

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION

TO

Japan

Tokyo, Japan
14-21 January 2020

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

IRRS



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Mission dates: *14 to 21 January 2020*

Representatives of the regulatory body: *Nuclear Regulation Authority of Japan*

Location: *Tokyo, JAPAN*

Regulated facilities and activities:	Nuclear Power Plants, Fuel Cycle Facilities, Research Reactors, Radiation Facilities, Transport Safety, Occupational Exposure and Emergency Preparedness and Response.
Organized by:	International Atomic Energy Agency (IAEA)

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

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EXECUTIVE SUMMARY

At the request of the Government of Japan, an international team of senior safety experts met representatives of the Nuclear Regulation Authority (NRA) of Japan from 14 to 21 January 2020 to conduct an IRRS follow-up mission. The purpose was to peer review the actions taken to address the recommendations and suggestions made during the IRRS initial mission in 2016.

A preparatory meeting for the mission was conducted from 25 to 26 April 2019 at NRA Headquarters in Tokyo to discuss the purpose, objectives, scope and detailed preparations of the review. It was agreed that the review will be extended to include transport safety which was not part of the initial mission.

The IRRS team comprised 12 senior regulatory experts from 11 IAEA Member States, 1 observer, and 6 IAEA staff members.

The IRRS review addressed all facilities and activities regulated by the NRA. The mission was also used to exchange information and experience between team members and the Japanese counterparts in the areas covered by the mission.

The NRA provided the IRRS team with advance reference material including the follow-up self-assessment report. The mission included interviews and discussions with NRA staff. It was noted that the NRA made extensive preparation to ensure the success of the mission.

The IRRS team noted that the NRA has considered the recommendations and suggestions made by the 2016 mission and significant improvements have been made in many areas. Of the original 13 recommendations and 13 suggestions, 10 recommendations and 12 suggestions have been closed. The team made one new recommendation in the area of occupational radiation protection.

With respect to transport safety, the team concluded that the NRA generally implements transport safety requirements in Japan in accordance with IAEA regulations. However, areas for improvement were identified and the IRRS team made 4 recommendations and 1 suggestion.

The IRRS team noted that the Japanese Government and the NRA showed a strong commitment to nuclear and radiation safety.

Since 2016, the Government increased NRA resources for regulatory oversight and amended relevant legislation.

The IRRS team acknowledged the NRA has increased its participation within the Global Nuclear Safety Regime and the IRRS team encourages the Government to ensure the NRA has sufficient resources for continued international engagement on the development of safety standards and the exchange of information on nuclear and radiation safety.

Since 2016, the NRA has made a number of achievements in the following areas:

- improved inspection programme, including enhanced training and strengthening the powers of inspectors
- staff qualification and training programmes aimed at building and maintaining expertise necessary for discharging its responsibilities
- process for regularly reviewing regulations and guides
- emergency preparedness and response framework for both nuclear and radiological emergencies
- decommissioning requirements considered during all life stages of nuclear facilities

The NRA is encouraged to continue its efforts to:

- Document and fully implement its new integrated management system for all regulatory and supporting processes including development of tools to measure its performance and use of resources;
- Further strengthen its regulatory oversight of radiation protection based on international standards;
- Review and enhance the current emergency and response framework in line with the IAEA General Safety Requirements GSR Part 7.

In the area of transport safety, the IRRS team identified four recommendations and one suggestion. The NRA is encouraged to:

- Extend inspection programmes to all package types based on a graded approach
- Ensure the periodic testing of the emergency arrangements for responding to a nuclear or radiological emergency during the land transport of radioactive material.

Furthermore, the NRA is encouraged to coordinate, with relevant regulatory agencies, the implementation of the IAEA's Safety Standard SSR-6, 2018 Edition, for land transport.

The IRRS team noted a good performance by the NRA in the development and publishing of detailed application forms for package design approvals.

The policy discussion between the NRA and the IRRS team highlighted that in most countries:

- open, frequent, formal and informal communication between the regulator and the licensee is very positive and beneficial for nuclear safety. This is also recognised in the IAEA General Safety Requirements GSR Part 1 (Rev. 1);
- there are benefits available to regulatory body staff from taking advantage of the training programmes and courses offered by the licensees.

Throughout the mission, the IRRS team received the full cooperation in regulatory and technical areas and policy issues by all parties. In particular, the NRA staff provided excellent assistance and demonstrated extensive openness and transparency.

Appendix IV lists all Recommendations and a Suggestion that remain open from the initial 2016 mission.

The IRRS team's new findings are summarized in Appendix V.

At the end of the mission an IAEA press release was issued and a joint IAEA and NRA press conference was conducted.

I. INTRODUCTION

At the request of the Government of Japan, an international team of senior safety experts met representatives of the Authority for Nuclear Regulation Authority (NRA), the Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Internal Affairs and Communications (MIC) from 14 to 21 January 2020 to conduct an IRRS follow-up mission. The purpose of the peer review was to review the Japanese regulatory framework for nuclear and radiation safety. The follow-up mission was formally requested by the Government of Japan on 15 August 2017. A preparatory meeting was conducted from 25 to 26 April 2019 at NRA Headquarters in Tokyo to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the regulated facilities and activities in Japan.

The IRRS team comprised 12 senior regulatory experts from 11 IAEA Member States, 1 observer from Canada, 6 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the areas covered by the initial mission in 2016.

The Regulatory Body prepared a follow-up summary report addressing the findings of the initial mission. The results of Japan's follow-up report and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission. In addition, the NRA prepared a SARIS summary report for Transport Safety.

During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from NRA.

All through the mission the IRRS team received excellent support and cooperation from Japanese counterparts.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of Japan's radiation and nuclear safety regulatory framework and activities to evaluate its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by the NRA, in some cases in collaboration with other regulatory bodies, with the exception of off-site emergency preparedness as well as medical facilities and activities. Current activities at the Fukushima Daiichi site was not included in the scope of this mission. The Japanese Government has asked the IAEA to extend the scope of the follow-up mission by adding the subject of Transport Safety. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS follow-up mission will facilitate regulatory improvements in Japan and other Member States from the knowledge gained and experiences shared between Japanese regulatory staff and IRRS reviewers and through the evaluation of the effectiveness of Japanese regulatory framework for nuclear and radiation safety.

The key objectives of this mission were to enhance nuclear and radiation safety, emergency preparedness and response by:

- Providing Japan and the NRA, with an opportunity for self assessment of its activities against IAEA safety standards;
- Providing Japan and the NRA, with a review of their regulatory programmes and policy issues relating to nuclear and radiation safety and emergency preparedness;
- Providing Japan and the NRA, with an objective evaluation of the regulatory framework for radiation and nuclear safety and emergency preparedness and response within Japan with respect to IAEA safety standards;
- Contributing to the harmonization of regulatory approaches among IAEA Member States;
- Promoting the sharing of experience and exchange of lessons learned;
- Providing reviewers from IAEA Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- Providing key NRA staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Japan and the NRA, with recommendations and suggestions for improvement; and
- Providing other Member States with information regarding good practices identified in the course of the review.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Japan, a preparatory meeting for the IRRS follow-up was conducted from 25 to 26 April 2019. The preparatory meeting was carried out by the appointed Team Leader Mr Ramzi Jammal, the Deputy Team Leader Mr Carl-Magnus Larsson and the IRRS IAEA team representatives, Mr Miguel Santini, IAEA Team Coordinator, Mr Ibrahim Shadad, IAEA Deputy Team Coordinator.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of the NRA.

The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Nuclear power plants;
- Fuel cycle facilities
- Research reactors;
- Waste facilities;
- Radiation sources facilities;
- Decommissioning;
- Emergency Preparedness and Response;
- Public and environmental exposure control;
- Policy Discussion: human resources, technical expertise and infrastructure for research.

In addition, Japanese government had asked the IAEA to extend the scope of the follow-up mission by adding the subject Transport Safety.

Representatives of the NRA made presentations on the national context for nuclear and radiation regulatory framework and the progress made by the NRA since the initial mission of 2016.

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 2020.

The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, lodging and transportation arrangements were also addressed.

The Japanese Liaison Officers for the IRRS mission was confirmed as Mr Shuichi Kaneko from the NRA.

The NRA provided the IAEA (and the review team) with the ARM for the review at the beginning of November 2019. In preparation for the mission, the IAEA review team members conducted a review of the ARM and provided their initial review comments to the IAEA Team Coordinator prior to the follow-up mission.

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. A more complete list of IAEA publications used as the reference for this mission is given in Appendix VI.

C) CONDUCT OF THE REVIEW

The initial IRRS follow-up team meeting was conducted on 14 January 2020 in Tokyo, led by the IRRS Team Leader and the IRRS IAEA Team Coordinator, to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. They also presented the agenda for the mission.

In addition, the Team Leader and IAEA staff provided refresher training to the IRRS team to ensure a common understanding of the IRRS process, methodology and report preparation. The reviewers also reported their first impressions of the ARM.

The Liaison Officer was present at the opening IRRS team meeting, in accordance with the IRRS guidelines.

The IRRS entrance meeting was held on Wednesday, 15 January 2020, with the participation of NRA senior management and staff. Opening remarks were made by Mr. Toyoshi Fuketa, Chair of the NRA, and Mr Ramzi Jammal, IRRS Team Leader. Mr Tomoya Ichimura, gave an overview of the current status of the national context, regulated facilities and activities, legal and regulatory safety infrastructure, the main changes which have happened since the IRRS initial mission in 2016, including main organization strategy documents.

The NRA had prepared a national follow-up report addressing the findings of the initial mission. The results of Japan's follow-up report and supporting documentation were provided to the IRRS team as ARM for the mission. During the mission the IRRS team performed a systematic review of all topics by assessing the information provided in the ARM, and supplementing that information conducting interviews with management and staff from the NRA. At the request of the NRA the IRRS mission included discussions on policy issues regarding human resources, technical expertise and infrastructure for research.

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

The IRRS exit meeting was held on Tuesday, 21 January 2020. The opening remarks at the exit meeting were presented by Mr. Toyoshi Fuketa, and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Ramzi Jammal. Closing remarks were made by Mr Greg Rzentkowski, Director of the Division of Nuclear Installation Safety, IAEA. A press conference followed the final presentations whereby the NRA Chair, the Senior Representative of the IAEA and the Mission Team Leader answered questions from the press.

An IAEA press release was issued at the end of the exit meeting.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

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

Original mission RECOMMENDATIONS, SUGGESTIONS

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 authorizations, 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.”
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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, authorizations, inspections and enforcement actions to provide coordinated and effective regulatory oversight that should also ensure a harmonized regulatory framework under their respective responsibilities.
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Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *The 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 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)	<p>BASIS: GSR Part 1 Requirement 29 Paragraph 4.53 states that “<i>In conducting inspections, the regulatory body shall consider a number of aspects, including:</i></p> <p style="margin-left: 20px;"><i>- Liaison with the relevant organization for joint inspections, where necessary.</i>”</p>
(2)	<p>BASIS: GSR Part 1 Requirement 20 Paragraph 4.19 states that “<i>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</i>”.</p>
S1	<p>Suggestion: The NRA should consider improving its liaison with the relevant organizations for joint inspections and oversight of outsourced inspections.</p>

Changes since the initial IRRS mission

Recommendation 1: The initial IRRS mission found that there was extensive coordination between the NRA and the Office for Nuclear Emergency Preparedness (Cabinet office). However, the IRRS Team observed that the arrangements for coordination that existed at the time did not sufficiently ensure the effective coordination between involved authorities in several areas, and recommended that the coordination between agencies should be strengthened.

In this regard the IRRS Team reviewed the interagency coordination in the fields of transport, radiation protection (including research), fire protection, industrial safety and inspections.

Transportation

In the transportation field the Interagency Coordination Meeting for the Safe Transport of Radioactive Material was established before the initial mission. Within this framework the relevant regulatory authorities meet and exchange information on matters of transport safety and harmonize their approaches and actions on various issues, such as the development and revision of the IAEA safety standards on transportation, or national legislation based on these IAEA safety standards. The IRRS team noted that these newly introduced meetings improve the coordination between involved authorities.

Radiation protection research

Regarding the coordination of radiation protection including its research, interagency meetings under the Radiation Council have been established. Within this framework, the relevant regulatory authorities meet and exchange information on their plans and research projects. In addition, since fiscal year 2017, the NRA has its own research budget of around 300 million yen per year, which it can use in a manner that suit its needs. The IRRS team noted that the exchange of information in the field of radiation protection research has been improved.

Fire protection

The collaboration in the area of fire protection has been improved. The training of the NRA inspectors also includes fire protection. Staff are exchanged based on a job rotation approach in order to strengthen the common knowledge basis and promote mutual understanding of issues of common interest. Based on a request from the NRA, the Fire and Disaster Management Agency encouraged the Local Fire Departments to cooperate with the Regional Offices of the NRA regarding the licensees’ systems for fire protection management and their fire exercises. There are also joint inspections organised on a case by case basis. The IRRS Team concluded that the collaboration between the NRA and the Fire and Disaster Management Agency has improved but remains informal.

Industrial safety

First steps towards a better collaboration in the area of industrial safety have been taken. The NRA inspectors are trained in industrial safety matters. In addition, the NRA has initiated discussions on strengthened collaboration with MHLW.

Inspections

The initial IRRS team noted that 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 inspection findings. This has not changed significantly in the meantime between the initial and follow-up missions.

Suggestion 1: Regarding the Nuclear Reactor Regulation Act, Joint inspections of the Regional Offices of NRA and the Local Fire Departments regarding the licensees' fire protection management and fire exercises have been introduced and are carried out on an ad hoc basis. In other areas than fire protection the NRA indicated only limited scope for cooperation in joint inspections.

Within the framework of the Registered Organization System under the Act on Regulation of Radioisotopes, etc. (RI Act), regulatory duties, such as inspections, can be delegated to registered certification organizations. The NRA has improved its oversight of these delegated regulatory inspections through revision of the "Implementation Guidelines for On-Site Inspections" and expanded the scope of the on-site inspections regarding registered certification organizations. Additionally, the standards for NRA's oversight of registered organizations were clarified.

Following the above, the NRA inspected all 17 registered certification organizations in FY2016. Since FY2017 the registered certification organizations are inspected by the NRA every two years.

Status of the findings in the initial mission

Recommendation (R1) remains open, although it is recognized that initiatives have been taken to improve communication and collaboration between agencies that have relevant roles in nuclear and radiation safety, such mechanisms remain informal and the level of interaction in matters of common interest is variable.

Suggestion 1 (S1) is closed on the basis of progress made and confidence in effective completion. This is based on the observation of the introduction of joint inspections in the area of fire protection and the improved oversight of delegated regulatory inspections.

New findings from the follow-up mission

No new findings were identified.

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

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

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

1.8. COMPETENCE FOR SAFETY

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

POLICY DISCUSSION: HUMAN RESOURCES, TECHNICAL EXPERTISE, AND INFRASTRUCTURE FOR RESEARCH

A policy issue discussion took place in relation to the development of human resources, technical expertise and infrastructure for research.

The NRA stated that the recruitment, development and retention of Human Resource (HR) is a high priority for the organization.

Background

The NRA provided background information noting that when the organization was established in 2012, there was a good cohort of senior expert research resources but with an age profile predominantly in the range 40-60 yrs with many staff approaching the compulsory retirement age of 60 yrs. Following staff retiring from the NRA, the organization has recruited mainly younger staff to replace retirees and this has resulted in a reduction in the overall knowledge and experience of the staff conducting nuclear safety research. The problem is compounded by the changing scope of the regulatory programmes with an increased demand in the decommissioning and radiation waste management areas creating a need for an increased diversity of knowledge and expertise.

The NRA team expressed their interest in how the international regulatory community has overcome the challenges to maintain and enhance the human resources and technical competency within their organizations.

Discussion

The IRRS team members shared their Member State experience and practices. The challenges and situation of most of the regulatory bodies represented within the IRRS team were comparable to those of the NRA and similar strategies had been adopted dependent on the specific national situation to recruit and retain staff.

The retirement of highly experienced staff was noted as a challenge for most countries and various measures had been put in place to manage the effects whilst recognising the need for proper succession planning. The measures adopted included obtaining exemptions from the Government to allow regulatory staff to continue working beyond the date they could take their retirement pension without losing benefits, proactive knowledge transfer to allow younger and less experienced regulatory staff prepare to take on key responsibilities before the retirement of their senior expert colleagues. A further approach described was a Human Resources plan that allowed a new generation of employees to join the regulatory organization whilst in parallel allowing existing senior professionals dedicated time to mentor the newcomers through changed job functions. A number of countries had also established Alumni programmes to bring retired staff back to support the development of new staff. The Alumni programmes also enabled the retention of corporate memory through the transfer of knowledge on specific projects and for the training of new staff. Effective Knowledge Management arrangements and processes were highlighted by the IRRS team members including maintaining electronic records for each nuclear facility to allow new staff to draw information from past regulatory activities and highlighting the need for good record search engine tools.

Noting that the training and development of staff is a costly commitment, some countries had taken action to enable the regulatory body to become a more attractive employer to help with staff retention and avoid losing staff after the initial training period. The measures adopted included maintaining competitive salaries, providing a good work-life balance and benefits such as working from home and flexible parental leave. The IRRS team also highlighted an approach to recruit individuals on a temporary basis to work at the regulatory body and on returning to industry the benefits that result from the sharing and use of their regulatory expertise. The IRRS team also noted IAEA can assist Member States to train and develop their staff through for example the International School of Nuclear and Radiation Safety which features a broad curriculum covering nuclear law, nuclear and radiation safety, emergency preparedness, transport, radiation waste safety and knowledge management. The IAEA Junior Professional Officer secondment programme also offers individuals from regulatory bodies 12-24 months experience at the Agency to grow and develop technical and international standards competence and, in turn, take that back to their organizations.

The NRA team explained that in Japan the public are very sensitive to any indications of too close contact between the regulatory staff and the staff from licensees. The NRA also asked how the regulators overcome the issue of maintaining independence and the possible conflict of interest when secondment or training is provided by the licensees or there is direct recruitment.

The IRRS team emphasised that in most countries open, frequent, formal and informal communication between the regulator and the licensee is very positive and beneficial for nuclear safety. This is also recognised in the IAEA Safety Standard GSR Part 1 (Rev. 1) Requirement 23, which states: “The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison” and also “The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships, providing constructive liaison on safety related issues and in-depth technical dialogue between experts”.

The IRRS team members also emphasised the benefits available to regulatory body staff from taking advantage of the training programmes and courses offered by the licensees. The training of new inspectors is enhanced and accelerated using licensees training courses for operator and specialist functions. This approach can also be supplemented through regulatory body graduates being part of a wider graduate training programme that involve periods spent with operating/licensee organizations. It was stated by the IRRS team that by putting the necessary controls in place this issue can be managed through restricting the placement of the staff on return to the regulatory body and precluding the possibility of staff working on the regulatory programmes of the specific licensee for a period of two to three years from whom they benefited.

The issue of academic versus industrial background of regulatory staff was discussed. The IRRS team noted that in general the nuclear industry staff make decisions about technical or organizational issues almost on daily basis. In contrast academic scientists are often reluctant to make final decisions as they are always looking for more exact answers and solutions. The regulatory bodies have to be aware of this difference when recruiting and training staff, including staff with operational experience from industry.

The IRRS team also noted that in general it will not always be possible for the regulatory body to have the best experts for each and every technical area and they will have to rely on expertise of external support organizations. However, the regulatory staff should have enough scientific knowledge to be able to ask the right questions and to be intelligent customers when working with external experts.

In response to a challenge identified by the NRA, the IRRS team highlighted that regulatory organizations must be prepared to diversify their capabilities in order to be better prepared to earn increased trust with the public; it was noted that it is just as important to consider the way a message is communicated as well as the technical content of the message. This requires the regulatory body to consider increasing its resources and expertise in areas such as communication/ social media skills which, under budgetary constraints, may result in reduced resources in other areas.

1.9. PROVISION OF TECHNICAL SERVICES

Original mission RECOMMENDATIONS, SUGGESTIONS	
Observation: <i>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.</i>	
(1)	BASIS: GSR Part 3 requirement 25 para. 3.99 states that: <i>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.</i>
(2)	BASIS: GSR Part 3 requirement 32 para. 3.135 states that: <i>“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 ...”</i>
(3)	BASIS: GSR Part 1 requirement 13 para. 2.41 states that: <i>“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</i>

Original mission RECOMMENDATIONS, SUGGESTIONS

	<i>for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.</i>
(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 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.

Recommendation 2: During the initial mission in 2016, the IRRS team concluded that relevant legal requirements had been placed on licensees to ensure that dosimetry and radiation monitoring is carried out for the purpose of occupational radiation protection. However, there were limited requirements on the quality assurance of the dosimetry and monitoring services offered by external service providers. Quality assurance was left to the service providers on a voluntary basis and no authorization or approval process for such technical services existed in Japan.

The NRA has addressed R2 by strengthening the requirements on licensees to apply and implement appropriate quality criteria, either the services are carried out by the licensees themselves or by external service providers. The NRA is in the process of revision of relevant regulatory documentation based on, and implementing, the requirements of the Acts, including an ordinance for enforcement of the RI Act. It is anticipated that the revision will be finalised in 2020.

The NRA has established a “Technical Study Team on Environmental Radiation Monitoring” to address the technical and quality aspects of radiation dose estimates. Implementation of requirements on accreditation of services for determination of individual dose in accordance with ISO/IEC 17025:2017 “General Requirements for the Competence of Testing and Calibration Laboratories” is being pursued, in cooperation with the Japan Accreditation Board (JAB). Three service providers have achieved the required accreditation as of January 2020.

The compliance with the regulatory requirements for quality assurance in occupational exposure monitoring is assessed in the regulatory inspections carried out under the terms of the Reactor Regulation Act and the RI Act.

Environmental monitoring around nuclear installations is carried out by the local governments, and is thus not a responsibility of the licensee. The Team was informed that the aforementioned "Technical Study Team on Environmental Radiation Monitoring" examined the effectiveness of the quality assurance of the environmental radiation monitoring by local governments and confirmed that it meets international standards.

The concept of quality assurance in environmental radiation monitoring was incorporated in the NRA guidelines “Ordinary Radiation Monitoring (supplementary reference materials for Nuclear Emergency Response Guideline)” and presented to the local governments in May 2018 for their consideration.

Status of the finding in the initial mission

Recommendation (R2) is closed on the basis of progress made and confidence in effective completion, based on the observation that actions initiated by the NRA are nearing completion and have already strengthened the quality arrangements among providers of dosimetry and monitoring services;

New findings from the follow-up mission

No new findings were identified.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

There were no findings in this area in the initial IRRS mission.

The initial IRRS team concluded that Japan and the NRA fulfil their international obligations by participating in activities including Conventions, standard setting and technical committees and others as required. They have also implemented a system for the feedback from international operational experience.

Based on its self-assessment the NRA recognized that its attendance at international peer review missions is limited. The following Section was therefore included in its Action Plan:

“In evaluating the performance of staff for international affairs, safety research, improvement of regulations and guides, and other relevant positions, contribution to international activities (in particular for peer review) should be included in such personnel evaluation. In order to establish global human networks, the frequency of personnel rotation and the opportunities for working in international organizations should be optimized.”

As referenced in the Action Plan, the IRRS team noted that the NRA has increased its international engagement. Those staff who will be involved in international activities receive the appropriate training. Furthermore, the NRA provides appropriate support such as language training, for the staff to be assigned to the international organizations. The NRA also seconds staff to international organizations.

The NRA cited its participation in the recent Review Meetings of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention) and the Convention on Nuclear Safety (CNS) as two examples. In total, 13 NRA staff members participated in the 6th Review Meeting of the Joint Convention held in 2018 with one member serving as Vice-Chairman of a Country Group. More than 20 NRA staff members are involved in the preparation of the upcoming 8th Review Meeting of the CNS. The NRA is providing two Officers, a Country Group Chair and a Coordinator.

The IRRS team recognises the progress made to date and encourages the NRA and the Government of Japan to take an active role in international activities including promotion of international framework for safety.

New findings from the follow-up mission

No new findings were identified.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Original mission RECOMMENDATIONS, SUGGESTIONS

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 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: **The 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.**

Changes since the initial IRRS mission

Recommendation 3: The NRA has revised its organizational structure and strengthened the department responsible for the regulation of radioisotopes by increasing its number of inspectors. Since 2016 the number of inspectors responsible for radiation safety oversight of the licensed operators has been increased from 12 to 19. Furthermore, Cabinet Order Number 259 on the Regulation of Radioisotopes has been revised to increase the number of radiation inspectors to 50. According to the NRA, the recruiting process is ongoing for further enhancement in regulatory oversight of licensees.

The NRA established a new management post, “In-Charge of International Affairs”, to enhance the involvement in IAEA activities, especially the Safety Standards Committees, to enable it to incorporate international experience into the NRA regulations. The NRA representatives now participate in the IAEA safety standards committees on a regular basis as well as in the activities of the ICRP.

Regarding research activities, the NRA initiated the “Strategic Promotion Project for Radiation Safety Regulatory Study” in 2017. The objective of this project was to conduct surveys and research to improve regulations related to prevention of radiation hazards, to strengthen radiation protection, and to provide a basis for the systematic development and effective implementation of regulation in the radiation area.

In addition, the NRA has enhanced collaboration with the National Institute for Quantum and Radiological Science and Technology (QST) which was set up by reorganizing National Institute of Radiological Science (NIRS).

Status of the finding in the initial mission

Recommendation R3 is closed on the basis of progress made and confidence in effective completion as the NRA has allocated additional resources for the regulatory oversight of the licensees as well as for its participation in the development of international standards in radiation protection and related research activities in Japan.

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

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *The current organizational 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 “ <i>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.</i> ”
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R4	Recommendation: The NRA should evaluate the effectiveness of its current organizational 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.
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Changes since the initial IRRS mission

Recommendation 4: The NRA evaluated its organizational structure and the personnel necessary to conduct its operations effectively and efficiently, in accordance with the NRA Management Rules. Based on this evaluation, the NRA modified the organizational structure of the department for the regulation of nuclear power plants and nuclear fuel facilities to a task-based structure. The NRA increased the number of nuclear inspectors to strengthen the inspection programme and increased number of radiation safety reviewers to enhance the oversight of the implementation of nuclear safety regulations and radiation protection measures.

The NRA, as an administrative organization, has implemented a number of government-wide cross-cutting processes such as document control and policy evaluation. The NRA will develop and implement further cross-cutting processes under its management system development plans, see Chapter 4.

The NRA management system requires each department to collect information from licensees and other stakeholders to formulate an annual plan. The information collected includes schedule of applications for authorization for inspections from operators and technical evaluation of industrial standards. Additionally, when regulations or guidelines are revised, the NRA solicits public comments based on the Administrative Procedures Law.

Status of the finding in the initial mission

Recommendation R4 remains open on the basis of the remaining tasks to be completed within the framework of the management system, while recognizing significant improvements in several areas.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *The 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 the NRA has started or is planning to initiate adequate corrective actions to ensure it has sufficient number of qualified staff.*

Original mission RECOMMENDATIONS, SUGGESTIONS

(1)	BASIS: GSR Part 1 Requirement 18, para. 4.11 states that <i>“The regulatory body has to have appropriately qualified and competent staff...”</i>
(2)	BASIS: GSR Part 1 Requirement 18, para. 4.13 states that <i>“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 ...”</i>
R5	Recommendation: The 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 organizations (JAEA), universities, research organizations and international and overseas organizations, to ensure it has both qualified and experienced staff to fulfil its regulatory responsibilities in nuclear and radiation safety.

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: <i>The IRRS team identified concerns regarding the attractiveness of the NRA to recruit and retain suitable numbers of staff to enable it to fulfil its regulatory mandate and responsibilities.</i>	
(1)	BASIS: GSR Part 1 Requirement 11, para. 2.36(b) states that <i>“Shall make provisions for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body’s responsibilities in relation to safety”.</i>
(2)	BASIS: GS-G-1.1 para. 4.6 states that <i>“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”.</i>
S2	Suggestion: The 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.

Changes since the initial IRRS mission

Recommendation 5: The NRA defined the basic qualifications for its staff involved in licensing and inspection of nuclear facilities; radiation regulations; emergency preparedness and response; and safeguards and identified the general and technical skills for its staff. This programme covers mandatory training, on-the-job training and self-directed learning. In addition, staff participate in national and international workshop/seminars. The NRA is also using a multi-plant full scope simulator for practical training of its staff especially for those who are involved in licensing, review, inspection, safety research or emergency preparedness. Following training courses are conducted using these simulators:

- PWR & BWR basic and startup/shutdown operation (5-day each for PWR & BWR)
- PWR & BWR abnormal operation and emergency operation (5-day each for PWR & BWR)
- PWR & BWR severe accident course(4-day each for PWR & BWR)

The NRA appointed its managers to conduct oral examinations and interviews of the individuals involved in review and assessment, and granted the individuals as Basic, Medium and High level qualification depending on their abilities.

The NRA initiated collaboration with national and international organizations for safety research, such as technical support organizations, universities and academic societies, overseas research institutions and international organizations to retain and develop its human resource. The NRA participated in safety research projects hosted by (OECD/NEA), actively exchanges information with overseas organizations (NRC, IRSN, GRS and others). The NRA has implemented many joint research projects with JAEA and universities. The Reactor Safety Examination Committee and the Nuclear Fuel Safety Examination Committee also provided valuable guidance relevant to recruitment, maintenance and development of human resources at the NRA.

Suggestion 2: The NRA is making the jobs more attractive for new as well as current technical experts by sending them abroad for training, expanding opportunities for exchange with other organizations (e.g. universities, research institutes, international organizations), and improving welfare programmes (e.g. housing) for the employees. The NRA provides funds to universities and internships to students to attract them to the NRA. The IRRS team notes that the NRA is taking special measures to extend the appointment of employees with specialized skills that are not easily replaceable.

Status of the finding

Recommendation R5 is closed on the basis of progress made and confidence of effective completion as the NRA is performing activities as recommended.

Suggestion S2 is closed on the basis of progress made and confidence of effective completion as the NRA is working to attract new personnel and to retain its technical experts by giving them incentives.

New findings from the follow-up mission

No new findings were identified.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the initial IRRS mission.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *The IRRS team was advised of a significant number of meetings between the 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, judgments 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.”*

Original mission RECOMMENDATIONS, SUGGESTIONS

S3

Suggestion: The 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 licensees/applicants.

Changes since the initial IRRS mission

Suggestion 3: The NRA commissioners meet and exchange information with the CEOs of licensees on a monthly basis or when needed. The NRA is aiming to improve communication with stakeholders through a newly established framework for opinion exchange between the Chief Nuclear Officers (CNOs) of the licensees and the NRA commission. In addition, the NRA staff carry out information exchange with operators at many different levels; from inspector level to management level.

The IRRS team was informed that communication with licensees is improving, ensuring the operational transparency of the authority. The NRA continuously seeks feedback from the licensees to identify any areas where improved communication may be needed. As an example, the NRA made improvements to its examinations and compliance monitoring system based on the licensees' feedback and suggestions. Public safety review meetings are also held at regular intervals.

Status of the finding in the initial mission

Suggestion S3 is closed on the basis of progress made and confidence in effective completion as the NRA is making efforts to improve the communication with licensees and other stakeholders.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

3.7. SAFETY RELATED RECORDS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

Original mission RECOMMENDATIONS, SUGGESTIONS	
<p>Observation: <i>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 the 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.</i></p>	
(1)	<p>BASIS: GSR Part 1 Requirement 19 states that <i>“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.”</i></p>
(2)	<p>BASIS: GS-R-3 para. 2.4 states that <i>“The organization shall be able to demonstrate the effective fulfilment of its management system requirements”.</i></p>
(3)	<p>BASIS: GS-R- 3 para. 2.6. states that <i>„The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:</i></p> <ul style="list-style-type: none"> • <i>The significance and complexity of each product or activity;</i> • <i>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;</i> <p><i>The possible consequences if a product fails or an activity is carried out incorrectly.</i></p>
(4)	<p>BASIS: GS-R- 3 para. 2.8. states that <i>„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 ...”</i></p>
(5)	<p>BASIS: GS-R- 3 para. 6.1 states that <i>„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”.</i></p>
R6	<p>Recommendation: The 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 and measured in a comprehensive way to identify opportunities for improvement.</p>

Original mission RECOMMENDATIONS, SUGGESTIONS	
<p>Observation: <i>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.</i></p>	
(1)	<p>BASIS: GS-R-3 para. 2.5 states that <i>“The management system shall be used to promote and support a strong safety culture by:</i></p> <ul style="list-style-type: none"> • <i>Ensuring a common understanding of the key aspects of safety culture within the organization;</i> • <i>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</i>

Original mission RECOMMENDATIONS, SUGGESTIONS

	<ul style="list-style-type: none"> • <i>organization;</i> • <i>Reinforcing a learning and questioning attitude at all levels of the organization;</i> <p><i>Providing the means by which the organization continually seeks to develop and improve its safety culture.</i></p>
S4	<p>Suggestion: The 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.</p>

Changes since the initial IRRS mission

Recommendation 6: The NRA is establishing its management system to reflect its operational activities and processes in accordance with the existing framework that governs the administrative organizations of the government of Japan. This ensures an appropriate management in the NRA as an administrative organization. The NRA Management Rules require it to have a management system specific for the nuclear regulatory authority. These Rules are, in general, in line with the IAEA GSR Part 2.

Update of the NRA management system is a continuous process. Following the 2016 IRRS mission, further development of the NRA management system has been organised in line with “Roadmap for Improvement of NRA Management System”, with an initial focus on “maintaining and improving the NRA operational quality”.

The Roadmap is formulated for the period 2016-2020. Following the 2016 IRRS mission, a new, hierarchical management system structure was developed to replace the old flat management system structure. Centralized control of the management system documents has been started, including posting the interactive database of the management system documentation on the intranet of the NRA. “Operational Manual Development Rules” were established in order to put in place a consistent model for the operational manuals that describe the individual management system procedures.

In addition to the above mentioned efforts, the NRA subjects its management system to internal audits to ensure it remains compliant with its rules and to identify opportunities for improvement, e.g. proposals made by NRA employees.

Successful completion of above mentioned actions contributes to the process of upgrading the existing NRA management system. In particular, the IRRS team was informed, that NRA’s plan for improving its management system includes:

- Preparation of documents that would complement the NRA Management Rules and include details on how the individual requirements are implemented within the NRA management system;
- Continued transformation of the management system documents into new hierarchical structure;
- Continued classification of the processes according to different types (core processes, support processes, management processes) and categories (I to IV in accordance with the level of granularity);
- Transformation of management system procedures to new format with the use of “Operational Manual Development Rules” and applying the principle of graded approach.

Full application of actions listed above would move the NRA management system towards full compliance with IAEA standards. In addition, it will help in achieving consistency in the application of regulatory processes within the organization. The IRRS team encourages the NRA management to continue its strong commitment to the above-mentioned activities.

Suggestion 4: The NRA has expanded efforts to improve its management system. In support of this effort, in the second half of 2016, the NRA developed its “Roadmap for Improvement of NRA Management System”. Since then following measures were implemented with respect of safety culture:

- Dialogue between executives and staff members: This activity started since January 2017. The dialogues were carried out in small groups to foster improved safety culture through exchange of experience and to promote a culture of openness and encourages open-minded discussions. The discussion topics include those such as “NRAs ways of being”;
- Promotion of staff support: Following the development in 2015 of “Statement on Nuclear Safety Culture”, a practical guide was formulated in October 2017 to promote staff understanding of this statement;

- The workshops for consideration of safety were held twice in March and in September 2018. These were supplemented by site tours of the TEPCO Fukushima Daiichi Nuclear Power Station;
- E-learning related to the NRA management system and basic knowledge of safety culture was made available in February 2019;
- Survey of employee awareness and behaviour: Surveys were conducted from 2016 to 2018 and the results were analysed to gain an understanding of staff awareness and behaviour. In 2019, the NRA brought external consultants to help with conducting interviews to identify specific issues and good practices. About 40 interviews were conducted and analysis is underway.

Establishment of above mentioned measures creates a good basis for continuous promotion of a high level of safety culture within the NRA.

Status of the finding in the initial mission

Recommendation (R6) remains open since efforts to complete, document and fully implement new NRA integrated management system for all regulatory and supporting processes are still in progress.

Suggestion (S4) is closed on the basis of progress made and confidence in effective completion, since a set of specific measures to promote and sustain high level of safety culture in regulatory activities was implemented.

New findings from the follow-up mission

No new findings were identified.

4.2. MANAGEMENT RESPONSIBILITY

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *The 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: **The 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.**

Changes since the initial IRRS mission

Suggestion 5: The “Roadmap for Improvement of NRA Management System” include actions related to “improvement of operational quality” and “fostering of safety culture and organizational culture”. The Roadmap is formed as a multi-year development programme which is approved by the Commission and is regularly subject to management review. A number of items from the Roadmap have already been implemented. For more details see text related to Recommendation 6 and Suggestion 4.

Status of the finding in the initial mission

Suggestion (S5) is closed, given that the “Roadmap for Improvement of Management System” is being used to assist with the implementation of necessary changes to the NRA management system.

New findings from the follow-up mission

No new findings were identified.

4.3. RESOURCE MANAGEMENT

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

4.4. PROCESS IMPLEMENTATION

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *The 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)	<p>BASIS: GS-R- 3 para. 2.8. states that “<i>The documentation of the management system shall include the following:</i></p> <ul style="list-style-type: none">• ...• <i>A description of the management system;</i>• ...• <i>A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;</i> <p><i>A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.</i></p>
(2)	<p>BASIS: GS-R- 3 para. 2.9. states that „<i>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.</i></p>
S6	<p>Suggestion: The 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.</p>

Changes since the initial IRRS mission

Suggestion 6: The NRA has introduced the concept of a hierarchical structure for its management system documentation and proceeded with the re-organization of the existing management system documents. The interactive database of the management system related documents was posted on the NRA portal and centralized control of the documents was started.

Together with this, the NRA standardised its operational manuals through the use of “Operational Manual Development Rules”. When this new standardised format is implemented, the operational manuals will describe

management system processes in a consistent format including description of requirements, risks, interactions, inputs, process flow, outputs and records and measurement criteria. Existing NRA management system consist of approximately 500 processes of different categories. The plan is to gradually transform operational manuals to new format at the time of their prescribed periodic revisions.

In addition, IRRS team was informed, that the development of documents aimed at complementing the NRA Management Rules is planned. This is to provide further details on how the individual requirements are implemented within the NRA management system. Introduction of such documents would support effective and consistent implementation of the NRA activities.

For additional details see text of Recommendation 6.

Status of the finding in the initial mission

Suggestion (S6) remains open, since efforts to develop a new comprehensive description of its management system are still in progress.

New findings from the follow-up mission

No new findings were identified.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified

5. AUTHORIZATION

5.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: Ageing management at NPP is to be addressed by licensees and examined by the 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. The 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.”

S7

Suggestion: The NRA should consider enhancing the interfaces and overall coherence of the existing three regulatory processes related to NPP ageing management.

Changes since the initial IRRS mission

Suggestion 7: The NRA amended the “Commercial Reactors Ordinance” in August 2017. In the amended ordinance (regulations), when the deterioration status evaluations for approval of operation beyond 40 years are integrated with the aging management technical evaluation, the licensee can take credit for previous submissions and need not resubmit the evaluations. In this way, administrative work was simplified and corresponding safety reviews could be performed together.

Additionally, in the “Periodic Safety Assessment of Continuous Improvement System,” the NRA amended the operational guide for the system related to commercial nuclear reactors in March 2017, so that the results of the Aging Management Technical Evaluation System can be utilized for the mid to long-term assessment relating to aging of nuclear facilities that have been operating over 30 years.

Additionally, the IRRS team was informed that the same NRA review teams would be involved in the assessment of the (1) operational safety reviews beyond 30 years, (2) Periodic Safety Assessment of Continuous Improvement System; and (3) approval for operation beyond 40 years. This is intended to ensure continuity in the tracking of facility improvement.

Status of the finding in the initial mission

Suggestion (S7) is closed. The NRA has revised the requirements to eliminate duplication of submissions made by licensees and harmonised the approach to review amongst the three processes related to consideration of aging management.

5.3. AUTHORIZATION OF RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *While an operator may be authorized by the NRA, it can only commence operations when it receives a certificate of compliance from the Registered Inspection Body. In practice NRA’s authorization in relation to radiation sources is essentially a hold point in the authorization 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 the NRA prior to full authorization.*

(1)	BASIS: GSR Part 1 Requirement 25 states that <i>“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...”</i>
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R7	Recommendation: The NRA should incorporate the findings of the facility inspection into the review and assessment and the authorization process for radiation sources.
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Changes since the initial IRRS mission

Recommendation 7: Article 12-8 (1) of The Radiation Hazards Prevention Act of December 2017 empowered the NRA or an Organization Registered with the NRA (Registered Inspection Body) to inspect radiation facilities. According to this Article no facility shall use sources unless it has passed the inspection done by the NRA or the Registered Inspection Body.

The NRA revised the Standard Review Plan for Operational Rules of the registered organization in December 2017, and required the Registered Organizations to revise their Operational Rules in order to make them report the result of the facility inspection to the NRA immediately after completion of the inspections (Article 22 item (vi) (3)). The IRRS Team was informed that these operation rules provide information on the methods and the capabilities of the Registered Inspection Body for conducting inspections.

In the authorization process of radiation facilities, the NRA issues authorization for construction and use prior to the construction of the facility. In order to ensure that the construction and the radiation safety matters are in accordance to the license issued by the NRA the facility is required to go through inspection for verification, which will be done by a Registered Inspection Body. The facility can commence operations once it is deemed compliant by the Registered Inspection Body. If the facility does not pass an inspection, the facility cannot go into operation. The licensee is required to correct the points of non-conformity and request a follow-up inspection. If the facility design needs to be modified in order to pass an inspection, the licensee is required to submit a revised application for the amendment of permission and this triggers a new review and assessment by the NRA.

Status of the finding in the initial mission

Recommendation (R7) is closed on the basis that the NRA has taken action to meet the intent of the Recommendation.

New findings from the follow-up mission

No new findings were identified.

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Original mission RECOMMENDATIONS, SUGGESTIONS

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, the 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, the 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 <i>“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.</i>
(2)	BASIS: GSR Part 6 Requirement 5, para 3.3 states that <i>“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;</i>
(3)	BASIS: GSR Part 6 Requirement 15, para 9.2 states that <i>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.</i>
(4)	BASIS: GSR Part 6 Requirement 15, states that <i>“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.</i>
R8	Recommendation: The 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.

Changes since the initial IRRS mission

Recommendation 8: With regard to nuclear facilities authorised under the Nuclear Reactor Regulation Act, the licensees are required to apply for the confirmation of completion of their decommissioning work. The status of decommissioning is confirmed by the NRA through on-site inspections conducted prior to the completion of the

decommissioning or on the basis of the licensee's final decommissioning report. A report of such inspections is then produced, and the NRA gives notice of the result of confirmation to the applicants. With regard to non-nuclear facilities authorised under the RI Act, the licensees are required to submit a report to the NRA, to notify it of completion of their decommissioning work. The NRA informed the IRRS team that the NRA still does not provide a formal confirmation to the operator regarding completion of decommissioning and release from further responsibility. The status of decommissioning is however confirmed by on-site inspections conducted prior to the completion of the decommissioning or the licensee's report confirmation completion of decommissioning, that is legally required to be submitted to the NRA. The IRRS team continues to encourage the NRA to consider issuing formal confirmation of end of responsibility to the licensees upon successful completion of decommissioning activities.

Japan Radioisotope Association (JRA), authorized by the NRA, has centralized control over the collection and disposal of radiation sources from these installations and has a proven record to effectively complete these activities in Japan. Consequently, the NRA decided that, due to the proven effectiveness of JRA, and based upon a graded approach taking into account the difference of radiation hazards with that of nuclear facilities, further consideration of decommissioning at the time of design and construction of RI facilities is not warranted.

The Nuclear Reactor Regulation Act was amended and the NRA revised relevant regulations to add requirements for all nuclear facilities and radioactive waste disposal and/or storage facilities to develop and publish decommissioning policies and procedures for their licensed activities ("Decommissioning Measures Implementation Policy"). The NRA also developed an operational guide that shows the basic concept regarding preparation and publishing of the policy. The aim of this policy is to ensure smooth transition from the end of operation into the period of decommissioning to adequately address the preparations for decommissioning in advance of the end of operations. Licensees are required to promptly publish the policy and the policy should be reviewed every five years and updated as appropriate.

The IRRS team recognized that whilst the NRA has made some progress toward the development of site release criteria, the work is still ongoing and is expected to be completed in the fiscal year 2020.

Status of the finding in the initial mission

Recommendation (R8) is closed on the basis of progress made and confidence in effective conclusion. The IRRS team noted the progress made with respect to nuclear facilities and encouraged the NRA to consider issuing formal confirmation of end of responsibility to the licensees upon successful completion of decommissioning activities.

New findings from the follow-up mission

No new findings were identified.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: The NRA is collecting operating experience of national nuclear facilities beyond the reporting requirements defined in the laws and regulations. Few events are reported to the NRA on a mandatory basis, by licensees. The 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:** The 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.

Changes since the initial IRRS mission

Suggestion 8: The NRA conducted a survey on the existing criteria for legal reporting of events in other countries such as USA and France and the results were considered by the NRA’s Technical Information Committee.

In October 2017, the NRA expanded the criteria and rules for collecting information on the operational experience feedback process, to include information related to maintenance activities, unplanned scrams, component failures and quality assurance information. Additionally, the NRA collects operating experience and feedback information from various international sources such as IAEA and OECD/NEA.

In the operational experience feedback process of the NRA, the collected domestic and international operational experience information are analysed and screened on a weekly basis and the results are reported to the open meetings of the Technical Information Committee, the Committee on Examination of Reactor Safety, and the Committee on Examination of Nuclear Fuel Safety.

Findings requiring further investigating or regulatory action are submitted to the Nuclear Safety Committee with requests for inclusion as updates to regulations or guides as appropriate. The NRA confirmed that the results of operational feedback are incorporated into the NRA's regulatory inspection programme. Further, the NRA has established a collaborative information sharing agreement with Japan Nuclear Safety Institute (JANSI), a nuclear power industry association, aimed at ensuring continuous improvement of safety. The NRA and JANSI exchange information related to operational safety.

Status of the finding in the initial mission

Suggestion 8 (S8) is closed. The NRA has revised the requirements relating to safety relevant events and has introduced a screening process to evaluate operational experience feedback that require additional regulatory actions.

6.1.3 BASES FOR REVIEW AND ASSESSMENT

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.1.4 PERFORMANCE OF REVIEW AND ASSESSMENT

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.2 REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.3 REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.4 REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

Original mission RECOMMENDATIONS, SUGGESTIONS

Observation: *A systematic approach was not evident as part of the application process, or by the NRA, to understand the factors that affect human performance, and minimize the potential for human errors to contribute to or escalate faults.*

Original mission RECOMMENDATIONS, SUGGESTIONS

(1)	BASIS: GSR Part 1 Requirement 32, states that <i>“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.”</i>
(2)	BASIS: GSR Part 4 Requirement 11, states that <i>“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.”</i>
S9	Suggestion: The 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.

Changes since the initial IRRS mission

Suggestion 9: The NRA established the “Study Team on Consideration of Human and Organizational Factors for the Regulations” consisting of members of the NRA Commission, other officials of the NRA and external experts. Based on recommendations from the study team, the NRA developed two guidance documents related to safety culture and casual analysis. Trial versions of these guides were prepared and released in 2018. The NRA also initiated the development of a guide on human engineering factors in control rooms. In developing this guide, the NRA consulted existing literature and IAEA guidance documents such as the draft DS492.

Additionally, the IRRS Team was informed that human factors will be included as part of the NRA’s new inspection system (Reactor Oversight Program) in fiscal year 2020. Based upon the outcome of these inspections, the NRA will make a determination on the required amendments to the existing ordinances related to the submission of safety evaluations of human and organizational factors in plant designs.

The IRRS team was informed that the NRA has recruited five experts in the fields of human and organizational factors. Additionally, the training course on the new guides regarding safety culture and causal analysis have been established for the NRA officials including inspectors. The training takes the form of class-based instruction, self-study and practical experience at the nuclear power plants.

Status of the finding in the initial mission

Suggestion 9 (S9) is closed on the basis of progress made and confidence in effective completion noting the guidance documents developed to date and the appointment of additional staff with competence in human and organizational factors.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

7. INSPECTION

7.1. GENERIC ISSUES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

7.2. INSPECTORS

Original mission RECOMMENDATIONS, SUGGESTIONS

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. The 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. The NRA does not perform unplanned and unannounced inspections.

The 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.

(1)	<p>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:</p> <p>...</p> <p>(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;</p> <p>...”</p>
(2)	<p>BASIS: GSR Part 1 Requirement 27 states that “The regulatory body shall carry out inspections 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.”</p>
(3)	<p>BASIS: GSR Part 1 Requirement 28 states that “Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.”</p>
(4)	<p>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.”</p>
(5)	<p>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.”</p>

Original mission RECOMMENDATIONS, SUGGESTIONS

(6)	<p>BASIS: GSR Part 1 Requirement 29 Paragraph 4.53 States <i>“In conducting inspections, the regulatory body shall consider a number of aspects, including:</i></p> <ul style="list-style-type: none"> - 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; <p><i>Liaison with the relevant organization for joint inspections, where necessary.”</i></p>
(7)	<p>BASIS: GSR Part 3 Requirement 2 paragraph 2.14 states <i>“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.”</i></p>
R9	<p>Recommendation: The government should improve and simplify the inspection framework to:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>

Original mission RECOMMENDATIONS, SUGGESTIONS

<p>Observation: <i>The initial training provided to NRA inspectors is very limited in time. There is no retraining programme in place.</i></p>	
(1)	<p>BASIS: GSR Part 1 Requirement 18 Paragraph 4.13 states <i>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”.</i></p>
S10	<p>Suggestion: The NRA should consider improving training and retraining of its inspectors in order to improve their competencies for inspections, associated assessments and decision making.</p>

Changes since the initial IRRS mission

Recommendation 9: The NRA took actions to address this recommendation very soon after the original IRRS mission. They established a “Study Team on Inspection Reform” consisting of the members of the NRA commission, the officials of the NRA and the external experts. The study team examined solutions and different approaches with the goal of making the inspection system more effective. Ultimately, they decided to integrate and build upon the example of the Reactor Oversight Program (ROP) being used in the United States. The program was augmented by considering the IAEA safety standards, the practices of international regulatory bodies and status of safety activities conducted by the licensees. The NRA revised the Reactor Regulation Act to allow for the adoption and implementation of the new ROP, which would replace overly prescriptive checklists based inspection methods. The revision was accepted by the Japanese Parliament, the Diet, on April 7, 2017. Immediately after this adoption, the NRA started to implement changes brought by the revised Law. To help with the transition from the former inspection process to the new one, the NRA sent several of its employees to be trained in ROP in the USA. These trained employees assisted with the implementation of the ROP in Japan. The ROP was implemented in a staged approach, meaning that the program was introduced gradually over a period of about 2 years.

Currently, the ROP has been developed and is being used on a trial basis by all resident inspectors. Full implementation including deployment of specialist inspectors is planned to be implemented from April 2020. At the time of the IRRS follow-up mission the inspections of nuclear power plants are still performed according to the previous legal requirements, while in parallel also the new system was followed.

As for the conformity of nuclear facilities to safety standards, the NRA obliged the licensees to perform inspections of their facilities in regular intervals as part of an operational safety program which are prepared by the licensees and accepted by the NRA. The NRA then conducts inspections to ensure that the operational safety programs are being followed as well as other inspections required by the ROP. This approach ensures that the primary responsibility for safety remains with the licensees.

The IRRS team was initially concerned by the use of term “inspections by licensees” which was used many times in the self assessment. Through interviews it was clarified that these “inspections by licensees” are similar to practices in other countries, where these activities are described as surveillance, quality control, maintenance, audit or similar terms. It should be noted that the NRA has the authority to inspect the operational safety program activities performed by licensees to confirm that legal requirements in this respect are being followed.

The NRA has made significant progress in the implementation of the new ROP for nuclear power and fuel cycle facilities. The development and implementation of the ROP has taken considerable effort including, but not limited to:

- Revising the law to allow the implementation of a new reactor oversight program
- Extensive trials by inspectors at many facilities
- Development of inspection processes and guides to be used by resident inspectors.

The new reactor oversight program is substantially different from the previous process. It makes greater use of objective performance indicators which are obtained from the licensees operational safety programme. Together, the indicators and inspection findings provide the information needed to support reviews of nuclear power plant performance. The IRRS team encourages the NRA to complete the full implementation of the ROP.

The law has been modified to ensure inspectors have free access to all facilities and activities at any time. To ensure inspectors use this new right appropriately training programmes have been developed and changes have been discussed with licensees. This is to ensure NRA inspectors are permitted to enter facilities and perform their work independently, free from licensee oversight. In addition, NRA inspectors are encouraged to interact with licensee staff and contractors alike.

Under the new inspection program inspectors conduct surveillance activities and walkdowns. Depending on what the inspectors see on these walkdowns, they could trigger additional activities based on clearly defined criteria in the ROP. Essentially, inspectors perform assessment of risk according to approved processes and depending on the safety significance additional regulatory activity may be undertaken. This is a well documented process and appears to be well understood. It is currently undergoing a trial phase; full implementation is scheduled for April 2020.

Based on the revised inspection framework the NRA will develop and implement a programme of inspections for all facilities specifying types and frequency of regulatory inspections (including scheduled inspections and unannounced inspections) in accordance with a graded approach. However, the detailed annual plans of inspections are yet to be developed.

The NRA inspectors now have the ability to conduct unannounced inspections and this has been practiced through the trial of the new inspection system.

The NRA has started implementing joint inspections and exchange of information with fire protection inspectorate. However, there is still room for improvement in performing joint inspections with other authorities. There could be also more communication and coordination of inspectors' work between different departments of the NRA. See also Suggestion 1.

Suggestion 10: The NRA has developed a comprehensive inspector training programme including but, not limited to:

- Classroom training
- Simulator training
- Walkdown training
- ROP training
- Probabilistic Safety Assessment (PSA) training. Note that, in Japan the term Probabilistic Risk Assessment (PRA) is in use.

New inspectors must complete a 2 year training programme to ensure they have adequate competence to do their job as an inspector. At the end of the training and qualification process an interview is conducted by the NRA managers to ensure key concepts have been learned. Behavioral competencies are also assessed to ensure trainees will be able to execute their duties of an inspector.

Experienced inspectors must complete some of the same training for new inspectors including a familiarization with the new ROP, as well as a review of their qualification records to ensure they meet predetermined criteria.

Status of the finding in the initial mission

Recommendation R9 is closed based on progress made and confidence in effective completion as significant progress has been made with respect to the inspection framework and confidence that outstanding tasks will be completed soon.

Suggestion S10 is closed as the NRA has demonstrated enhancements in the area of inspector training and retraining.

New findings from the follow-up mission

No new findings were identified.

7.3. INSPECTION OF RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

7.4. INSPECTION OF FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

8.2. ENFORCEMENT IMPLEMENTATION

Original mission RECOMMENDATIONS, SUGGESTIONS	
Observation: <i>There is no clear written enforcement policy in place at the NRA. There is no documented process in place at the NRA for determining the level of sanctions. The 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 the NRA headquarters. This situation probably endures for inspectors at all licensed facilities in Japan.</i>	
(1)	BASIS: GSR Part 1 Requirement 30 states that <i>“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.”</i>
(2)	BASIS: GSR Part 1 Requirement 31 states that <i>“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.”</i>
(3)	BASIS: GSR Part 1 Requirement 31, para. 4.58 states that <i>“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.”</i>
R10	Recommendation: The 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.

Changes since the initial IRRS mission

Recommendation 10: Following the recommendation of the original IRRS mission the NRA has established and documented an enforcement policy which is included in the newly established ROP. Penalties are specified by law in many areas.

In the case of an observed non-compliance inspectors are instructed to request the licensee to take action to correct the non-compliance. If further escalation continues the inspectors are instructed to contact their manager at headquarters who will engage the commission to order necessary actions if required. The inspectors do not have legal power to order enforcement actions like the shutdown of the reactor or stopping of operation of the source of ionizing radiation by themselves. However, in case of imminent threat to safety, the inspector would communicate the situation and associated risk to headquarters and the Commissioners on duty would be immediately alerted. The minimum compliment for the NRA commission is three out of five, as such, there is a requirement that there must always be at least three out of five commissioners available to take action in such situations. So, in urgent cases the decision about strong immediate enforcement action can be made very quickly, in a matter of minutes, and communicated to the licensee.

Status of the finding in the initial mission

Recommendation R10 is closed based on progress made and confidence in effective completion that the new enforcement policy will be implemented and that arrangements are in place to implement quick enforcement actions if necessary.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Original mission RECOMMENDATIONS, SUGGESTIONS	
<p>Observation: <i>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.</i></p> <p><i>The 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.</i></p>	
(1)	<p>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 “</p>
(2)	<p>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”</p>
(3)	<p>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 judgments, decisions and actions are based.’</p>
(4)	<p>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.....’</p>
(5)	<p>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”.</p>
(6)	<p>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.”</p>
(7)	<p>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.... ”</p>
(8)	<p>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:.... ”</p>
R11	<p>Recommendation: The NRA should:</p> <ul style="list-style-type: none"> • 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 <p>improve its guidance on Periodic Safety Assessment of Continuous Improvement.</p>

Changes since the initial IRRS mission

Recommendation 11 – part 1 - Following the IRRS mission in 2016, the NRA developed a systematic process to for the development of new or review of existing regulations, standards or guidance. This process is referred to as “Latest Findings Reflection Process”, which brings together information from a wide range of sources, including research conducted in Japan or internationally, regulatory experience from inspections, international standards and information from academic conferences.

The information is screened and presented to the Technical Information Committee (TIC) with its membership including a Commissioner. The Committee meets every two months to consider the information presented and may request that further investigations is conducted as necessary in order to make any necessary recommendations to the NRA. The operators may be consulted as part of the evaluation process for any new requirements. Meetings of the TIC are broadcast and can be captured on YouTube. The decision on any necessary response, including any changes to NRA’s regulations are made through a majority vote by all of the Commissioners at its regular meeting.

Should an urgent safety matter arise, a streamlined process is in place and the matter may be raised directly, to the Commissioners, bypassing the TIC process. The Commissioners meet once a week but may also meet on demand to consider the evidence on urgent safety matters. An urgent safety matter may include improvements needed to regulations or guidance, or the need to consider a new backfit.

Both processes are captured within the management system. All processes within the management system are valid for 5 years at which point they must undergo a review (refer to Chapter 4).

A number of examples were quoted and details of two recent examples were provided and discussed. These were:

- phenomenon observed at the Onagawa Power Station Unit, 1, referred to as High Energy Ark Failure. An earthquake in Japan led to an arking event within an electrical unit which resulted in a fire. A similar event was observed in the USA. The NRA subsequently modified the regulation to introduce the need for consideration of this fault as part of the safety case. The process of technical evaluation and research from identification of the issue to placing requirements on licensees (2017), took approximately 18 months;
- a shortfall in NRA’s guidance when compared with the IAEA standard, GSR Part 2, relating to safety culture and leadership; as well as on quality management. Following instigation of the process, the NRA guidance was modified to capture the IAEA standard. The guidance now requires review and assessment of the licensees’ safety culture.

Recommendation 11- Part 2 - As stated above, the “Latest Findings Reflection Process” is used to identify and capture any issues including those related to implementation of NRA’s regulations through development of necessary guidance. Guidance is developed as necessary to aid licensees with implementation of regulatory requirements. Guidance is internal NRA ordinance and one of the ways that the licensees can meet the requirements of the regulation. Other means of complying with the regulations may be presented to the NRA. In response to the findings of the IRRS 2016 mission, examples of guidance developed for radiation safety were presented. These are:

1. Perspective of Examination Standards for Operational Rules of Design Certification, etc. and Confirmation of Operational Rules of Periodic Training for Radiation Protection Supervisors, etc., at Registered Certification Organizations; [December 13, 2017]
2. Interpretation of Accident Reports, etc. to Nuclear Regulation Authority under the Provision of Article 28-3 of the Enforcement Regulation of the Act on the Prevention of Radiation Hazards due to Radioisotopes, etc. Based on the Provision of Article 31-2 of the Act on the Prevention of Radiation Hazards due to Radioisotopes, etc established December 13, 2017;
3. Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program, established December 13, 2017;
4. On-site Inspection Guide for Registered Certification Organization, established December 13, 2017.

Recommendation 11- Part 3- The NRA now has a backfit process which identifies any gaps in existing regulations/ordinance and then places new regulatory requirements on the licensees to meet the new requirement which are considered minimum safety standards. There is a provision for a grace period to enable the licensees to meet these new requirements. The process is applicable to prospective, new and existing licensees.

The backfit process is complemented by the requirement to conduct periodic safety reviews every 10 years in line with IAEA guidance and international good practice. Following the 2016 IRRS mission, the NRA now has revised

its guidance that addresses the findings raised by the mission. This process requires a comprehensive review of the totality of the safety case. The guidance (“Operational Guide for the periodic safety assessment of continuous improvement of commercial nuclear reactors – revised 29 March 2017”) makes explicit reference to the IAEA SSG-25 and has full coverage of all the specified safety factors including equipment qualification.

Upon receipt, an NRA review team assesses the report to confirm whether it complies with the requirement of its guidance. Reviewers may follow-up on issues or gaps they identify. The regulatory review of the PSR doesn’t result in the issuing of a permit or approval. Whilst a regulatory expectation, implementation of measures identified as part of the periodic safety review is a voluntary process. This is because the PSR process is in place to ensure continuous improvement over and above what is required by NRA regulations/ordinance. As discussed above, the NRA regulations/ordinance may be revised to place additional mandatory requirements on the licensees which then become subject to the backfit process.

The NRA may take enforcement action if the licensees don’t meet its regulations/ ordinance. Enforcement action may include, for example, requiring the facility to suspend operations. Furthermore, the new inspection regime (to be implemented from April 2020) will enable the NRA to satisfy itself of licensees’ continuous compliance with the regulation/ordinance and have oversight of any safety improvements made as part of the PSR process.

The licensees however are required to publish the findings from their periodic safety review which encourages them to implement the most significant findings, considering all reasonable practicable measures. The NRA is notified of any improvements the licensees identify as necessary following the review process.

The missions also reviewed NRA’s progress in respect of its self-identified Action Plan and discussed in details two Actions. The work undertaken so far demonstrates NRA’s commitment to developing standards and guidance for medium and near-surface repositories as well as for release of sites from the licensing regime. The IRRS team recognised the progress made and encourages the NRA to continue with its work.

Status of the finding in the initial mission

Recommendation R11 is closed.

New findings from the follow-up mission

No new findings were identified.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Original mission RECOMMENDATIONS, SUGGESTIONS

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 the NRA in deciding on mitigatory actions on the scene. There is a lack of emergency response arrangements within the NRA to address response role of the 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)	<i>In addition, the following paragraphs provide basis for this recommendation:</i> 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: The 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: The NRA should consider strengthening its plans and procedures to consistently respond to emergencies related to radiation sources.

Changes since the initial IRRS mission

Recommendation 12: The NRA established in December 2017 new requirements within the RI ordinance and guidance for preparedness and response to emergency situations that are designed specifically for licensees of radiation sources. The guidance is incorporated in the “Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program”, a document that supports the licensee’s development of their Radiation Hazards Prevention Program, as required by the RI Act. The Radiation Hazards Prevention Program is to be submitted by the operator/licensee to the NRA before conducting any regulated activities. The requirements and guidance cover the necessary elements of EPR arrangements and plans, including defining the roles and responsibilities of licensee and conducting training for radiological emergencies. The NRA has also required RI operators to specify in their Radiation Hazards Prevention Program the actions to be taken outside of RI facilities during an emergency, and develop guidelines regarding the collaboration with off-site response agencies in an emergency situation.

The RI Act has been amended to make reporting to the NRA from the licensee in the event of an emergency situation legally mandatory. The NRA also stipulated which matters need to be specified in the Radiation Hazards Prevention Program in the NRA Ordinance for Enforcement of the Act on Regulation of Radioisotopes, which came into force in April 2018.

The RI Act was amended requiring all licensees to have the responsibility for taking necessary measures on improvement of operations by taking the latest findings into consideration. The NRA stipulated that the implementation system and the recording of activities required for operational improvement among the quality assurance activities needs to be described in the licensee’s Radiation Hazards Prevention Program. This addresses the development of the requirement for a quality assurance programme using the graded-approach.

These efforts have led to the establishment of a comprehensive set of requirements and guidance for EPR in relation to sources of ionizing radiation regulated under the Radiation Hazards Prevention Act and the actions

expected from licensees/operators of radiation facilities. The IRRS team was informed that the above-mentioned approach is not applicable to the pharmaceutical products which are regulated by the MHLW.

Suggestion 11: The NRA conducted a study to determine the required emergency response and information transmission for the 28 identified RI facilities (16 research institutes, 10 industrial facilities, and 2 pharmaceutical facilities). The study classified the potential risk for each facility based on their hazards. In April 2019, the NRA implemented a response system for emergencies involving radiation sources and developed its own response manual (NRA Initial Response Manual for the Accident and the Trouble in RI Facilities). This includes the requirement of RI licensees to report to the NRA in the event of fire, earthquake or other natural disaster at its facilities.

The NRA is responsible for regulating RI facilities (research institutes and industrial facilities) with the exception of pharmaceutical facilities. For pharmaceutical sources, the NRA regulates raw materials and MHLW regulates pharmaceutical products. Depending on the nature of the emergency the licensee will notify the NRA and/or the MHLW which in turn will coordinate the regulatory oversight of the event and notify the public and other government agencies as appropriate.

Based on NRA’s implementation of a response system and the development of a response manual for radiation sources in cooperation with MHLW for pharmaceutical sources, the NRA has strengthened its emergency plans and procedure to consistently respond to emergency related to radiation sources.

Status of the finding in the initial mission

Recommendation R12 is closed based on NRA’s establishment of a comprehensive set of requirements and guidance for EPR in relation to sources of ionizing radiation including the actions expected from licensees/operators of radiation facilities.

Suggestion S11 is closed based on that the NRA has strengthened its emergency plans and procedure to consistently respond to emergencies related to radiation sources, and NRA’s implementation of a response system and the development of a response manual for radiation sources in cooperation with MHLW for pharmaceutical sources.

New findings from the follow-up mission

No new findings were identified.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Original mission RECOMMENDATIONS, SUGGESTIONS

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 <i>“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 [...]”</i>
(2)	BASIS: GS-R-2 para. 4.54 states that <i>“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.”</i>
(3)	<i>In addition, the following paragraphs provide basis for this recommendation:</i>

Original mission RECOMMENDATIONS, SUGGESTIONS

	<i>GS-R-2, paras. 4.23, 4.25,</i>
R13	<p>Recommendation: The NRA should establish:</p> <ul style="list-style-type: none"> • 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.

Original mission RECOMMENDATIONS, SUGGESTIONS

<p>Observation: <i>Since the TEPCO Fukushima Daiichi accident efforts were made to enhance requirements for emergency workers. The 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.</i></p>	
(1)	<p>BASIS: <i>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. [...]”</i></p>
(2)	<p><i>In addition, the following paragraphs provide basis for this recommendation:</i> GS-R-2, paras. 4.62, 4.63</p>
S12	<p>Suggestion: The Government should consider ensuring that the relevant authorities establish consistent requirements for categories of emergency workers performing similar tasks.</p>

Changes since the initial IRRS mission

Recommendation 13: To address the need to establish a complete set of Emergency Action Levels (EALs) for nuclear facilities other than NPP’s, the NRA conducted a high-level study performed by a team consisting of external experts, members of the NRA commission and officials of the NRA. Based on the results, which included hazard assessments for each facility, the Precautionary Action Zone (PAZ) and Urgent Protective action planning Zone (UPZ) zones were decided to be set individually for each of these facilities. The EALs were also organized according to individual facilities based on the decision to derive EALs depending on the characteristics of each facility even if the hazard classification is the same. For nuclear facilities other than NPPs, the NRA added conditions or parameters for determining EALs for the different emergency classifications for each facility. The NRA subsequently amended the NRA EPR Guide in July 2017 to include this new information.

For development of associated guidance to promptly define EALs for all nuclear operators, the NRA used the results of a Nuclear Energy Disaster Prevention Drill conducted in 2016 to optimize EAL activation. The descriptions related to Site Emergency and General Emergency have been modified. Regarding Alert for all the facilities the requirements for natural disasters were re-examined and revisions were performed. Subsequently, in 2017 the relevant regulation of the Act on Special Measures Concerning Nuclear Emergency Preparedness and Explanations of Criteria for Determining Emergency Categories, which are associated guidance of the NRA EPR Guide, were amended. The latter includes modifications of descriptions related to NPPs and to add descriptions related to a nuclear fuel facilities. These amendments provide the licensees/operators with instructions to properly establish a Nuclear Operator Emergency Action Plan and appropriately determine the emergency classification and the notification of the occurrence of abnormalities in the facilities.

These efforts have resulted in a complete set of guidance that prescribes the methodology for the development of EALs for nuclear facilities other than NPPs, and the development of associated guidance to promptly define EALs for all nuclear facilities.

In September 2017, the NRA revised its internal regulation and amended the document “Viewpoints in Reviewing the Nuclear Operator’s EPR plan” to add a description that the NRA will review and confirm the implementation status of information provision to the public at the time when the NRA receives the notification of the Nuclear Operator Emergency Action Plan from the licensees. The licensee is required to submit its emergency plans to the NRA for verification prior to implementation. The NRA publishes the emergency plans and any supporting information on its websites, and licensees publish the outline of their emergency plans.

Suggestion 12: The NRA’s Radiation Council (composed of external experts with NRA acting as the secretariat) discussed the issue of changing radiation doses for different emergency workers, using the experience of the emergency work activities of the operators, police officers, firefighters, self-defence officials, etc., that worked at the accident at the TEPCO Fukushima Daiichi Nuclear Power Station into consideration. The Radiation Council decided that the predefined dose limit of 250 mSv for emergency workers is only applied to licensees and resident inspectors since they are the only emergency workers who undertake actions preventing and mitigating catastrophic situations where doses might exceed an effective dose of 100 mSv. This decision was made based on the actual results of the accident at Fukushima Daiichi NPS and through the consultations to all related competent authorities.

Post August 2015, the Ordinance on Prevention of Ionizing Radiation Hazards, the Regulation on Radiation Hazard Prevention for Staff – National Personnel Authority’s Rules 10-5, and the Notification to Establish Dose Limits in Accordance with the Provisions of NRA Ordinance on Activity of Refining Nuclear Source or Nuclear Fuel Materials were amended to increase the exposure limit of emergency workers to 250 mSv effective dose. This dose limit is only applicable to emergency workers and resident inspectors with dedicated tasks to respond to catastrophic events. The dose limit for all other emergency workers is limited to 100 mSv effective dose.

Status of the finding in the initial mission

Recommendation R13 is closed based on the NRA’s establishment of a complete set of guidance for defining EALs for all nuclear facilities. The NRA has also implemented a procedure to review and confirm that nuclear operators provide information to the public under normal conditions.

Suggestion S12 is closed based on the confirmation that the categories of emergency workers performing similar tasks are consistent.

New findings from the follow-up mission

The NRA has made significant progress in recent years in the development of its emergency preparedness and response framework and in particular, its protection strategy. This includes the work with the development of operational intervention levels (OILs) and emergency action levels (EALs). The IRRS team encourages the NRA to work with the relevant authorities in order to review their current EPR framework and determine if there are any gaps that exist in meeting requirements in GSR Part 7 and, if any gaps exist, develop the appropriate regulatory requirements and any supporting documents needed to implement the requirements in accordance with GSR Part 7. The IRRS team encourages the government of Japan to request an EPREV mission.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

11. EXTENDED TOPIC: SAFE TRANSPORT OF RADIOACTIVE MATERIAL

The IRRS team was requested to review the area of Transport Safety, which was not covered in the 2016 initial mission. The review included discussions with representatives from the NRA, the Ministry of Health, Labour and Welfare (MHLW) and Ministry of Internal Affairs and Communications (MIC).

Transport of radioactive material in Japan takes place by all modes of transport and includes transport of radioisotopes, radiopharmaceuticals, nuclear source and nuclear fuel material for applications in industry, medicine and research and for nuclear power production.

It is important to note that the scope of this transport safety review within the IRRS follow-up mission has been limited, as requested, to the regulation of the following parts of land transportation of:

- nuclear fuel materials and nuclear source materials and radioisotopes that the NRA is responsible for (regarding nuclear fuel materials and radioisotopes, limited to the regulations related to packages),
- radiopharmaceuticals that MHLW is responsible for,
- radioactive materials by post etc. that MIC is responsible for

and the NRA liaison with the relevant bodies such as emergency response (interface related part only).

The areas of transport under the regulatory oversight of Ministry of Land Infrastructure, Transport and Tourism (MLIT) are not within scope of this mission.

11.1. REGULATORY FRAMEWORK AND RESPONSIBILITIES

The regulatory framework for Nuclear Safety and Radiation Protection in Japan is based on

- the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors,
- the Act on the Regulation of Radioisotopes,
- the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, and
- the Postal Act,

together with related Cabinet Orders, Ordinances, Standards, Notifications and Guides which contain specific provisions for the transport of radioactive material and assignments for certain responsibilities in this field.

There are several authorities responsible for the safe transport of radioactive materials depending on the type of materials to be transported (nuclear fuel material, nuclear source material, radioisotopes and radiopharmaceuticals) and the mode of transport (land, sea, air and post) as follows:

- a) the NRA is responsible for the regulations for packages for nuclear fuel material, nuclear source material and radioisotopes for land transport and, in case of nuclear source material, it is also responsible for the regulations regarding the transport method for land transport,
- b) the MHLW is responsible for the regulations for packages and transport methods for radiopharmaceuticals for land transport,
- c) the Ministry of Internal Affairs and Communication (MIC) is responsible for the regulations for transport of radioactive material by post, and
- d) the Ministry of Land Infrastructure, Transport and Tourism (MLIT) is responsible for the regulations regarding the transport method for nuclear fuel material and radioisotopes. It is also responsible for the regulations for sea transport and air transport of radioactive material both for packages and transport method.

For the purpose of liaison and coordination among these regulatory authorities, “Interagency Coordination Meetings for the Safe Transport of Radioactive Material” are regularly held (2 to 4 times a year). Opinions are shared regarding:

- information exchange,
- issues related to establishment and amendment of IAEA regulations for the safe transport of radioactive material,
- the matters related to domestic laws and regulations based on the these IAEA regulations, and
- the matters related to safety measures for transport.

These coordination meetings are based on a documented agreement among all involved authorities.

Currently, the SSR-6, 2012 Edition is in force in Japan. A new process has started to adopt the SSR-6, 2018 Edition into the national regulations. This is being coordinated by the “Interagency Coordination Meeting”. The

IRRS team was informed that the NRA has a document that maps each of SSR-6, 2018 Edition requirements to the corresponding national regulations and corresponding authorities. The NRA is encouraged to share this document within the “Interagency Coordination Meeting” to collaboratively implement SSR-6, 2018 Edition.

11.2. AUTHORIZATION OF TRANSPORT

For land transportation of nuclear fuel material and radioisotopes, the NRA is responsible to issue competent authority approval certificates for

- package designs containing 0.1 kg or more of uranium hexafluoride
- package designs containing fissile material,
- Type B(U) and Type B(M) package designs, and
- special arrangement

as required under para. 802 (a) (iv), (v), (vi) and 802 (b) of SSR-6.

Additionally, the NRA issues certificates for packaging approval and a “package confirmation certificate” prior to shipment of each package.

The NRA is also responsible for the approval of special form material, as required under para. 802 (a) (i) of SSR-6, and for the approval of the calculation of unlisted radionuclide values and alternative activity limits for exempt consignments of instruments or articles according to para. 802 (e) and (f) of SSR-6. The IRRS team found that the responsibilities for these approvals have not been explicitly assigned to the NRA within the Japanese legislation.

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The process for approvals according to paras. 802 (a) (i), 802 (e) and 802 (f) of the IAEA Transport Regulations SSR-6 are not explicitly specify in its regulatory documents.</i>	
(1)	BASIS: <i>SSR-6, para 802 states that “Competent authority approval shall be required for the following: (a) Designs for: (i) Special form radioactive material... (e) Calculation of radionuclide values that are not listed in Table 2... (f) Calculation of alternative activity limits for exempt consignment of instruments or articles”.</i>
RF1	Recommendation: <i>The NRA should specify process for approvals of special form radioactive material, unlisted radionuclide values and alternative activity limits for exempt consignments of instruments and articles in its regulatory documents.</i>

The land transport of radiopharmaceuticals is not subject to a competent authority approval for the package designs since the radioactive content of these materials are limited to less than or equal A2 values of SSR6. Authorization is also not required for transportation by the postal service.

Regarding the contents of the NRA package design approval certificates, the IRRS team found that the certificates do not contain all the prescribed information as per para. 838 of SSR-6.

The package design approval certificates for nuclear fuel material do not include the following information:

- any restriction of the mode of transport, para 838 (d),
- a list of applicable national and international regulations, including..., para 838 (e),
- reference to the documentation that demonstrates the criticality safety of the package, para 838 (n) (iv),
- the ambient temperature range for which the package design has been approved, para 838 (n) (vii), and
- a specification of the applicable management system, as required in para 306, para 838 (t).

The package design approval certificates for radioisotopes also do not contain the information described above (except paras 838 (n) (iv) and (n) (vii)) and in addition do not include:

- the competent authority identification mark, para 838 (b),
- specification of the design by reference to the drawings, para 838 (k), and
- a specification of the authorized radioactive contents, para 838 (l).

The approval certificates for the packaging and for the package confirmation before transport are both closely related to the package design approval certificate. It was found that the contents of these two certificates does not contain any reference to the relevant package design approval certificate.

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>The package design approval certificates issued by the NRA do not contain all information as required by IAEA Transport Regulations SSR-6, para 838. In addition, the NRA issues approval certificates for packaging and package confirmation before each transport which do not include reference to the certificate of package design they are based on.</i></p>	
(1)	<p>BASIS: SSR-6, para 838 states that “Each certificate of approval of the design of a package issued by a competent authority shall include the information as listed under para. 838 (a)-(x)”.</p>
(2)	<p>BASIS: SSG-26, para 503.4 states that “The package’s certificate of approval is the evidence that the package design of an individual package meets the regulatory requirements and that the package may be used for transport”.</p>
RF2	<p>Recommendation: The NRA should add the items of its certificates for package design approval to ensure compliance with the requirements of SSR-6.</p>
SF1	<p>Suggestion: The NRA should consider to revise structure and contents of its certificates for packaging and package confirmation such that reference to the relevant package design approval certificate is included and that a harmonized and interlinked structure and contents for both, the packaging and the package confirmation certificate, is achieved.</p>

The NRA approval procedures and the structure and contents of the NRA certificates must take into account that other regulatory authority (MLIT) is involved in the authorization of transport. This ensures compliance with SSR-6 requirements and consistency among involved authorities in the management of authorization processes which has been identified by the NRA in its self-assessment and included in the Action Plan as Action A1.

11.3. REVIEW AND ASSESSMENT FOR TRANSPORT

The NRA performs review and assessment for package design approval, packaging approval and package confirmation approval for nuclear fuel material and radioisotopes based on detailed application documents. However, the IRRS team found that internal documented guidance for the technical review of the applicants’ safety assessment of package designs do not exist. The IRRS encourages the NRA to develop such internal guidance.

11.4. INSPECTION OF TRANSPORT

Type B packages containing nuclear fuel materials are assessed by the NRA by reviewing application documents and by on-site inspections. All Type B packages containing radioisotopes are assessed by a registered organization by reviewing application documents, furthermore, radioisotopes over 1 PBq are subject to on-site inspections by the registered organization.

Type A packages containing nuclear fissile materials are subject to reviews by the NRA. However, other Type A packages are not subject to any review.

The IRRS team was informed that in the new inspection system, all package types containing nuclear fuel materials will be subject to inspection by the NRA. This concept should be extended to cover radioisotopes including Type B packages with contents less than 1 PBq as well as Type A packages, industrial packages and excepted packages.

In 2018, there were no packages containing nuclear fuel materials transported in Japan. In the same year, 490 Type B packages containing radioisotopes were transported in Japan and the registered organization assessed all of them by reviewing the application documents. Among them, 35 Type B packages containing 1 PBq or over radioisotopes were inspected by registered organization by on-site inspections. In 2018, 977 Type A packages containing nuclear fuel materials were transported and among them 949 Type A packages containing nuclear

fissile materials were assessed by the NRA by reviewing application documents. Approximately 19,000 Type A packages containing radioisotopes were transported but these were not inspected.

MHLW inspections of packages containing radiopharmaceuticals regularly take place in conjunction with the extension of the licence of the production facilities, which is once every 5 years. This results in a low number of inspections. There were 4 inspections of radiopharmaceutical manufacturing sites by MHLW in 2018 when more than 500 000 packages with radiopharmaceuticals have been transported from 23 manufacturing sites.

Consequently, the regulatory inspection programs for Type B, Type A packages, industrial packages and excepted packages are not sufficient to comply with the IAEA Transport Regulations. Most of the regulatory decisions are based on the review of application documents. More on-site inspections for all types of packages applying the graded approach should be carried out.

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The NRA inspection programmes do not extend to all package types used and in some instances do not include sufficient on-site inspections. Further, radiation protection programmes of consignors and consignees for transportation are not sufficiently inspected by the NRA. MHLW does not apply an appropriate graded approach to its inspection programme.*

(1)	BASIS: GSR Part 1 (Rev 1), Requirement 27 states that <i>“The regulatory body shall carry out inspections 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“</i>
(2)	BASIS: GSR Part 1 Requirements 29 states that <i>“Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced“.</i>
(3)	BASIS: SSR-6, Paragraph 302 states that <i>“A radiation protection programme shall be established for the transport of radioactive material. The nature and extent of the measures to be employed in the programme shall be related to the magnitude and likelihood of radiation exposures. The programme shall incorporate the requirements of paras 301, 303–305, 311 and 562. Programme documents shall be available, on request, for inspection by the relevant competent authority.“</i>
(4)	BASIS: SSR-6, Paragraph 307 states that <i>“The competent authority shall assure compliance with these Regulations.“</i>
(5)	BASIS: SSR-6, Paragraph 801 states that <i>“For package designs where it is not required that a competent authority issue a certificate of approval, the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all the applicable requirements”.</i>
RF3	Recommendation: The NRA should extend its inspection programmes to all types of packages based on a graded approach that includes announced and unannounced on-site inspections for the manufacture, maintenance and preparation for transport. The NRA should also inspect radiation protection programmes of consignors and consignees for transportation. The MHLW should review and revise its inspection programs, as appropriate, based on a graded approach.

11.5. ENFORCEMENT FOR TRANSPORT

The operators are required to report any theft or abnormal release of radioactive material, injury or potential injury of persons arising from transportation of nuclear fuel to the NRA.

For the transport of nuclear fuel materials, nuclear source materials and radioisotopes, the NRA has the powers to stop the transportation or take any necessary regulatory measures when there are non-compliance with the regulatory requirements for transport.

Based on the provisions of Article 72-4(1) of the “Pharmaceutical and Medical Devices Act”, MHLW is also empowered to take appropriate actions in case of non-compliances in transport of radiopharmaceuticals.

Also, MIC can take appropriate enforcement actions according to Article 16(1) of the Act on Japan Post Co., Ltd. or Article 37(2) of the Act on Correspondence Delivery by Private Business Operators.

11.6. REGULATIONS AND GUIDES FOR TRANSPORT

The system of regulations and guides for the land transport of radioactive material in Japan is split into different areas mainly depending on the type of material as follows:

- a) Transport of nuclear source material and nuclear fuel material based on the “Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors” and related Orders, Ordinances, Notifications and Guides,
- b) Transport of radioisotopes based on the “Act on the Regulation of Radioisotopes” and related Ordinance, Notifications and Guides,
- c) Transport of radiopharmaceuticals based on the “Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices” and related regulations and standards, and
- d) Transport by post based on the “Postal Act” and related other acts, public notices, regulations and conventions.

Areas a) and b) contain all requirements and guidelines the NRA is responsible for, c) contains all requirements and guidelines MHLW is responsible for and area d) contains all requirements concerning MIC’s responsibility.

The regulations for transport by post are consistent with SSR-6 since they are in compliance with the Convention of the Universal Postal Union (UPU) which incorporates SSR-6.

For the three other areas appropriate paragraphs of SSR-6 have been selected which are applicable for land transport of the appropriate material types and have been incorporated into these Japanese regulations for each of the three areas. Based on this approach it is concluded, that the regulations and guides for a), b) and c) are in principle in accordance with applicable requirements of SSR-6.

The NRA participates in all the IAEA committee meetings related to the transport safety standards for radioactive material (TRANSSC). It is worth noting that the NRA requested a Technical Support Organization (TSO) to create an IAEA/TRANSSC Study Group, which consists of experts from academia, operators and industries and research organizations. The NRA attends as observer. This group contribute to the technical work of TRANSSC in relation to the ongoing development of the SSR-6 requirements.

Upon adoption of the IAEA transport safety requirements into domestic regulations, for the purpose of consistency of transport of radioactive materials in general, the NRA has the framework to conduct necessary liaison arrangement within the “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” in which all the relevant regulatory authorities participate. Additionally, regarding adoption of the latest IAEA transport regulations (SSR-6), the NRA considers their adoption together with the technical standard related to hazardous materials transportation (ICAO-TI) based on ICAO convention and the technical standard related to hazardous materials transportation based on SOLAS convention (IMDG Code), in cooperation with the relevant regulatory authorities.

The NRA Commercial Reactor Ordinance has been amended and enacted in April 2019 to include casks for transport and storage (dual purpose casks) as a specific type of equipment which allows to obtain approval for such casks for transport as well as for storage in advance. Discussions relating to Dual Purpose Casks (DPCs) revealed that the development of specific regulations and guidance material is ongoing in the NRA.

Within the NRA, regulatory oversight of NPPs and Transport are in separate parts of the organization. It is recognised within the NRA that those procedures must be aligned. Technical criterion for transport and storage are common in some respects. A new process is under development to avoid overlapping activities for manufacture, inspection and approval. Completion of this work is important as the use of DPCs as a component of the spent fuel strategy is continuing to grow. This has been recognised by the NRA in its self-assessment and Action Plan, see Action 3.

The IRRS team found that some provisions of the application procedure for the NRA approvals as specified in the Nuclear Off-Site Transportation Notice and related guides need more specification and to be modified appropriately. This has been recognised by the NRA in its self-assessment and Action Plan, see Action 2.

The NRA has developed and published very detailed forms for users to apply for package design approvals which has been identified by the IRRS team as a good performance.

11.7. EMERGENCY RESPONSE FOR TRANSPORT

The nuclear operator is obliged to report any accident to the relevant competent authority and to take necessary measures. It is further described that a framework for emergency preparedness exists based on

- the document about “Measures Regarding Safety Measures Against Accidents of Transport of Radioactive Materials” prepared by “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” that composes of the departments and divisions in charge of the competent authorities related to safe transport of radioactive materials, and
- the Act on Special Measures Concerning Nuclear Emergency Preparedness,

by which “the following matters are organized in advance by specifying the sharing of roles of the relevant organizations:

- Notification/liaison system
- Organizational system that consists of the relevant organizations
- Collecting/summarizing/sharing of information
- Dispatch of the staff and experts to the site
- Response on the site (lifesaving, fire extinguishing, contamination prevention, restricted entry,..)
- Public relation
- Measures for restoration from nuclear emergency (termination of restrictions, evaluation of dose exposure, health consultation, measures against reputational damage etc.).

At the occurrence of the accidents, the relevant organizations will promptly respond in collaboration within these frameworks.”

Existing national emergency plans are reviewed and updated. Nonetheless the self-assessment identified improvements in this area which have been included in the NRA Action Plan, see Actions A4 and A5.

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The IRRS team was informed that no emergency exercises have been performed to check the efficiency and effectiveness of the emergency preparedness framework.*

(1)

BASIS: GSR Part 1 (Rev 1) Requirement 8, para 2.24A states that “The government shall ensure that adequate training, drills and exercises, involving authorized parties and response organizations, including decision makers, are carried out regularly to contribute to an effective emergency response [5]. The training, drills and exercises shall cover a full range of postulated emergencies (e.g. events affecting several facilities on the same site, emergency exercises of long duration and emergencies with transboundary consequences)“.

RF4

Recommendation: The NRA, collaborating with other relevant competent authorities should ensure that the emergency arrangements for responding to a nuclear or radiological emergency during the land transport of radioactive material are periodically tested.

12. ADDITIONAL AREAS

12.1. OCCUPATIONAL RADIATION PROTECTION

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

The initial IRRS team noted that the concept of dose constraints was not introduced into the legislation to serve as an optimization tool. The view of the Radiation Council was that “dose constraints are not necessary since they may hinder the flexible and optimized management of licensees’ radiation protection measures” and the situation has not changed in the meantime.

The occupational dose limits in Japan conform to the IAEA safety standards and actions are under way to implement revised dose limits for the lens of the eye, based on revised ICRP recommendations. The Radiation Council promotes consistent implementation of dose limits across nuclear and research facilities, industrial applications, as well as for limiting occupational exposure in medical applications.

The IRRS team found inconsistencies in the implementation of the optimization principle across facilities and activities. Optimization for worker protection in nuclear facilities is carried out in accordance with the Reactor Regulation Act, which is based on ICRP recommendations that have now been superseded by ICRP Publication 103 (2007). Transition to a system consistent with requirements of GSR Part 3 is planned for new licences and for licence renewal applications. NRA’s publication, “Standard of Examination for Operational Safety Program”, provides guidance on optimization to licence holders. The IRRS team was informed that similar requirements and guidance have not been developed under the terms of the RI Act and consequently do not apply to licensees under the RI Act.

The need for strengthening the focus on optimization in the inspection program has been recognised by the NRA and will be included in its inspection program commencing in April 2020, for facilities authorized under the Reactor Regulation Act.

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Optimization is not consistently implemented for the purpose of worker protection and dose constraints are not used when such constraints are relevant, and there is no process for establishing such constraints. The NRA could take a leading role in promoting an enhanced approach to optimization and work with the Radiation Council in that regard.*

- | | |
|-----|---|
| (1) | <p>BASIS: GSR Part 3, requirement 11 para 3.22 states that “The government or the regulatory body</p> <ul style="list-style-type: none">• Shall establish and enforce requirements for the optimization of protection and safety;• Shall require documentation addressing the optimization of protection and safety;• Shall establish or approve constraints on dose and on risk, as appropriate, or shall establish or approve a process for establishing such constraints, to be used in the optimization of protection and safety”. |
|-----|---|

RF5	<p>Recommendation: The NRA should strengthen its approach to optimization, including the use of dose (or risk) constraints as appropriate, and promote consistent application of the optimization principle across all facilities and activities.</p>
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13. INTERFACE WITH NUCLEAR SECURITY

13.1. LEGAL BASIS

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

13.2. REGULATORY OVERSIGHT ACTIVITIES

Original mission RECOMMENDATIONS, SUGGESTIONS

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 the 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 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: **The NRA should consider expediting improvements in the arrangements to assess, oversee and enforce nuclear safety and security in an integrated manner.**

Changes since the initial IRRS mission

Suggestion 13:

The NRA issued “Official Directives on Confirming the Trustworthiness of Staff in the NRA” in April of 2018 in order to ensure that access to protected documents is granted throughout the NRA consistently and facilitates the review of the safety security interface.

For the coordination and cooperation between the organizational units of the NRA with respective responsibilities for safety and security, the following approach has been established. When an application for approval and permission is submitted from a licensee to the division in charge of safety review, the respective division will consult the division in charge of nuclear security and asks for comments on potential adverse effects from their perspective, and vice versa. In case of conflicts between safety and security, an interview with the licensee will be organized to resolve them.

The above mentioned approach has been operational since July 2018 and was documented and published in NRA’s management system in April 2019.

Concerning the avoidance of conflicting safety and security requirements at the licensees, the NRA requested 27 licensees to identify and to eliminate mutual adverse effects from their Physical Protection Programs based on the Reactor Regulation Act in 2018.

Status of the finding in the initial mission

Suggestion S13 is closed based on the implementation of the coordination approach between the divisions responsible for safety review and security.

New findings from the follow-up mission

No new findings were identified.

13.3. INTERFACE AMONG AUTHORITIES

There were no findings in this area in the initial IRRS mission.

New findings from the follow-up mission

No new findings were identified.

APPENDIX I – LIST OF PARTICIPANTS



INTERNATIONAL EXPERTS:

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APPENDIX II – FOLLOW-UP MISSION PROGRAMME

Time	Day 1 - Tue Jan 14	Day 2 - Wed Jan 15	Day 3 - Thu Jan 16	Day 4 - Fri Jan 17	Day 5 - Sat Jan 18	Day 6 - Sun Jan 19	Day 7 - Mon Jan 20	Day 8 - Tue Jan 21	Time			
08:15		Team Meeting	Team Meeting	Team Meeting	Team Meeting	Team Meeting	Team Meeting		07:30			
09:30	Arrival of IRRS Team Members	Entrance Meeting	Interviews	TM write Report TL and DTL review introductory part	Discussion Counterpart/Expert Finalisation	Preparation for Exit Meeting, Press Release and Press Conference (TL, DTL, TC, DTC, Press officer)	Written comments by the Host to the team Team discussions on the comments	Exit Meeting	09:30			
10:00									10:00			
10:30		Grup Photo						Preparation for Press Conference TL, Press Officer	10:30			
11:00					11:00							
11:30		Interviews		Press Conference	11:30							
12:00					12:00							
12:30	Lunch	Standing Lunch	Standing Lunch	Standing Lunch	Standing Lunch	Standing Lunch	Standing Lunch		12:30			
13:00									13:00			
13:30	Initial Team Meeting (Attended by the LO): • Admin and logistical issues (LO) • IRRS objectives, process • Report writing • Schedule • First observations	Interviews	Policy discussion	Secretariat edits the report	Cross-reading	Host reads Draft and prepares written comments	TL finalises the presentation	TC drafts the Press Release	Team Free / Social Event	Team disposition of comments discussed with the Host		13:30
14:00												
14:30			Interviews/ TM Write findings	Preliminary Draft Report Ready	Discussion of Executive Summary (TL, DTL, TC, DTC)	Finalization of the draft report	Departure of IRRS Team Members				14:30	
15:00												
15:30		Daily team Meeting	Daily team Meeting Discussion of findings	Daily team Meeting	Finalization of the draft report	Departure of IRRS Team Members		15:30				
16:00												
16:30		Daily team Meeting	Daily team Meeting Discussion of findings	Daily team Meeting	Finalization of the draft report	Departure of IRRS Team Members		16:30				
17:00											17:00	
17:30		Daily team Meeting	Daily team Meeting Discussion of findings	Daily team Meeting	Finalization of the draft report	Departure of IRRS Team Members		17:30				
18:00											18:00	
19:00	Welcome Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Farewell Dinner	Departure of IRRS Team Members		19:00		
19:30												
20:00		TM Writing of the report	Written preliminary findings delivered	TM write Report Secretariat edits Report				Departure of IRRS Team Members		20:00		
20:30												20:30
21:30									21:30			

APPENDIX III – LIST OF COUNTERPARTS

	IRRS Experts	Lead Counterpart	Support Staff
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT		
	SCHWARZ Georg LARSSON Carl-Magnus HAEGG Anki	NAGASAKA Yuichi MIYAMOTO Hisashi MORISHITA Yasushi KOGANEYA Toshiyuki ICHII Naoto KINJO Shinji	OJIMI Maria HORI Akio KITAIUE Hiroki SATOU Kazuko
2.	THE GLOBAL SAFETY REGIME		
	SCHWARZ Georg LARSSON Carl-Magnus HAEGG Anki	ICHII Naoto KINJYO Shinji	SUGIMOTO Fumitaka
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY		
	ARSHAD Muhammd Naeem HAEGG Anki LARSSON Carl-Magnus	KOJIMA Youhei MOTOHASHI Takayuki ICHII Naoto KINJO Shinji NAGASE Fumihisa OKUMA Kazuhiro MIYAMOTO Hisashi MORISHITA Yasushi TAKEMOTO Akira	MORI Mihoko SUGIMOTO Fumitaka NAOI Yukiko KOBAYASHI Syunji SATO Kiyokazu KITAIUE Hiroki
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY		
	KRS Petr	MOTOHASHI Takayuki	FUNADA Teruyo
5.	AUTHORIZATION		
	SHAFFER Mark PATHER Thiagan GOLSHAN Mina	MUKAE Takashi MIYAMOTO Hisashi MORISHITA Yasushi	TAKAHASHI Hiroaki HORI Akio KITAIUE Hiroki SATOU Kazuko

	IRRS Experts	Lead Counterpart	Support Staff
		TAGUCHI Tatsuya KOGANEYA Toshiyuki	
6.	REVIEW AND ASSESSMENT		
	SHAFFER Mark PATHER Thiagan GOLSHAN Mina	TOYAMA Makoto NAGASE Fumihisa KOGANEYA Toshiyuki	NARITA Tatsuzi NAOI Yukiko
7.	INSPECTION		
	STRITAR Andrej BURTA John	KOGANEYA Toshiyuki TAKEMOTO Akira	SATOU Kazuko SATO Kiyokazu
8.	ENFORCEMENT		
	STRITAR Andrej BURTA John	KOGANEYA Toshiyuki	SATOU Kazuko
9.	REGULATIONS AND GUIDES		
	GOLSHAN Mina SENIOR David	TOYAMA Makoto FUNAYAMA Kyoko MUKAE Takashi OKUMA Kazuhiro MIYAMOTO Hisashi TAGUCHI Tatsuya ONO Yuji HASEGAWA Kiyomitsu KOGANEYA Toshiyuki	NARITA Tatsuzi SUZUKI Chihiro AOKI Yoshie KANEKO Masayuki TAKAHASHI Hiroaki
10.	EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS		

	IRRS Experts	Lead Counterpart	Support Staff
	HUBBARD Lynn	KOGANEYA Toshiyuki MIYAMOTO Hisashi MORISHITA Yasushi	OOMORI Takayuki HORI Akio MATSUMOTO Kazuto KITAIUE Hiroki
11.	EXTENDED TOPIC: SAFE TRANSPORT OF RADIOACTIVE MATERIAL		
	NITSCHKE Frank WHITTINGHAM Stephen	KOGANEYA Toshiyuki OKUMA Kazuhiro MIYAMOTO Hisashi ONO Yuji OSHIMA Toshiyuki SAMUKAWA Takumi KUDO Toshiaki IINO Akira YOKOMORI Yuki SHINOHARA Makoto	HOSHI Takayuki OKETANI Mitsuhiro TAGUCHI Ko MOMOSE Takafumi KOJIMA Yuuya SAKAI Youko
12.	ADDITIONAL AREAS - OCCUPATIONAL RADIATION PROTECTION		
	HAEGG Anki	NAGASAKA Yuichi MIYAMOTO Hisashi MORISHITA Yasushi	KITAIUE Hiroki
13.	INTERFACE WITH NUCLEAR SECURITY		
	SCHWARZ Georg LARSSON Carl-Magnus HAEGG Anki	MORISHITA Yasushi	KITAIUE Hiroki

APPENDIX IV – RECOMMENDATIONS (RF), SUGGESTIONS (SF) from the 2016 IRRS mission that remain open

AREA	R: Recommendations S: Suggestions	Recommendations, Suggestions or Good Practices
1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE 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, authorizations, inspections and enforcement actions to provide coordinated and effective regulatory oversight that should also ensure a harmonized regulatory framework under their respective responsibilities.
3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES	R4	Recommendation: The NRA should evaluate the effectiveness of its current organizational 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.
4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM	R6	Recommendation: The 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 and measured in a comprehensive way to identify opportunities for improvement.
4.4. PROCESS IMPLEMENTATION	S6	Suggestion: The 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.

APPENDIX V – RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF)

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
11.2. AUTHORIZATION OF TRANSPORT	RF1	Recommendation: The NRA should specify process for approvals of special form radioactive material, unlisted radionuclide values and alternative activity limits for exempt consignments of instruments and articles in its regulatory documents.
11.2. AUTHORIZATION OF TRANSPORT	RF2	Recommendation: The NRA should add the items of its certificates for package design approval to ensure compliance with the requirements of SSR-6.
11.2. AUTHORIZATION OF TRANSPORT	SF1	Suggestion: The NRA should consider to revise structure and contents of its certificates for packaging and package confirmation such that reference to the relevant package design approval certificate is included and that a harmonized and interlinked structure and contents for both, the packaging and the package confirmation certificate, is achieved.
11.4. INSPECTION OF TRANSPORT	RF3	Recommendation: The NRA should extend its inspection programmes to all types of packages based on a graded approach that includes announced and unannounced on-site inspections for the manufacture, maintenance and preparation for transport. NRA should also inspect radiation protection programmes of consignors and consignees for transportation. MHLW should review and revise its inspection programs, as appropriate, based on a graded approach.
11.7. EMERGENCY RESPONSE FOR TRANSPORT	RF4	Recommendation: The NRA, collaborating with other relevant competent authorities should ensure that the emergency arrangements for responding to a nuclear or radiological emergency during the land transport of radioactive material are periodically tested.
12.1. OCCUPATIONAL RADIATION PROTECTION	RF5	Recommendation: The NRA should strengthen its approach to optimization, including the use of dose (or risk) constraints as appropriate, and promote consistent application of the optimization principle across all facilities and activities.

APPENDIX VI – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW

1	Self-Assessment of Regulatory Infrastructure for Safety
2	The NRA Establishment Act
3	The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority
4	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act
5	The Commercial Reactors Ordinance
6	The RI Act Article 20
7	The RI Ordinance Article 20
8	Ordinary Radiation Monitoring (supplementary reference materials for Nuclear Emergency Response Guideline) (April 4, 2018 Nuclear Regulation Authority, Radiation Monitoring Division)
9	The RI Cabinet Order
10	Framework for management of the NRA
11	NRA Management Rules
12	Improvement of the NRA Management System
13	Annual Priority Plan for FY2019
14	List of Items for Education and Training (the materials of the Reactor Safety Examination Committee and the Nuclear Fuel Safety Examination Committee, Attachment 3, November 1, 2018)
15	Official Directives Related to Appointment of Positions that Require Highly Specialized Expertise and Experience (Chairman of the NRA, July 2 of 2019).
16	Basic Policy of Human Resource Development for NRA Officials (NRA, June 25 of 2014)

17	Basic Policy for Safety Research in NRA (NRA, July 6 of 2016)
18	Joint Research Implementation Rules (Nuclear Regulatory Agency, April 21 of 2017)
19	The RI Act Article 12-2, 12-8, 41-5, 43-3
20	The RI Ordinance Article 14-16
21	Perspective of Examination Standards for Operational Rules of Design Certification, etc. and Confirmation of Operational Rules of Periodic Training for Radiation Protection Supervisors, etc., at Registered Certification Organizations, etc.
22	The Commercial Reactors Ordinance
23	Operation guide related to preparation of decommissioning measures implementation policy (November 22 of 2017, NRA)
24	The RI Act Article 27, Article 28
25	The RI Ordinance Article 26
26	List of relevant regulations/guides etc.
27	Enforcement Guide (for trial operation)
28	The Latest Findings Reflection Process
29	List of 76 Latest Findings
30	List of Correspondence Relations between Reviewed Regulatory Requirements and Guides
31	Operational Guide for the Periodic Safety Assessment of Continuous Improvement of Commercial Nuclear Reactors (established by NRA on November 27 of 2013, amended on March 29 of 2017)
32	Interpretation of Accident Reports, etc. to Nuclear Regulation Authority under the Provision of Article 28-3 of the Enforcement Regulation of the Act on the Prevention of Radiation Hazards due to Radioisotopes, etc. Based on the Provision of Article 31-2 of the Act on the Prevention of Radiation Hazards due to Radioisotopes, etc.

33	Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program
34	On-site Inspection Guide for Registered Certification Organization, etc.
35	The RI Ordinance Article 21
36	Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program
37	NRA EPR Guide 2.8,9 (October 1 of 2018 NRA)
38	Regulations relating to the events etc. to be reported by Nuclear Emergency Preparedness Manager based on Act on Special Measures Concerning Nuclear Emergency Preparedness (September 24 of 2012, Ordinance of Ministry of Education, Culture, Sports, Science and Technology, Ministry of Economy, Trade and Industry No.2)
39	Order Concerning Nuclear Operator's EPR Plan and Others that should be Prepared by Nuclear Operators Pursuant to the Act on Special Measures Concerning Nuclear Emergency Preparedness (September 24 of 2012, Ordinance of Ministry of Education, Culture, Sports, Science and Technology, Ministry of Economy, Trade and Industry No.4)
40	Explanations of Criteria for Determining the Emergency Categories in NRA EPR Guide (July 5 of 2017 NRA)
41	Viewpoints in reviewing the nuclear operator's EPR plan (September of 2017 NRA)
42	The RI Act Article 12-2, 39, 41, 41-5, 41-11, 41-14, 43-3
43	The procedures for Conducting on-site inspections based on the Act on the Prevention of Radiation Hazards due to Radioisotopes, etc. (July 3 of 2013 NRA (amended on April 2 of 2018))
44	Track record of adoption of new graduates and experienced workers
45	The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority
46	Statements on Nuclear Safety Culture

47	The Commercial Reactors Ordinance
48	Operational Guide for the Periodic Safety Assessment of Continuous Improvement of Commercial Nuclear Reactors (established by NRA, amended on March 29 of 2017)
49	The Technical Information Committee
50	Nuclear Regulation Authority Initial Response Manual ~NRA's response to large-scale natural disasters that do not lead to information gathering and alert situation ~ (NRA Radiation Protection Division Document No.1605256, May 25, 2016)
51	Categorization of Emergency Worker
52	Ordinance on Prevention of Ionizing Radiation Hazards Article 7-2
53	Radiation Hazard Prevention for Staff -National Personnel Authority's Rules 10-5
54	The Notification to Establish Dose Limits in Accordance with the Provisions of NRA Ordinance on Activity of Refining Nuclear Source or Nuclear Fuel Materials
55	Practical work to coordinate the departments responsible for nuclear safety, nuclear security and safeguards
56	NRA Organization Chart
57	Image of Education and Training Courses (FY2018 Annual Report Figure 4-2)
58	Procedures related to Development of Staff.(September 3, 2014, the NRA Secretariat / the NRA Human Resource Development Centre)
59	The interpretation of the regulations regarding the location, structure, and equipment standards of Category 2 waste disposal facilities
60	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act
61	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act
62	The RI Ordinance Article 21
63	SARIS Summary Report (Safety Requirements for Transport of Radioactive Material)

64	SARIS (for transport safety)
65	the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Act No. 166 of 1957)
66	the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Act No. 166 of 1957) 【amended】
67	the Cabinet Order for the Definition of Nuclear Source Material, Nuclear Fuel Material, Nuclear Reactors and Radiation (the Cabinet Order No. 325 of 1957)
68	the Cabinet Order for Enforcement of the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Cabinet Order No. 324 of 1957)
69	the NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc. (Ministerial ordinance issued by the Prime Minister's Office No. 57 of 1978)
70	the NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc. (Ministerial ordinance issued by the Prime Minister's Office No. 57 of 1978) 【Amendment proposal in public comment】
71	the NRA Ordinance Concerning the Installation and Operation of Commercial Power Reactors (Ordinance for Ministry of International Trade and Industry No. 11 of 1978)
72	the NRA Ordinance on Use of Nuclear Source Materials (Ministerial ordinance issued by the Prime Minister's Office No. 46 of 1968)
73	the Notification on Technical Details for Off-Site Transportation of Nuclear Fuel Materials, etc. (Notice issued by Science and Technology Agency No. 5 of 1990)
74	the Notification to Establish Dose Limits in Accordance with the Provisions of NRA Ordinance etc. on Activity of Refining Nuclear Source or Nuclear Fuel Materials (Notice issued by NRA No. 8 of 2015)
75	Operational Guide for Confirmation of Nuclear Fuel packages for Off-Site Transportation (Decision by Secretary-General, Secretariat of NRA, No. 1402263 of Gen Kan Hai Hatsu of 2014)
76	Administrative Procedure Guide for Confirmation, Etc. of Nuclear Fuel Packages for Off-Site Transportation (METI NISA) (Notification Gen In NISA-316a-11-1, No. 7 of March 7 of 2011)
77	Procedure Guide for Describing the Explanatory Documents Appended to Application Documents for Approval of Vehicle Transport, Application Documents for Approval of Packaging and Application Documents for Approval of Nuclear Fuel Package Design (METI NISA) (Notification Gen In NISA-316a-11-2, No. 8 of March 7 of 2011)

78	Guidelines for Quality Management of Manufacturing Method of the Packaging (METI NISA) (Notification Gen In NISA-316a-08-2, No. 1 of June 10 of 2008)
79	the Act on the Regulation of Radioisotopes, etc. (Act No. 167 of 1957)
80	the NRA Ordinance for Enforcement of the Act on Regulation of Radioisotopes, etc. (Ministerial ordinance issued by the Prime Minister's Office No. 56 of 1960)
81	the Notification on Technical Details for Off-Site Transportation of Radioisotopes, etc. (Notice issued by Science and Technology Agency No. 7 of 1990)
82	the Notification on the Details of Standards Concerning the Carriage of Radioactive Material by Ships (Notice of Ministry of Transport of 1977)
83	the Notification to Specify Standards for Amount of Radioisotopes (Notice issued by Science and Technology Agency No. 5 of 2000)
84	Regulatory Guide for Reviewing Quality Control of the Manufacture of Nuclear Fuel Material Transport Containers (Notice issued by Ministry of Education, MEXT, Director of Nuclear Safety Division, Science and technology Policy Bureau, 18, Gen An, No. 139, January 11, 2007)
85	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of August 10, 1960)
86	Regulation on Manufacture and Handling of Radiopharmaceuticals (February 1, 1961) (Order of the Ministry of Health and Welfare No. 4)
87	Standards for Transport of Radioactive Materials (November 24, 2005) (Public Notice of the Ministry of Health, Labour and Welfare No. 491)
88	Standards for Activities of Radioactive Materials (December 26, 2000) (Public Notice of the Ministry of Health and Welfare No. 399)
89	the Postal Act (Act of No. 165 of 1947)
90	the Public Notice on Designation of Explosive, Inflammable or Other Dangerous Substances under Article 12, Item (i) of the Postal Act (Public Notice of the Ministry of Communications No. 384 of 1947)
91	the Act on Correspondence Delivery by Private Business Operators (Act No. 99 of 2002)

92	the Public Notice on Designation of Explosive, Inflammable or Other Dangerous Substances under Article 48, Paragraph (1), Item (i) of the Act on Correspondence Delivery by Private Business Operators (Public Notice of the Ministry of Internal Affairs and Communications No. 203 of 2003)
93	the Act on Japan Post Co., Ltd. (Act No. 100 of 2005)
94	Regulation for Enforcement of the Act on Correspondence Delivery by Private Business Operators (Order of the Ministry of Internal Affairs and Communications No. 27 of 2003)
95	Universal Postal Convention (Convention No. 16 of 2017)
96	Convention Regulations
97	the Act on Special Measures Concerning Nuclear Emergency Preparedness (Act No. 156 of 1999)
98	the Cabinet Order for Enforcement of the Nuclear Emergency Act (Cabinet Order No. 195 of 2000)
99	Order on events, etc. pertaining to transport outside the nuclear site, which nuclear emergency preparedness manager should notify, based on Act on Special Measures Concerning Nuclear Emergency Preparedness (Ministerial Order No. 2 by MEXT, METI, MLIT)
100	the NRA Guide for Emergency Preparedness and Response (July 3, 2019 NRA)
101	the Manual for Nuclear Emergency Preparedness and Response (transport version)
102	Basic Plan for Emergency Preparedness (May of 2019, Central Disaster Prevention Council)
103	Emergency Preparedness for Nuclear Facilities etc. (partly amended on October of 2008, Nuclear Safety Commission) "Virtual Accident Evaluation Concerning Transport of Nuclear Fuel Materials etc."
104	Order regarding notification procedures, etc. for events involved in transport outside the nuclear site that nuclear emergency preparedness manager should notify based on the Act on Special Measures Concerning Nuclear Emergency Preparedness (Ministerial Order by MEXT, METI, MLIT No. 3 of 2012)

APPENDIX VII – 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)

APPENDIX VIII – ORGANIZATIONAL CHART

