES OF REGISTRANTS, LICENSEES AND EMPLOYERS

The Standard Review Plan of Approval of Operational Safety Programmes require that the licensee establishes and implements a radiation protection programme for the management and the assessment of activities where exposure to ionizing radiation is likely to occur. The programme aims at keeping the dose of the workers and of persons with frequent access to the facility within the annual limits and as low as reasonably achievable. For NPPs, there are no regulations or guides giving neither the details of the programme nor the expected competencies of the safety manager and his or her staff, and the number of staff required to carry out the programme. The operator has to regularly monitor compliance with the safety measures and keep records on occupational exposure and protective measures as prescribed by the technical specifications.

The Act on Prevention of Radiation Hazards due to Radioisotopes establishes in Articles 34 to 38 the requirement of the employer to contract one or more Radiation Protection Supervisor(s) (RPS), Class I, II or III depending on the risk assessment, whether open or sealed sources are handled and the activity of the source inventory. The position of Qualified Expert is not recognized in NRA regulations.

GENERAL RESPONSIBILITIES OF WORKERS

Under the Reactor Regulation Act, the Standard Review Plan of Approval of Operational Safety Programmes establish indirectly (through the employer) the obligations and responsibilities of workers. Workers must fulfil their obligations, receive training and carry out their duties for protection and safety such as correctly using personal protective equipment and monitoring devices. Occupationally exposed workers must carry out all radiation protection and safety procedures and are expected to report unsafe working conditions. There is no obligation for workers to provide information on their dose history; but employers are required to manage information regarding the dose records of all workers working in their installations

REQUIREMENTS FOR RADIATION PROTECTION PROGRAMMES

Nuclear facilities implement occupational radiation safety programmes as part of the Operational Safety Programmes. NRA carries out periodic inspections of nuclear facilities and activities in order to check and monitor compliance of the radiation protection programmes. For nuclear facilities, the regulations establish the responsibilities of the employer and also the need for cooperation between operators and contractors in order to ensure compliance with the regulations for external workers. Licensees are required to establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas consistent with GSR Part 3 and they must establish local rules, written instructions and radiation safety procedures. In Japan, no supervised areas are established, a requirement of GSR Part 3. Too little information was made available to evaluate whether the absence of designated supervised areas is conservative or not.

Licensees are responsible for making arrangements for the assessment and recording of occupational exposures, workplace monitoring and for workers' health surveillance, and they must provide workers with adequate information, instruction and training in radiation protection and safety.

MONITORING PROGRAMMES AND TECHNICAL SERVICES

Today around 600 000 workers are individually monitored for external radiation (photons and neutrons), with around 100 000 of these working in NPPs or FCFs. There are two main suppliers of this service, and a number of smaller laboratories attend to the rest. The techniques used are OSL, TLD, glass dosimetry and film. In the nuclear power plants (NPP) electronic personal dosimeters are used in conjunction with the legal dosimeter. Most workers in installations licensed by the NRA are monitored monthly.

With reference to internal monitoring, there is a requirement for quarterly monitoring for workers in nuclear facilities. This monitoring is carried out by direct measurement (Whole Body Counters). There are also bioassay laboratories available, and NIRS is considered to be the reference laboratory in this area. There are also laboratories for biological (cytogenetic) dosimetry.

Portable dose rate and surface contamination meters are required to be calibrated annually. Eight Secondary Standard Calibration facilities are available for calibration as part of the Japanese Calibration Service System. The national measurement standards for radiation are maintained by the National Institute of Advanced Industrial Science and Technology (AIST), through the National Metrology Institute of Japan, connected to METI. In some NPPs the calibration of the workplace equipment is carried out by the operator on site. Five registered certification training organizations carry out the training of radiation protection supervisors.

There is no government national dose register; however a non-profit organization called the Radiation Effects Association (REA) stores individual dose records. REA is financed by nuclear reactor and fuel cycle facilities. An attribution of REA is to receive and store individual dose records from companies that have shut down. However, there is no legal requirement to store dose records of occupationally exposed workers in the medical area. The medical area is outside the scope of the IRRS mission; however it is clear that all doses records should be kept, regardless of the occupationally exposed workers work area.

NRA requires that the licensees should carry out quality control and assurance activities on the occupational radiation protection services they contract. There is no authorization or approval process for these services in place (see Recommendation R2).

11.2. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

Control of Radioactive Discharges and Material for Clearance

The Reactor Regulation Act and the Radiation Hazards Prevention Act establishes regulations regarding control of discharges and clearance criteria for nuclear facilities and radiation facilities respectively. Both Acts require an application from licensees before granting authorization for releasing radioactive materials to the environment and for clearance.

Discharge criteria for authorized discharge limits for nuclear facilities are derived using the dose limit of 1 m Sv/year effective dose for the most affected members of the public. Optimization of discharge limits is achieved using the ALARA principle with a target dose value of 50 μSv/year, and is documented in the Operational Safety Programme. This Programme is developed by each licensee and approved by the NRA. The target value is in principle a dose constraint that is applied equally to all facilities.

The regulations for radiation facilities under the Radiation Hazards Prevention Act specify the criteria for discharges from these facilities. No target value is used for optimization of discharge limits for these cases. Instead conservative derivations of discharge limits are obtained with the conclusion that a large safety-margin is reached.

Criteria for clearance from regulatory control of materials used in nuclear facilities are established in the Reactor Regulation Act and its regulations. These criteria are based on dose criteria in accordance with the IAEA Safety Standards and the ICRP adopting reference level of 10 μSv/year. A similar clearance system is stipulated in the Radiation Hazards Prevention Act for radiation facilities. The IRRS team confirmed that for facilities regulated under the Radiation Hazards Prevention Act a set of clearance criteria consistent with the values in GSR Part 3 has been developed. In the case of nuclear facilities regulated under the Reactor Regulation Act a smaller set of clearance values (33 nuclides) has been developed for NPPs. NRA may consider having only a single consolidated list of clearance values that are applied to all facilities.

The licensee is required to prepare a plan including an evaluation of the target items for clearance and the measurement and evaluation methods, which has to be approved by NRA. NRA verifies and evaluates the results of this plan. If the material is under the prescribed limit for clearance, the material is either recycled or disposed of as industrial waste.

Environmental monitoring and control of public exposure

Requirements for monitoring at nuclear facilities are prescribed in the Reactor Regulation Act and the same requirements for radiation facilities are prescribed in the Radiation Hazards Prevention Act. The responsibility for monitoring on-site and in the vicinity of the regulated facility lies with the licensees for all regulated practices

Additionally regional governments and other agencies undertake environmental monitoring in their areas of jurisdiction as part of the national environmental monitoring programme. The regional monitoring programmes comprise an important part of the national monitoring programme, and the regional governments receive financial support and training from NRA. NRA collects and stores the relevant environmental data on a national basis.

NRA regularly receives data from the various components in the national monitoring programme, conducts weekly evaluation of the results and makes all monitoring results publically available by displaying it in a variety of formats on its public web site. In addition, the regional governments and other agencies display their regional data on their public web sites. NRA verifies the national monitoring programme data by entrusting the Japan Chemical Analysis Centre (JCAC), to organize inter-comparison for measurements performed by the regional monitoring programmes.

NRA maintains a series of 34 booklets called the Radiation Measurement Series that detail standard procedures for measurement and sampling. Although there are no regulations regarding use of these standards, they are widely distributed and used by measurement professionals in Japan. The quality of the programme is enhanced by this consistent use of standardised procedures. In addition, NRA arranges independent checks to be performed on the monitoring carried out by the local governments. Some of the monitoring organisations participate in IAEA inter-comparison exercises, in particular the marine monitoring capabilities. The monitoring measurements comprising the national monitoring programme are outsourced and performed by companies, some of which are accredited by relevant ISO standards.

The analyses of samples collected by the licensees are routinely outsourced to private radio-analytical laboratories although some licensees also have their own radiation measurement capabilities or laboratories. NRA does not require accreditation of the service providers performing the radiation measurements for the facilities or calibrations of equipment used for the environmental monitoring. Since the licensees have the responsibility to ensure their activities do not impact the surroundings according to the regulations prescribed by NRA, it follows in the current system that the licensees also have the responsibility to ensure that the measurements performed as part of their monitoring programme are quality-assured. A national calibration service is provided by the Japan Calibration Service System (JCSS), managed and funded under METI. The NRA uses the results of the

environmental monitoring performed by the local governments in the vicinity of nuclear facilities to verify the monitoring done by the licensees.

Licensees' inspections are performed as part of the Operational Safety Programme. The main objective of these inspections is to ensure that the procedures for operational safety, as part of the management system, are implemented. These inspections also include checking the procedures for radiation monitoring and measurement methodology.

Stricter quality assurance requirements regarding accreditations or calibrations, and quality control, would enhance compliance with IAEA Safety standard requirements regarding radiation protection of the public (see Recommendation R2).

11.3. SUMMARY

The regulations on occupational exposure require up-dating to be brought into line with GSR Part 3. The roles and responsibilities of NRA and the MHLW in the area of occupational radiation protection should be clearly established. Optimization techniques and tools should be made available and guidance on optimization provided to the licensee. The technical services should be subject to approval or authorization processes so that the technical quality of the services may be ensured.

The appropriate regulatory frameworks for control of radioactive discharges, material for clearance, and environmental monitoring and control of public exposure are covered well in the Japanese laws and regulations, but are not fully in line with the relevant requirements in IAEA Standards GSR Part 1 and GSR Part 3. A recommendation on authorization or approval processes for the providers of measurement services for environmental monitoring will ensure the technical quality of the measurement services and enhance quality assurance (see Recommendation R2).

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

Article 2 of the Atomic Energy Basic Act provides the basis of the regulatory framework for nuclear safety, nuclear security as well as for safeguards. It stipulates that the utilization of nuclear energy shall be limited to peaceful purposes and that ensuring safety shall be performed taking into account an established international standard for the purpose of assuring national security.

The NRA Establishment Act mandates NRA as a single governmental body for integrated management of nuclear safety, security and safeguards.

Under the Japanese regulatory framework, several measures are in place to ensure that interaction between security and safety is not compromised. The IRRS team was informed that:

- Licensees are required to evaluate the impact of security measures on safety;
- Safety officers can be granted access to information on physical protection.

Security and safety aspects need to be reviewed before granting the authorization prior to the restart of NPPs, which were shutdown following the TEPCO Fukushima Daiichi accident, based on the new regulatory requirements.

If the review of an application reveals a conflict between safety and security, NRA has the competence to request correcting modifications to the application.

12.2. REGULATORY OVERSIGHT ACTIVITIES

The legal framework establishes NRA as the single organization responsible for regulation of nuclear safety, security and safeguards. This is a good basis for effective and efficient regulatory oversight of the above areas.

In general, the Japanese regulatory framework does not differentiate between oversight activities in the fields of nuclear safety, security or safeguards. However, IRRS team observed NRA had recognized the importance of adequately balancing nuclear safety and security.

NRA's Code of Conduct on Nuclear Security Culture and the Statement on Nuclear Safety Culture stipulate that NRA shall endeavour to achieve a balance between safety and nuclear security and implement appropriate organizational measures in case of a conflict between the two areas.

The improvement of the safety and security interface is also stated as a mid-term NRA goal for the actual period and is planned to be implemented within the frame of the annual plans within the next four years. IRRS team observed the corresponding implementation activities are actually at a very early stage.

The IRRS team observed that currently the coordination and cooperation between the organizational units of NRA with safety respectively security responsibilities is taking place on an ad hoc basis and not formalised. A concrete concept and project planning to put an effective safety and security interface into place, has not been established yet.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The improvement of the safety and security interface is one of the priority goals of actual NRA mid-term planning period. The corresponding implementation activities are actually at a very early stage. Currently, the coordination and cooperation between the organizational units of NRA with safety respectively security responsibility is taking place on an ad-hoc basis and is not formalised. A concrete concept and project planning to put an effective safety and security interface into place, has not been established yet.*	
(1)	**BASIS: GSR Part 1, Requirement 12 states that** *"The government shall ensure that, within the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material"
S13	**Suggestion: NRA should consider expediting improvements in the arrangements to assess, oversee and enforce nuclear safety and security in an integrated manner.**

12.3. INTERFACE AMONG AUTHORITIES

Other authorities are also involved in tasks related to nuclear safety and security, such as the Cabinet Office for the Nuclear Emergency Preparedness, the National Police Agency, the Japan Coast Guard. The NRA's interaction with these authorities includes the performance of exercises connected to contingency and emergency plans.

Since 2015 the security division of NRA participates in the comprehensive emergency exercise.

12.4. SUMMARY

The NRA Establishment Act mandates NRA as a single governmental body for integrated management of nuclear safety, security and safeguards. The improvement of the safety and security interface is one of the priorities of the actual mid-term planning period of NRA.

The IRRS team recommends that, NRA should continue its efforts to improve the interface between nuclear safety and security based on a clear concept and an efficient project organization.

APPENDIX I – LIST OF PARTICIPANTS

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GROUP PHOTO

APPENDIX II – MISSION PROGRAMME

First Week

Time	SAT 09.01	SUN 10.01	MON 11.01	TUE 12.01	WED 13.01		THU 14.01			FRI 15.01			SAT 16.01			SUN 17.01
9:00	Arrival of Team Members			TL's Briefing to NRA Commissioners	TL's Briefing to NRA Commissioners		Interviews	Site Visits		Interviews	Site visits		Discussing and improving Draft Report	Cross-Reading	TL, DTL, TC and DTC read everything	**Free day, Social Tour**
9:45			Entrance Meeting (NRA, IAEA, TL)	Interviews	Observation meeting of NRA Commissioner Meeting	Interviews			Writing of the rep ort			DTC writes introductory parts				
11:00																
12:00		Team Lunch	Lunch	Lunch	Lunch		Lunch			Lunch			Lunch			
14:00		Initial Team Meeting: • Self-introduction • IRRS process and refresher training • Main objectives • Report writing • Schedule • First observations • In-Group discussions	Interviews	Interviews	Observation of NRA Press Conference	Interviews	Interviews	Site Visits	DTC writes introductory parts	Interviews	Site Visits	Cross-reading by TM	Finalisation of a Preliminary Draft Report			
15:00																
16:00					**Written preliminary findings delivered**		Daily Team Meeting									
17:00			Daily Team Meeting	Daily Team Meeting	Daily Team Meeting: discussion of findings	Leaving for site visits	Writing of the report		Leaving for site visits	Daily Team Meeting **Draft text to the Secretariat**						
18:30	Dinner	Team Dinner	Welcome Reception	Dinner	Dinner		Dinner			Dinner			Dinner			
20:00			Writing of the report	Writing of the report	Secretariat edits the report	Writing of the report	Writing of the report			Secretariat edits the report **Preliminary Draft Report Ready**			Secretariat edits the report			

Second Week

<table>
<tr><th>Time</th><th>MON
18.01</th><th>TUE
19.01</th><th>WED
20.01</th><th>THU
21.01</th><th>FRI
22.01</th></tr>
<tr><td>9:45</td><td></td><td rowspan="2">Cross-Reading
TL, DTL, TC and DTC read everything
Finalisation</td><td rowspan="2">Host reads Draft</td><td rowspan="2">Written comments by the Host
General discussion on the draft report with host</td><td></td></tr>
<tr><td>10:00</td><td>Policy Issues
Discussion</td><td>Exit Meeting
Press Conference</td></tr>
<tr><td>12:00</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td>Lunch</td><td rowspan="2">Lunch</td></tr>
<tr><td>13:00</td><td rowspan="3">Individual discussions of follow-up analysis and R, S and GP with counterparts</td><td rowspan="4">Discussion of the report by the team</td><td rowspan="4">TC, DTC prepare Executive Summary and exit presentation</td><td rowspan="3">Host reads Draft</td><td rowspan="3">TL finalises Executive Summary and exit presentation</td><td rowspan="3">TC Drafts the Press Release</td><td rowspan="3">Team meeting for finalisation of the Report</td><td rowspan="5">Departure Home</td></tr>
<tr><td>14:00</td></tr>
<tr><td>15:00</td></tr>
<tr><td>17:00</td><td>Daily Team Meeting</td><td>Discussion of Executive Summary with the team</td><td>Briefing of the DDG
Finalisation of the press release
Submission of the Final Draft</td></tr>
<tr><td>18:00</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td rowspan="2">18:30
Farewell Party</td></tr>
<tr><td>19:30</td><td rowspan="2">TL, DTL, TC and DTC include changes</td><td rowspan="2">Secretariat finalises text
Submission of the Draft to the Host</td><td rowspan="2">Free</td></tr>
<tr><td>21:00</td><td>Free</td></tr>
</table>

APPENDIX III – SITE VISITS

Fukushima Daiichi NPP
Takahama NPP
Rokkasho Reprocessing Plant
JAEA Tokai Research Reactor
JAEA Tokai Facility for Radioactive Sources (J-PARC)

APPENDIX IV – POLICY ISSUES

Human Resource Development (HRD)

The NRA explained the challenges it is facing on HRD, namely lack of sufficient number of qualified experts, and asked for IRRS team members' experience with particular focus on the combination of HRD and the improvement of regulatory framework. The inspection was suggested as one example for the discussion.

IRRS Team members shared their experiences as senior experts on the given issue, as in the following, with focusing on HRD for inspectors:

- Need to change mind-set of inspectors to have more active supervision on the licensees' activities rather than sticking to the current inspection manual
- Useful to recruit mid-career experts with experience in private sectors through strengthening the attractiveness of the NRA as a workplace
- Develop tailored HRD programme to each individual
- Utilize international cooperation in training inspectors
- Recognize clear role of the inspectors who supervises licensees and may take enforcement actions to them while licensees have prime responsibility for safety
- The training for inspectors takes 1 or 2 years and such trainings should take a holistic approach and include the development of questioning attitude and communication skills with operating staff.
- Enhancement of training for inspectors should start now, not waiting for the change of inspection system.

Implementation of back-fitting

The NRA explained that the Japanese legal system require back-fitting of new requirements into the existing nuclear facilities and its basic policy for its implementation, and asked for the IRRS team members' experience with focusing on the transition period for complying with the new regulatory requirements.

IRRS team members shared their experiences as senior experts on the given issue, as in the followings:

- Transition period may be determined taking into consideration of (a) risk information, (b) international reference such as the IAEA safety standard and (c) the maximum efforts by the licensees. Such decision should be made as regulatory body not by individual officer, taking into accounts of the views of different stakeholders.
- Urgency for applying transition period is set based on the frequency of hazards, and transition periods are set in accordance with graded approach, e.g. 1 to 5 years, in the national practice
- Once the regulatory body determines the implementation of back-fitting with transition periods, such order should be clear and stick to the determined transition periods for credibility.

APPENDIX V – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**		
	FERAPONTOV Alexey REGIMBALD Andre SCHWARZ Georg	MATSUURA Katsumi, Director, Policy Planning and Coordination Division SHIMA Masakazu, Director for Preparation for IRRS	HIRANO Masashi, Senior Coordinator for International Collaboration
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	FERAPONTOV Alexey REGIMBALD Andre SCHWARZ Georg	FUJITA Kenichi, Director, International Affairs Office SATO Gyo, Director, Nuclear Regulation Policy Planning Division	HIRANO Masashi, Senior Coordinator for International Collaboration
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	KRS Petr MUNUERA Antonio REGIMBALD Andre TIIPPANA Petteri	KANEKO Shuichi, Director, Personnel Division MUKAE Takashi, Director, Management Promotion Office KURASAKI Takaaki, Director, Regulatory Standard and Research Division	ABE Kiyoharu, Senior Expert
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	KRS Petr MUNUERA Antonio TIIPPANA Petteri	KANEKO Shuichi, Director, Personnel Division MUKAE Takashi, Director, Management Promotion Office KURASAKI Takaaki, Director, Regulatory Standard and Research Division	ABE Kiyoharu, Senior Expert
5.	**AUTHORIZATION**		
	FERON Fabien LEE Suk Ho	SATO Gyo, Director, Nuclear Regulation Policy Planning Division YAMAGATA Hiroshi, Director, Division of Regulation for PWR	ICHII Naoto, Nuclear Safety Specialist, International Affairs Office
6.	**REVIEW AND ASSESSMENT**		
	FERON Fabien LEE Suk Ho	SATO Gyo, Director, Nuclear Regulation Policy Planning Division YAMAGATA Hiroshi, Director, Division of Regulation for PWR	ICHII Naoto, Nuclear Safety Specialist, International Affairs Office
7.	**INSPECTION**		
	STRITAR Andrej WERT Leonard	SAWADA Atsuo, Director, Division of Regulation for Inspection of Nuclear Reactor Facilities	YAMADA Tomoho, Director-General for Nuclear Regulation

	IRRS EXPERTS	Lead Counterpart	Support Staff
8.	**ENFORCEMENT**		
	STRITAR Andrej WERT Leonard	SAWADA Atsuo, Director, Division of Regulation for Inspection of Nuclear Reactor Facilities	YAMADA Tomoho, Director-General for Nuclear Regulation
9.	**REGULATIONS AND GUIDES**		
	FOY Mark KRS Petr MUNUERA Antonio PATHER Thiagan REGIMBALD Andre RYAN Thomas TIIPPANA Petteri WALDMAN Ricardo	KURASAKI Takaaki, Director, Regulatory Standard and Research Division KUROMURA Shinzo, Director, Division of Regulation for Advanced Reactors, Research Reactors, and Decommissioning KATAOKA Hiroshi, Director, Division of Regulation for Nuclear Fuel (Fabrication and Reprocessing) Facilities and Use of Nuclear Material MAEKAWA Yukinori, Director, Division of Regulation for Radioactive Waste, Storage and Transport NISHIDA Ryozo, Director, Radiation Protection and Safeguards Division	ABE Kiyoharu, Senior Expert OGISO Zenichi, Senior Expert, Regulatory Standard and Research Division YAMANAKA Takeshi, Senior Specialist, Regulatory Standard and Research Division YONEHARA Hidenori, Specialist, Radiation Protection and Safeguards Division
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	AALTONEN Hannele	ARAKI Shinichi, Director, Emergency Preparedness/Response and Nuclear Security Division NISHIDA Ryozo, Director, Radiation Protection and Safeguards Division	AKASHI Kazuhiko, Director for International Affairs
11.	**ADDITIONAL AREAS**		
	HUBBARD Lynn HUNT John	NISHIDA Ryozo, Director, Radiation Protection and Safeguards Division SATO Gyo, Director, Nuclear Regulation KUROMURA Shinzo, Director, Division of Regulation for Advanced Reactors, Research Reactors, and Decommissioning KATAOKA Hiroshi, Director, Division of Regulation for Nuclear Fuel (Fabrication and Reprocessing) Facilities and Use of Nuclear Material MAEKAWA Yukinori, Director, Division of Regulation for Radioactive Waste, Storage and Transport AIHARA Yuko, Deputy Director, Radiation Monitoring Division	YAMANAKA Takeshi, Senior Specialist, Regulatory Standard and Research Division YONEHARA Hidenori, Specialist, Radiation Protection and Safeguards Division

	IRRS EXPERTS	Lead Counterpart	Support Staff
12	**INTERFACE WITH NUCLEAR SECURITY**		
	FERAPONTOV Alexey SCHWARZ Georg	SATO Gyo, Director, Nuclear Regulation YAMAGUCHI Hirotaka, Director, Nuclear Security Office	HIRANO Masashi, Senior Coordinator for International Collaboration

APPENDIX VI – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	GP1	Good Practice: The prompt establishment of a legal and governmental framework supporting a new independent and transparent regulatory body with increased powers.
	GP2	Good Practice: NRA's prompt and effective incorporation of the lessons learnt from the TEPCO Fukushima Daiichi accident in the areas of natural hazards, severe accident management, emergency preparedness and backfitting of existing facilities, into the new regulatory framework.
	R1	Recommendation: The government should ensure that the Japanese regulatory authorities having responsibilities relevant to nuclear and radiation safety develop and implement an effective, collaborative process for the exchange of information regarding policies, authorisations, inspections and enforcement actions to provide coordinated and effective regulatory oversight that should also ensure a harmonized regulatory framework under their respective responsibilities.
	S1	Suggestion: NRA should consider improving its liaison with the relevant organizations for joint inspections and oversight of outsourced inspections.
	R2	Recommendation: The Government should empower the regulatory body[5] to establish requirements for authorization or approval processes for service providers for monitoring of occupational and public exposures, and environmental monitoring in general, and verify that these requirements are met by licensees.
2. GLOBAL NUCLEAR SAFETY REGIME	-	-
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R3	Recommendation: NRA should put greater priority and allocate more resources on its oversight of the implementation of radiation protection measures by licensees as well as its participation in the development of

[5] An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory *process*, including issuing *authorizations*, and thereby regulating the *safety* of *nuclear installations*, *radiation safety*, the *safety* of *radioactive waste management* and *safety* in the *transport* of *radioactive* material. (IAEA Safety Glossary, 2016 Edition)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		international standards in radiation protection and related research activities in collaboration with NIRS.
	R4	Recommendation: NRA should evaluate the effectiveness of its current organisational structure, implement appropriate cross cutting processes, strengthen the collection of information from interested parties when planning its annual activities and develop tools to measure its performance and use of resources.
	R5	Recommendation: NRA should further develop and implement the activities related to the evaluation of competencies, execution of training programmes, on the job training, internal job rotation, and strengthening safety research, co-operation with technical support organisations (JAEA), universities, research organisations and international and overseas organisations, to ensure it has both qualified and experienced staff to fulfil its regulatory responsibilities in nuclear and radiation safety.
	S2	Suggestion: NRA should consider developing a strategy for attracting new and retaining its current technical expertise through seeking to improve the attractiveness of NRA as an employer of choice and the roles that its staff undertake by providing them with more responsibilities, the ability to directly influence safety performance of licensees, options to regulate in all various sectors of the industry, ability to develop legislative requirements that impact national policy, and having a clear career path to senior levels within the NRA.
	S3	Suggestion: NRA should consider reviewing the effectiveness of the mechanisms to communicate the outcomes of the regulatory review and assessment, further regulatory expectations and current issues to licenses/ applicants.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R6	Recommendation: NRA should complete, document and fully implement its integrated management system for all regulatory and supporting processes needed to deliver its mandate. Grading of the application of management system should be applied consistently and generic processes should be fully developed such as control of documents, products, records and management of change. The effectiveness of the NRA management system should be monitored

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		and measured in a comprehensive way to identify opportunities for improvement.
	S4	Suggestion: NRA should consider introducing specific measures such as awareness training or surveys to promote and sustain high level of safety culture in the conduct of its activities.
	S5	Suggestion: NRA Commissioners should consider taking a strategic approach to the implementation of the management system demonstrating their commitment to the project by initiating a specific multi-year management system development plan and by reviewing its implementation on periodic basis.
	S6	Suggestion: NRA should consider developing a hierarchical structure for the management system that is easy to use and which supports effective and consistent implementation of regulatory activities. Specific descriptions of each process should be developed in a unified format including requirements, risks, interactions, inputs, process flow, outputs, records and measurement criteria.
5. AUTHORIZATION	S7	Suggestion: NRA should consider enhancing the interfaces and overall coherence of the existing three regulatory processes related to NPP ageing management.
	R7	Recommendation: NRA should incorporate the findings of the facility inspection into the review and assessment and the authorization process for radiation sources.
	R8	Recommendation: NRA should establish requirements relating to consideration of decommissioning during all life stages of nuclear and radiation facilities and criteria for the release of sites at the end of decommissioning.
6. REVIEW AND ASSESSMENT	S8	Suggestion: NRA should consider reviewing its current operating experience feedback process to: • determine whether its criteria allow the reporting of enough safety significant events; • ensure lessons learned from these events, including return to service from extended shutdowns, are taken into account by the licensees and

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		actually result in appropriate and timely measures at the facilities.
	S9	**Suggestion:** NRA should consider reviewing the regulatory requirements for all nuclear facilities to ensure that submissions by licensees give full systematic consideration to human and organizational factors and human errors in the design of the plant, and the sufficiency of qualified and experienced NRA resource to assess this.
7. INSPECTION	R9	**Recommendation:** The government should improve and simplify the inspection framework to: • Increase NRA flexibility to provide for efficient, performance based, less prescriptive and risk informed regulation of nuclear and radiation safety; • Ensure NRA inspectors have formal rights for free access to all facilities and activities at any time; • Allow NRA decisions about reactive inspections to be made at the lowest possible level. Based on the revised inspection framework the NRA should develop and implement a programme of inspection of all facilities and activities specifying types and frequency of regulatory inspections (including scheduled inspections and unannounced inspections) in accordance with a graded approach.
	S10	**Suggestion:** NRA should consider improving training and retraining of its inspectors in order to improve their competencies for inspections, associated assessments and decision making.
8. ENFORCEMENT	R10	**Recommendation:** NRA should establish a documented enforcement policy with criteria and processes for determining graded sanctions or penalties for non-compliances, and a provision for processing orders to minimise the decision time for corrective actions if there is imminent likelihood of safety significant event.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
9. REGULATIONS AND GUIDES	R11	**Recommendation: NRA should:** • **improve and document its process for regularly evaluating and reviewing regulations and guides and as the emerging need arises;** • **supplement the regulations with guidance documents where necessary; and** • **improve its guidance on Periodic Safety Assessment of Continuous Improvement.**
10. EMERGENCY PREPAREDNESS AND RESPONSE	R12	**Recommendation: NRA and other authorities having jurisdiction for radiation sources should develop a single set of requirements and guidance for EPR in relation to radiation sources including requirements related to emergency plans, arrangements for timely notification and response, and quality assurance programme using graded approach.**
	S11	**Suggestion: NRA should consider strengthening its plans and procedures to consistently respond to emergencies related to radiation sources.**
	R13	**Recommendation: NRA should establish:** • **complete set of Emergency Action Levels for nuclear facilities other than NPPs and associated guidance to promptly define Emergency Action Levels for all nuclear operators;** • **verification process that licensees participate in provision of information to the public within emergency planning zones around nuclear facilities at the preparedness stage.**
	S12	**Suggestion: The Government should consider ensuring that the relevant authorities establish consistent requirements for categories of emergency workers performing similar tasks.**
11. ADDITIONAL AREAS	-	-
12. INTERFACE WITH NUCLEAR SECURITY	S13	**Suggestion: NRA should consider expediting improvements in the arrangements to assess, oversee and enforce nuclear safety and security in an integrated manner.**

APPENDIX VII – COUNTERPART'S REFERENCE MATERIAL USED FOR THE REVIEW

1	IRRS Japan 2016
2	SARIS Summary
3	Outline of Nuclear Regulation of Japan
4	List of Attachment Files
5	List of Legislation and Abbreviations
6	151217 List of Eratta and Additional Attachment Files
7	The Atomic Energy Basic Act
8	Review on an Organization in charge of Nuclear Safety Regulation(Understanding by Relevant Ministers)
9	Basic Policy on the Reform of an Organization in charge of Nuclear Safety Regulation(Cabinet Decision)
10	The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority
11	About requirements for ensuring transparency and neutrality in hearing opinions of external experts
12	Nuclear Regulation Authority Mid-term Goal(2015-2020)
13	Act on the National Institute of Radiological Sciences
14	The Cabinet Order for Organization of the Nuclear Regulation Authority
15	The Act on Special Measures Concerning Nuclear Emergency(For QID13 in SM1-1)
16	Basic Act on Disaster Control Measures(For QID13 in SM1-1)
17	NRA EPR Guide(For QID13 in SM1-1)
18	Act on the Japan Atomic Energy Agency, National Research Development Agency
19	Nuclear Regulation Authority Management Rules
20	Management Policy(NRA's Core Values and Principles)
21	List concerning laws overseen by the NRA
22	Statement on Nuclear Safety Culture
23	The NRA Ordinance on Technical Standards for QMS Concerning the Design and Construction of Commercial Power Reactor for Licensee of Commercial Reactor Operation and System for their Inspection
24	The NRA Ordinance on Technical Standards for Commercial Power Reactors Facilities
25	The NRA Ordinance on Standards for the Location, Structures and Equipment of Commercial Power Reactors
26	The Regulatory Guide of the NRA Ordinance on Standards for the Location, Structure, and Equipment of Commercial Power Reactors

27	(For SARIS module Module9-5 QID63) Article 35 of the Commercial Reactors Technical Standard Guide
28	(For SARIS module9-1 SQID7.2) Future Use of Commercial Standards by the Nuclear Regulation Authority
29	(For SARIS module9-1 SQID7.2) Measures for reflecting nuclear facility operating experiences
30	(For SARIS Module9-1 SQID7.2) Promotion of Research on Safety by the Nuclear Regulation Authority
31	(For SARIS Module9-5 QID8 9-6 QID3) Article 10 of the Commercial Reactors QMS Guide
32	(For SARIs Module9-5 QID63) Appendix7 of the Commercial Reactors Technical Standard Guide
33	(Module9-6 SQID17.1&14,15) Guidelines on Implementing Measures for Aging Management(Part)
34	Basic Act on Disaster Control Measures
35	Nuclear Emergency Act
36	NRA EPR Guide
37	Basic Plan for Disaster Preparedness
38	Nuclear Emergency Response Manual
39	NRA Initial Response Manual
40	Off-Site Center Manual
41	Japan Electric Association Guide
42	Order for Nuclear Operator's EPR plan
43	Guide for Nuclear Operator's EPR plan
44	NRA EPR Plan
45	NRA Organization Ordinance(For SARIS module3)
46	Nuclear Regulation Authority Management Rules(For SARIS module3)
47	Reactor Regulation Act (For SARIS Module 3)
48	Commercial Reactors Ordinance (For SARIS Module 3)
49	Research Reactors Ordinance (For SARIS Module 3)
50	Research Power Reactors Ordinance (For SARIS Module 3)
51	Refining Ordinance (For SARIS Module 3)
52	Fuel Fabrication Ordinance (For SARIS Module 3)
53	Spent Fuel Storage Ordinance(For SARIS Module 3)
54	Reprocessing Ordinance (For SARIS Module 3)

55	Category 1 Waste Disposal Ordinance (For SARIS Module 3)
56	Category 2 Waste Disposal Ordinance (For SARIS Module 3)
57	Waste Storage Ordinance (For SARIS Module 3)
58	Nuclear Fuel Materials Use Ordinance (For SARIS Module 3)
59	Nuclear Source Materials Use Ordinance (For SARIS Module 3)
60	Commercial Reactors Dose Limit Notice (For SARIS Module 3)
61	Refining Dose Limit Notice (For SARIS Module 3)
62	Fuel Fabrication Dose Limit Notice (For SARIS Module 3)
63	Research Reactors Dose Limit Notice (For SARIS Module 3)
64	Amount of RI Notice (For SARIS Module 3)
65	Industrial Safety and Health Act(For SARIS Module 3)
66	Handling of Environmental Pollution Ordinance
67	E Practical Measures for Evacuees to Return Their Homes
68	J Practical Measures for Evacuees to Return Their Homes
69	Act on Prevention of Radiation Hazards due to Radioisotopes, etc.
70	The Cabinet Order for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc.
71	The NRA Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes etc.
72	JIS concerning radiation sources
73	What to Do If You Find an Uncontrolled Radioactive Material
74	Notification on Technical Details for On-Site Transportation of Radioisotopes, etc.
75	The Notification on Technical Details for Off-Site Transportation of Radioisotopes, etc.
76	Ministerial Ordinance on the organization to which records are delivered, pursuant to the provisions of the Ordinance for Enforcement of the Act on Prevention of Radiation Hazards Due to Radioisotopes, etc.
77	Regarding the Change of the Name of the Designated Record Storage Body Pursuant to the NRA Ordinance for Enforcement of the Act on Prevention of Radiation Hazards Due to Radioisotopes, etc.
78	National laws to control the management and protection of radioactive sources (major ones) SQID 7.1-related
79	Notification to stipulate the number of hours for education and training
80	Overview of the Whistleblower Protection Act
81	Notification to stipulate the number of hours of training courses

82	Notification to Designate the Purpose of Use concerning the Notification for a Temporary Change of the Place of Use
83	For Enforcement of the Prime Minister's Office Ordinance on Partial Revisions of the NRA Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc., and Related Notifications (Notice)
84	Notification to Specify Standards for the Amount, etc. of Radioisotopes
85	Notification to Stipulate Detailed Technical Standards for Design Certification, etc.
86	Source Tracking System
87	Notification to Stipulate Certification Requirements for Radioisotope Equipped Devices with an Indicator that are regarded as Approved Devices with Certification Label
88	Major distribution channels of radioactive sources
89	Act on Technical Standards for Prevention of Radiation Hazards
90	Regulations for handling of radiation sources
91	Notification to Stipulate Sealed Radioisotopes that may have a Serious Influence on Human Health
92	Import procedure of radioactive sources
93	Whole Concept of Medical Care for Emergency Exposure
94	List of States that have made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources and the Supplementary Guidance on the Import and Export of Radioactive Sources (6 May 2014)
95	Answer to the State Self-Assessment Questionnaire (27 May 2010)
96	Table for SARIS Module 4-6 SQID 17.3
97	Report on Dose, etc. of Radiation Worker
98	The Fuel Fabrication Dose Limit Notice
99	The Commercial Reactors Dose Limit Notice
100	The Research Reactors Dose Limit Notice
101	The NRA Ordinance Concerning the Installation and Operation of Commercial Power Reactors
102	The Standard Review Plan on Approval of Operational Safety Program of Commercial Power Reactor Facilities
103	Rules for Requirements for Operations Manager
104	The Guideline for Periodic Safety Assessment of Continuous Improvement of Commercial Power Reactors
105	On-site Inspection Implementation Guideline (Instruction) upon Receipt of Reports on Deviations from the Power Reactor Facility Operation Limits
106	The Implementation Guideline for Operational Safety Inspection for Commercial Power Reactor Facilities
107	Guide for Pre-Service Inspection of Commercial Power Reactors

108	Guide for Periodic Facility Inspection of Commercial Power Reactors
109	Guide for Welding Safety Management Review
110	Guide for Periodic Safety Management Review
111	The NRA Ordinance Concerning the Installation and Operation of Research and Test Reactors
112	The Standard Review Plan on Approval of Operational Safety Program of Research and Test Reactors
113	The Regulatory Guide on the NRA Ordinance on Standards for the Location, Structure, and Equipment of Research and Test Reactors
114	NRA Ordinance on Technical Standards for the Design and Construction Methods of Research and Test Reactors
115	The NRA Ordinance on Technical Standards for the Capabilities of Nuclear Research and Test Reactors, etc.
116	The NRA Ordinance on Technical Standards for Quality Management System Concerning the Design and Construction of Research and Test Reactors for Licensee of Research and Test Reactors and System for their Inspection
117	The NRA Ordinance on the Installation and Operation of Power Reactors at the Research and Development Stage
118	The Standard Review Plan on Approval of Operational Safety Program of Power Reactor Facilities at the Research and Development Stage
119	The Cabinet Order for Enforcement of the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors
120	The NRA Ordinance on Standards for the Location, Structure, and Equipment of Nuclear Research and Test Reactors, etc.
121	The Regulatory Guide for Reviewing Safety Design of Water-cooled Test Reactor Facilities
122	Operational Safety Inspection Implementation Manual
123	The NRA Ordinance on Technical Standards for Power Reactor Facilities at the Research and Development Stage
124	The NRA Ordinance on Standards for the Location, Structure, and Equipment of Power Reactors Facilities at the Research and Development Stage
125	The NRA Ordinance on Activity of Spent Fuel Reprocessing
126	The NRA Ordinance on Activity of Fuel Fabricating and Enrichment
127	The NRA Ordinance on the Use, etc. of Nuclear Fuel Materials
128	The NRA Ordinance on Use of Nuclear Source Materials
129	The Reprocessing Permit Ordinances and Guide
130	The Fuel Fabrication Permit Ordinance and Guide
131	The Nuclear Fuel Materials Use Permit Ordinance and Guide
132	The NRA Ordinance on Technical Standards for Design and Construction Method of Reprocessing Facilities
133	The NRA Ordinance on Technical Standards for the Capabilities of Fuel Fabrication Facilities
134	The NRA Ordinance on Technical Standards for the Design and Construction Methods of Fuel Fabrication Facilities

135	The Standard Review Plan on Approval of Operational Safety Program of Reprocessing Facilities
136	The Standard Review Plans on Approval of Operational Safety Programs of Fuel Fabrication Facilities
137	The Standard Review Plan on Approval of Operational Safety Program of Facilities using Nuclear Fuel Materials
138	The NRA Ordinance on Technical Standards for the Capabilities of Reprocessing Facilities
139	The NRA Ordinance on Technical Standards for Quality Management System Concerning the Design and Construction of Reprocessing Facilities for licensee of Reprocessing Activity and System for their Inspection
140	The Guideline for Periodic Safety Assessment of Continuous Improvement of Fuel Fabrication Facilities and Reprocessing Facilities Safety
141	The NRA Ordinance on the Activity of Waste Interim Storage and Treatment of Nuclear Fuel Material or Material Contaminated by Nuclear Fuel Material
142	The NRA Ordinance on Activity of Interim Storage of Spent Fuel
143	The NRA Ordinance on Activity of Category 1 Waste Disposal of Nuclear Fuel Material and Materials Contaminated by Nuclear Fuel Material
144	The NRA Ordinance on Activity of Category 2 Waste Disposal of Nuclear Fuel Material or Materials Contaminated by Nuclear Fuel Material
145	The NRA Ordinance on Technical Standards for the Design and Construction Methods of Spent Fuel Interim Storage Facilities
146	The Regulatory Guide of the NRA Ordinance on Standards for the Location, Structure and Equipment of Spent Fuel Interim Storage Facilities
147	The NRA Ordinance on Technical Standards for the Capabilities of Spent Fuel Interim Storage Facilities
148	The Standard Review Plan on Approval of Operational Safety Program of Spent Fuel Interim Storage Facilities
149	The Regulatory Guide of NRA Ordinance on Standards for the Location, Structure, and Equipment of Category 2 Waste Disposal Facilities
150	The Guideline for Periodic Safety Review etc. for Category 2 Waste Disposal Facilities
151	The Regulatory Guide of NRA Ordinance on Standards for the Location, Structure, and Equipment of Waste Interim Storage and Treatment Facilities
152	The Guideline for Periodic Safety Review of Waste Interim Stroge and Treatment Facilities
153	The Standard Review Plan on Approval of Operational Safety Program of Waste Interim Storage and Treatment Facilities
154	The NRA Ordinance on Confirmation of Radioactive Concentrations of Material used in Activities of Refining Nuclear Source or Nuclear Fuel Materials, etc
155	The NRA Ordinance on Confirmation, etc of Radioactive Concentrations of Material used in Nuclear Research and Test Reactors, etc.
156	The NRA Ordinance on Technical Standards for the Design and Construction Methods for Specific Waste Disposal Facility or Specific Waste Interim Storage and Treatment Facility
157	The NRA Ordinance on Technical Standards for the Capabilities for Specific Waste Disposal Facility or Specific Waste Interim Storage and Treatment Facility
158	The Standard Review Plan on Approval of Operational Safety Program of Waste Disposal Facilities for Category 2 Waste Disposal Activities
159	Notification on Technical Details for Category 2 Waste Disposal Facilities
160	The NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc.

161	The Notification on Technical Details for Off-Site Transportation of Nuclear Fuel Materials, etc.
162	Establishment of the target level for management of radioactive materials in tap water
163	Public Announcement on the Items of Goods Subject to Import Quotas, the Places of Origin or Places of Shipment of Goods Requiring Approval for Import, and Other Necessary Matters concerning Import of Goods
164	Specifications and Standards for Foods, Food Additives, etc.
165	Strategy to Make Japan the Safest Country in the World
166	The Japan Coast Guard Act
167	The Act for Establishment of the Cabinet Office
168	The Regulations on Labour Standards for Minors
169	The Water Pollution Control Law
170	The Air Pollution Control Act
171	The Water Supply Act
172	Basic Policy for Emergency Decontamination Work
173	For Export Approval of Radioisotopes
174	Fundamental Approach to Ensuring Nuclear Security
175	Guidelines for Radiation Measurement in Export Containers at Ports and Bays
176	Handling of Permit of Use and Documents to Prove Registration of Use, Selling or Rental Business concerning Import of Radioisotopes
177	Notification of the Ministry of Economy, Trade, and Industry No. 334
178	Radioactive Substances Designated by the Minister of Health, Labour and Welfare
179	Strengthening of Japan's Nuclear Security Measures
180	Procedures for Issue of Verification Certificate for Export of Radioisotopes
181	The Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors
182	The Act for Establishment of the Nuclear Regulation Authority
183	Code of Criminal Procedure(Part I and Part II)
184	Electricity Business Act
185	Export Trade Control Order
186	Foreign Exchange and Foreign Trade Act
187	FY2013 Annual Report
188	Guideline for Ensuring Safety of Raw Materials and Products Containing Uranium or Thorium

189	Import Trade Control Order
190	Act on Securing, Etc. of Equal Opportunity and Treatment between Men and Women in Employment
191	Administrative Procedure Act
192	code-of-contact-status-list
193	Industrial Safety and Health Act
194	Labour Standards Act
195	National Public Service Act
196	National Public Service Ethics Act
197	Ordinance for Enforcement of the Civil Aeronautics Act
198	Ordinance of the Ministry Specifying Goods and Technologies Pursuant to Provisions of the Appended Table 1 of the Export Control Order and
199	Ordinance on Prevention of Ionizing Radiation Hazards
200	Public Records and Archives Management Act (Tentative translation)
201	Regulatory Guide for Reviewing Safety Design of Light Water Nuclear Power Reactor Facilities
202	The Police Law
203	Regulatory Guide for Reviewing Classification of Importance of Safety Function of Light Water Nuclear Power Reactor Facilities
204	Regulatory Guide for Reviewing Safety Assessment of Light Water Nuclear Power Reactor Facilities
205	Regulatory Guide for the Annual Dose Target for the Public in the Vicinity of Light Water Nuclear Power Reactor Facilities
206	Reviewing Evaluation of Dose Target for Surrounding Area of Light Water Nuclear Reactor Facilities
207	Examination Guide for Technical Capability of License Holders of Nuclear Power
208	Basic Guides for Safety Review on Dismantling of Nuclear Reactor Installations
209	Regulatory Guide for Meteorological Observation for Safety Analysis of Nuclear Power Reactor Facilities
210	IAEA_HP(Completes IPPAS Mission in Japan)
211	Code of Conduct on Nuclear Security Culture
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222	#5-1 基準の強化
223	#5 サイクル、ＲＲ
224	#6-0 火山影響評価ガイド
225	#6-1 外部火災ガイド
226	#6-2 竜巻ガイド
227	#7-1PSR
228	#7-2PSR スライド
229	#8 他省庁連携
230	#15 実用炉規則
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245	4 Competence Management at NRA
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252	11 Emergency response members and Detailed rules about duties of emergency response members
253	12 Copy of the Nuclear Regulation Authority homepage
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257	2_NRA Nuclear Safety Training Facility
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272	10 九州電力会社川内原子力発電所原子炉施設保安規定の変更に関する審査結果

273	11 原子力規制委員会告示第８号
274	12 Nuclear Regulation Authority Mid-term Goal (2015-2020) (原子力規制委員会第１期中期目標)
275	13 原子力災害対策特別措置法に係る放射線測定設備の検査実施要領（内規）の制定について
276	14 放射線測定設備に関する検査実施要領/検査成績書
277	15 事業者保安教育資料
278	16 原子力事業者が実施する訓練に係る対応について
279	17 実用発電用原子炉の安全性向上評価に関する運用ガイド
280	18 緊急作業従事者に関して　追加説明
281	19「実用発電用原子炉及びその付属施設の位置、構造及び設備の基準に関する規則とその解釈」の抜粋資料
282	Actions to Be Taken upon the Occurrence of Fire at Places of Authorized Operators of Radioisotope Handling Activity
283	Concerning planned on-site inspection based on the Radiation Hazards Prevention Act
284	Guideline for the NRA Administrative Document Management (extracted)
285	The NRA Ordinance on Registered Certification Body etc. (extracted)
286	Explanation for EPR framework in Radiation Hazards Prevention Act
287	Explanation for Inspections in Radiation Hazards Prevention Act
288	Explanation for Miscellaneous Regulation of Radiation Hazards Prevention Act
289	Explanation for Radiation Council

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1, IAEA, Vienna (2010).
3.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3, IAEA, Vienna (2006).
4.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear and Radiological Emergencies, Safety Requirement Series No. GS-R-2, IAEA, Vienna (2002).
5.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014).
6.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
7.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Predisposal Management of Radioactive Waste, General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009).
8.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Facilities, Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014).
9.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Design, Specific Safety Requirements No. SSR-2/1, IAEA, Vienna (2012).
10.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2, IAEA, Vienna (2011).
11.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Site Evaluation for Nuclear Installations, Safety Requirement Series No. NS-R-3, IAEA, Vienna (2003).
12.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Research Reactors, Safety Requirement Series No. NS-R-4, IAEA, Vienna (2005).
13.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Fuel Cycle Facilities, Safety Requirement Series No. NS-R-5, IAEA, Vienna (2014)
14.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Disposal of Radioactive Waste, Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
15.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements No. SSR-6, IAEA, Vienna (2012)
16.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002).
17.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002).

18.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002).
19.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Documentation Used in Regulating Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002).
20.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
21.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
22.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)
23.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review of Nuclear Power Plants, Safety Guide Series No. SSG-25, IAEA, Vienna (2013)
24.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
25.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. RS-G-1.1, IAEA, Vienna (1999)
26.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to Intakes of Radionuclides, Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
27.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to External Sources of Radiation, Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
28.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiological Protection for Medical Exposure to Ionizing Radiation, Safety Guide Series No. RS-G-1.5, IAEA, Vienna (2002)
29.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
30.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2006)
31.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
32.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
33.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
34.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010)
35.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010)

36.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
37.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
38.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
39.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Spent Nuclear Fuel Specific Safety Guide Series No. SSG-15, IAEA, Vienna (2012)
40.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
41.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
42.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
43.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008)
44.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)
45.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna, (2014)
46.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
47.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Regulatory Control of Radiation Sources, General Safety Guide No. GS-G-1.5, IAEA, Vienna (2004)
48.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Nuclear Power Plants and Research Reactors, Safety Guide Series No.WS-G-2.1, IAEA, Vienna (1999)
49.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Medical, Industrial and Research Facilities (1999) Safety Guide Series No.WS-G-2.2, IAEA, Vienna (1999)
50.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No.WS-G-2.3, IAEA, Vienna (2000)
51.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Fuel Cycle Facilities, Safety Guide Series No.WS-G-2.4, IAEA, Vienna (2001)
52.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Low and Intermediate Level Radioactive Waste, Safety Guide Series No.WS-G-2.5, IAEA, Vienna (2003)
53.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of High Level Radioactive Waste, Safety Guide Series No.WS-G-2.6, IAEA, Vienna (2003)

54.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Management of Waste from the Use of Radioactive Materials in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No.WS-G-2.7, IAEA, Vienna (2005)
55.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008)
56.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
57.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)