

Self-Assessment of Regulatory Infrastructure for Safety

November 2019
Nuclear Regulation Authority, Japan

Contents

1	Responsibilities and functions of the government	4
1.1	Conclusions	4
1.2	National policy and strategy for safety	4
1.3	Establishment of a framework for safety	4
1.4	Establishment of a regulatory body and its independence	4
1.5	Responsibility for safety and compliance with regulations	5
1.6	Coordination of authorities with responsibilities for safety within the regulatory framework	5
1.7	Provisions for the decommissioning of facilities, the management of radioactive waste, and of spent fuel	9
1.8	Competence for safety	9
1.9	Provision of technical services.....	9
2	Global nuclear safety regime	14
2.1	Conclusions	14
2.2	International obligations and arrangements for international cooperation	14
2.3	Sharing operating experience and regulatory experience	14
2.4	Action plans.....	15
3	Responsibilities and functions of the regulatory body	16
3.1	Conclusions	16
3.2	Organizational structure of the regulatory body and allocation of resources.....	17
3.3	Effective independence in the performance of regulatory functions	20
3.4	Staffing and competence of the regulatory body	20
3.5	Liaison with advisory bodies and support organizations.....	23
3.6	Liaison between the regulatory body and authorized parties	24
3.7	Stability and consistency of regulatory control.....	25
3.8	Safety-related records.....	25
3.9	Communication and consultation with interested parties.....	26
3.10	Action plans.....	26
4	Management system of the regulatory body	31
4.1	Conclusions	31
4.2	Management system of the regulatory body.....	31
4.3	Action Plan (Action plans)	36
5	Authorization	37
5.1	Conclusions	37
5.2	Generic issues	37
5.3	Authorization of nuclear power plants.....	38
5.3.1	Authorization of nuclear power plants.....	38
5.3.2	Staffing of the operating organization	39
5.3.3	Operational limits and conditions.....	40
5.3.4	Qualification and training of personnel	40
5.3.5	Management of modification	40
5.3.6	Commissioning.....	41
5.3.7	Operating procedures.....	41
5.3.8	Maintenance programs.....	41
5.4	Authorization of research reactors.....	42
5.5	Authorization of fuel cycle facilities	42
5.6	Authorization of waste management facilities	42
5.7	Authorization of radiation sources facilities and activities	42
5.8	Authorization of decommissioning activities	44
5.9	Action Plan (Action plans)	47
6	Review and assessment	50
6.1	Conclusions	50
6.2	Generic issues	50
6.2.1	Management of review and assessment.....	50

6.2.2	Organization and technical resources and bases for review and assessment.....	50
6.3	Action Plan (Action plans)	54
7	Inspection	55
7.1	Conclusions	55
7.2	Generic issues	55
7.2.1	Inspection approaches, methods and plans	55
7.2.2	Inspection processes and practices.....	56
7.2.3	Inspectors.....	57
7.3	Action Plan (Action plans)	61
8	Enforcement.....	63
8.1	Conclusions	63
8.2	Generic issues.....	63
9	Regulations and guides	66
9.1	Conclusions	66
9.2	Generic issues	66
9.3	Regulations and guides for nuclear power plants	70
9.4	Regulations and guides for research reactors	71
9.5	Regulations and guides for Fuel cycle facilities	71
9.6	Regulations and guides for waste management facilities	71
9.7	Regulations and guides for radiation sources ¹⁸ applications.....	71
9.8	Regulations and guides for decommissioning activities	71
9.9	Action Plan (Action plans)	72
10	Emergency preparedness and response.....	80
10.1	Conclusions	80
10.2	General EPR Regulatory Requirements	80
10.3	Functional regulatory requirements.....	82
10.3.1	Establishing emergency management and operations.....	82
10.3.2	Identifying, notifying, and activating.....	83
10.3.3	Taking mitigation actions	83
10.3.4	Taking urgent protective action	83
10.3.5	Providing information and issuing instructions	83
10.3.6	Protecting emergency workers	85
10.3.7	Assessing the initial phase.....	86
10.3.8	Managing the medical response.....	87
10.4	Regulatory requirements for infrastructure.....	87
10.5	Role of regulatory body during response	87
10.6	Action Plan (Action plans)	87
11	Additional areas.....	90
11.1	Occupational radiation protection	90
11.1.1	Conclusions	90
11.2	Control of discharges and material for clearance; Environmental monitoring for public radiation protection	90
11.2.1	Conclusions	90
11.3	Remediation safety requirements for regulatory authorities	90
11.3.1	Conclusions	90
11.4	Safety requirements for management of radioactive waste.....	90
11.4.1	Conclusions	90
11.5	Code of conduct on the safety and security of radioactive source	91
11.5.1	Conclusions	91
11.5.2	Action Plan (Action plans)	91
12	Interface with nuclear security	93
12.1	Conclusions	93
12.2	Legal basis and regulatory oversight activities	93
12.3	Interface among authorities.....	94

Introduction

On December 12, 2013, the Nuclear Regulation Authority (NRA) requested that the International Atomic Energy Agency (IAEA) conduct an Integrated Regulatory Review Service (IRRS) mission (hereinafter referred to as “initial mission.”) The NRA received the peer review for the framework of the regulations within Japan from January 11 through 22, 2016 by the international team composed of the experts concerned with nuclear and radioactive safety that were invited from outside of Japan by the IAEA. The NRA has received the IRRS, not with a passive attitude but with the attitude that it will voluntarily continue to improve its performance through self-assessment prior to the initial mission and the discussions made during the mission. As a result, along with extracting 24 issues by the self-assessment, it has received 13 recommendations and 13 suggestions from the initial mission.

After the initial mission, based on the self-assessment and the results of the initial mission, the NRA positioned continuous improvement of organizational structure and operation related to regulations and regulation systems as the mid-term objectives in activities for fostering safety culture of the organization and in the management system of the NRA. The NRA has planned and implemented the specific measures for the issues extracted in the process of the self-assessment and the recommendations and suggestions pointed out during the initial mission. Additionally, for considering and implementing the response measures, the NRA consolidated its framework by organizing study teams that consist of the NRA commissioners, officials of the NRA, and external experts in response to individual issues. The NRA has solicited evaluation/advice by the Committee on Examination of Reactor Safety/Committee on Examination of Nuclear Fuel Safety that consists of the external experts in order to implement study and deliberation of the safety matters related to nuclear reactor and radioactive materials. Especially, both review committees gave advice that the initial mission report includes not only issues identified as recommendations and suggestions, but also the issues behind them and matters to be addressed, thus it is also necessary to recognize these as issues. The NRA reflected this advice in the response measures.

The NRA will have international feedback on our progress through an IRRS follow-up mission and continues our efforts for further improvements.

Additionally, in this material, the significant changes to the Advanced Reference Material (hereinafter referred to as “ARM.”) provided for the initial mission, the response status of recommendations/suggestions set out in the initial mission, the results of a self-assessment for the said response status to recommendations/suggestions, and the status of implementation of the action plans after the initial mission are incorporated, which is required to be submitted prior to implementation of the follow-up mission. This material is based on the “SARIS Summary Report” that was submitted prior to the initial mission as part of the ARM and consists of the contents with the amendments to the Summary Report. Significant changes and newly added descriptions are highlighted in blue and the amendments for proper expressions are also made. Furthermore, in cases where the single recommendation/suggestion/action plan includes multiple elements to be improved, such recommendation/suggestion/action plan is divided into each element and described for clarification of response relationship to individual elements.

The self-assessment for the response status to recommendations/suggestions/action plans has been implemented in accordance with the following criteria based on achievement of the response.

【Closed】: All the responses have been completed at present.

【Closed on the basis of progress made and confidence in effective completion in due time】: While a part of responses are uncompleted, the specific time for completion has been determined.

【Open】: Responses have not been completed at present and the specific time for completion has not been determined.

In addition, even if the responses assessed as **【Closed】** in the self-assessment, such evaluation does not mean completion of permanent response. While assessing propriety of the response status in accordance with the changes in the status surrounding the said matters, the NRA will continue the efforts for improvement. For necessary issues, the NRA will continue improvements with positioning such issues in the fiscal year’s work plan of each division in charge in accordance with the NRA management system. On the other hand, in the responses that are assessed as **【Open】**, the ones for which the due time for completion has not been determined at present, for which some appropriate responses are provided and for which efforts have been continuously made for improvement are included.

1 Responsibilities and functions of the government

1.1 Conclusions

Based on the self-assessment (SARIS) covering the responsibilities and functions of the government, it finds that, as shown in 1.2 through 1.9, Japan's national policy and strategy for ensuring the safe use of nuclear energy are provided by the Atomic Energy Basic Act, the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (hereinafter the "Reactor Regulation Act"), the Act on Prevention of Radiation Hazards due to Radioisotopes, etc. (hereinafter the "RI Act")¹, and the Act on Special Measures Concerning Nuclear Emergency Preparedness (hereinafter the "Nuclear Emergency Act"). The restructuring of the nuclear regulation agencies following the Fukushima Dai-ichi accident led to the establishment of the NRA, which regulates nuclear energy and radiation facilities and activities in an integrated manner and has effective independence. Therefore, it concluded that the framework and measures are, in principle, in accordance with the relevant IAEA safety requirements.

However, the IRRS team provided the NRA with the recommendations/suggestions on the process of information exchange between regulatory authorities, implementation of joint inspections, oversight of outsourced inspections and measures for technical service. The NRA addressed these issues after considering individual responses to them.

1.2 National policy and strategy for safety

Japan's national policy for nuclear safety is stated in the Atomic Energy Basic Act: "In ensuring the safe use of nuclear energy, such nuclear energy shall be utilized with the objectives of (a) contributing to the protection of people's lives, health, and properties, (b) maintaining environmental conservation, and (c) protecting Japan's national security, based on established international standards (Article 2, paragraph 2). In addition, the Act for the Establishment of the NRA (hereinafter the "NRA Establishment Act") stipulates the establishment of the NRA and its authorities to ensure nuclear safety (Article 3-2). Furthermore, the Reactor Regulation Act provides regulations on nuclear source materials and nuclear facilities; the RI Act provides regulations on radioisotopes, etc., and the Nuclear Emergency Act provides the required measures for emergency preparedness and response to nuclear emergencies. The objective provisions of these acts prescribe national policies for safety.

1.3 Establishment of a framework for safety

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

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

1.4 Establishment of a regulatory body and its independence

Before the Fukushima Dai-ichi accident, the Nuclear and Industrial Safety Agency (NISA), which regulates nuclear facilities and activities, had been a subordinate organization of the Ministry of Economy, Trade, and Industry (METI), which promotes the use of nuclear energy. After the Fukushima Dai-ichi accident, the lack of independence of the regulatory authority was cited as one of the causes of the accident. For this reason, combined with other lessons learned, the government separated the safety regulation department from METI. It established the NRA as a new regulatory body and incorporated the regulations on the use of nuclear energy and radiation administered by other ministries to the NRA. That act clearly states that the NRA independently performs duties from a neutral and fair standpoint based on its expertise.

The Reactor Regulation Act, the RI Act, and the Nuclear Emergency Act grant the NRA legal authority to perform its statutory responsibilities of regulating facilities and activities.

¹ As "Protection of specified radioisotopes" was added to the purpose of this Act by the amendment of this Act, the name of the Act was changed to "Act on the Regulation of Radioisotopes etc. Act" and it has been enacted on September 1 of 2019. While the details of implementation before and after changing of the name of the Act are mixed, the "RI Act" shall be integrally described as abbreviation.

These legal frameworks ensure the NRA’s effective independence in safety-related decision making.

1.5 Responsibility for safety and compliance with regulations

The Reactor Regulation Act and the RI Act assign licensees safety responsibilities over all activities in manufacturing, using, storing, transporting, or processing nuclear material and radioisotopes. The Reactor Regulation Act assigns licensees responsibility for enhancing safety by taking into account the latest findings, through installation of components or equipment, or other measures such as strengthening a safety training program.

Additionally, after the initial mission, aiming to clarify the responsibilities of permission, notification users, etc., the Act was amended based on the latest scientific knowledge associated with safety in use of nuclear energy, etc. The RI Act stipulates that the permission, notification users, etc., have the responsibility to take necessary measures to prevent radiation hazards and protect specified radioisotopes (see 10.2 Response to Recommendation 12.).

Neither the Reactor Regulation Act nor the RI Act allows the delegation of licensees’ safety responsibilities to other parties, which means that such maneuvers are legally prohibited for the licensee.

1.6 Coordination of authorities with responsibilities for safety within the regulatory framework

The NRA Establishment Act stipulates that the NRA shall be the organization to provide the measures required to ensure safety in use of nuclear energy, to centrally manage affairs to be implemented, and can fulfill its responsibilities with effective independence. However, for the following affairs (including duties not related to nuclear regulation), multiple ministries and agencies continue to bear responsibility within administrative function under their jurisdiction of respective ministries.

The NRA is solely responsible for nuclear safety regulation, except in the following circumstances (including measures not for regulations.)

- Safety regulations on transportation (air and marine transportation, transporting methodology of land transportation): Ministry of Land, Infrastructure, and Transport, land transportation of radiopharmaceutical: Ministry of Health, Labour, and Welfare, postal transport of radioactive materials: Ministry of Internal Affairs and Communications, etc.)
- Safety regulations on occupational exposure in terms of labor safety, medical exposure, and control of radioactive material in food and tap water: Ministry of Health, Labour, and Welfare
- Emergency preparedness and response (off-site radiation protection measures): Cabinet Office
- Monitoring of radioactive materials in the atmosphere, water for public use, and ground water during normal situations: Ministry of the Environment
- Security of nuclear facilities: National Police Agency and Japan Coast Guard (These Ministries have the responsibilities for the above measures within their mandate)

The NRA communicates and coordinates with the above authorities when necessary, but also establishes the following standing mechanisms for collaboration and cooperation.

On the other hand, in the initial mission, the IRRS team noted that the existing arrangement 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. The NRA responded to the recommendations introduced based on the said indication as follows.

Recommendation	Contents of Recommendation
1	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

IRRS Follow-up Mission to JAPAN 2020

Recommendation 1	actions to provide coordinated and effective regulatory oversight that should also ensure a harmonized regulatory framework under their respective responsibilities.	
	Basis	
	GSR, Part 1 Requirement 7 states that “Where several authorities have responsibilities for safety within regulatory framework for safety, the government shall make provision for effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.”	
	Response Status	
	As mentioned above, the IAEA safety standards stipulate that the government shall make provision for effective coordination of their regulatory functions to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties, in cases where several authorities have responsibility for safety within regulatory framework for safety. Currently, the following have been established as the framework that enables necessary collaboration/cooperation with the relevant authorities.	
	Radiation Council	Reports on promoting consistency of related technical standards, based on consultation for radiation protection as requested from other government agencies. Possible to express opinions to the head of relevant organizations regarding matters related to the technical standards for the prevention of radiation hazards. (Secretariat: NRA)
	Interagency Coordination Meeting for the Safe Transport of Radioactive Material	Provides opportunities for government officers responsible for the transportation of radioactive material to share information and exchange views 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. (Secretariat: NRA)
	Interagency Meeting on Nuclear Security	Provides opportunities to discuss urgent issues on nuclear security issues. (Secretariat: NRA)
	Nuclear Emergency Preparedness Commission (NEPC)	Promotes implementation of measures to ensure comprehensive Government efforts to prepare for nuclear accidents. The Prime Minister is the chair of the Commission and the NRA Chair is one of the members. (Secretariat: Cabinet office)
	<p>Additionally, the NRA Establishment Act (Article 4-2) allows the NRA to make recommendations on nuclear safety to the heads of other ministries, and to request follow-up action reports on said recommendations, when necessary for the NRA to fulfill its legal mandates.</p> <p>Furthermore, when there is a need for matters related to securing safety in the use of nuclear energy, the NRA exchanges information with the relevant government agencies, etc., using regular public meetings; and, based on the policies to secure transparency of operation, voluntarily discloses the process of policy decision and administrative documents including licensing information to the general public as well as to specific regulatory authorities, unless it falls under nondisclosure information based on the Information Disclosure Law. Based on this, the NRA has taken the following measures in each of the nuclear safety and radiation safety fields, in addition to the fields where regular cooperation is implemented, such as nuclear security and nuclear emergency preparedness and responses:</p> <p>【Nuclear Safety】</p> <p>The NRA reaffirmed that the fields that require mutual coordination among regulatory authorities regarding nuclear safety policies and licensing are limited to the fields of transportation of radioactive material and occupational exposure. In these fields, as mentioned above, the necessary framework has already been established and operated. For transportation, a framework has been</p>	

IRRS Follow-up Mission to JAPAN 2020

Recommendation 1	<p>established in which the relevant regulatory authorities meet and exchange information at the Interagency Coordination Meeting for the Safe Transport of Radioactive Material. In that framework, there is proper harmonization between regulators. For occupational exposure, technical standards for the prevention of radiation hazards are being standardized through the Radiation Council. Additionally, voluntary investigation, deliberation, and proposal functions are newly added to the Radiation Council through the revision of the “Act on Technical Standards for Prevention of Radiation Hazard,” consequently, the function of the council was strengthened. Based on these, the NRA confirmed that there is no need to establish new information exchange processes between regulatory authorities at present.</p> <p>While the systematic framework has not been established for exchange of information regarding inspections and enforcement, as a result of examination to reform the inspection system as will be described in Chapter 7, “inspections”, the NRA decided to establish a system for collaboration among the relevant authorities in FY2020 that enables the authorities to share the inspection schedules and results, and grasp status by accompanying the inspections. etc. in time to start operation of nuclear regulatory inspection newly developed through revision of the Reactor Regulation Act.</p> <p>【Radioactive Safety】 Starting with studies related to safety management of medical radiation, some government measure-related activities that have mutual needs have been implemented as needed. In addition, the NRA plans to share information on the matters that have been pointed out and noticed in on-site inspections for licensees which should be shared with other regulatory authorities, and is going to establish this process in FY2020.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> • The NRA Establishment Act, Article 4, para. 2 • The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (Act on Technical Standards for Prevention of Radiation Hazard, Article 5, para. 2)
	Results of Self-Assessment
	Closed on the basis of progress made and confidence in effective completion in due time

Further, in the initial mission it was pointed out that the NRA did not coordinate nor exchange information about inspections with regulatory bodies performing inspections at the licensed facilities in areas that are influencing the nuclear or radiation safety (radiation protection or fire protection). Also, the NRA outsourced certain inspection activities to Registered Inspection Bodies but did not exercise sufficient regulatory oversight to ensure the quality of their work and confidence in their assessments. The NRA responded to the suggestion and introduced the following based on the said indication.

Suggestion 1	Contents of Proposal
	The NRA should consider improving ①its liaison with the relevant organizations for joint inspections and ②oversight of outsourced inspections.
	Basis
	GSR Part 1 Requirement 29 Paragraph 4.53 states that “In conducting inspections, the regulatory body shall consider a number of aspects, including: Liaison with the relevant organization for joint inspections, where necessary.”
GSR Part 1 Requirement 20 Paragraph 4.19 states that “Technical and other expert professional advice or services may be provided in several ways by experts external to the regulatory body. The regulatory body may decide to establish a dedicated support organization, in which case clear limits shall be set for the degree of control and direction by the regulatory body over the work of the support organization. Other forms of external support would require a formal contract between the regulatory body and the provider of advice or services.”	

Suggestion	Response Status
1	<p>【Nuclear Safety】 (Response to ①) As for the joint inspections related to nuclear safety, as with the response to Recommendation 1, the NRA is going to establish a system for collaboration among the relevant authorities in FY2020 to share the inspection schedules and results. They will grasp the status by accompanying the inspections etc. in time to start operation of nuclear regulatory inspection that has been developed through revision of the Reactor Regulation Act.</p> <p>(Response to ②) This item is not applicable because outsourcing of inspections is not expected under the Reactor Regulation Act.</p> <p>【Radiation Safety】 (Response to ①) Since the regulatory perspectives and inspection frequencies of each regulatory authority are different, and the common inspection items are extremely limited, the NRA eventually decided not to implement joint inspections themselves as a result of consideration. Consequently, no liaison with the relevant organization is required for joint inspections.</p> <p>(Response to ②) Under the RI Act, a registered organization² system is in place that allows the registered certification organizations² etc., to act for a part of regulation duties that the government normally performs such as design certification, etc. Based on this system, the registered certification organizations, etc., act for facility inspections³ to be carried out prior to the start of facility operation, etc., of specified permission users and permission waste management operators and periodic inspections⁴ of the facilities that the NRA uses to carry out. The NRA has been authorized to perform on-site inspections⁵ for registered certification organizations from the time of its establishment, but there has been no record of such inspections.</p> <p>The NRA revised the “Implementation Guidelines for On-Site Inspections” which is an internal code related to on-site inspections of the NRA in March of 2016, and also expanded the scope of the on-site inspections that had been implemented only for the permission users to the registered certification organizations. Additionally, by formulating and publishing of the Standard Review Plan of Operational Rules and guideline for on-site inspections for registered examination organizations that have the authority to take administrative actions for inspection duties in 2017, the standards for oversight on registered organizations were clarified. Based on that, on-site inspections have been implemented for the registered organizations from the same year and the quality of its work and reliability of its assessment have been confirmed.</p> <p>In FY2016, on-site inspections were conducted for all the registered certification organizations, etc. (17 organizations in total), in accordance with the revised on-site inspection procedure. After FY2017, in principle, the on-site inspection of a certain facility will be performed within 2 years from the date of registration or the renewal of registration, or the date of the latest inspection. In FY2017, out of the total of 17 organizations, the NRA carried out on-site inspections for 8 organizations that renewed the registration in FY2017 or received relatively many indications in the one-site inspections in FY2016, and in FY2018, 9 organizations where on-site inspections were not performed in FY2017.</p>

² Registered certification organizations etc.: registered certification organizations, registered inspection organizations, registered periodic confirmation organizations, registered package confirmation organization, registered burying confirmation organizations, registered concentration confirmation organizations, registered examination organizations, registered qualification training organizations, or registered periodic training organizations.

³ Facility inspections: the inspections for location, structure, equipment of the facilities etc. that NRA or the registered inspection organization perform, according to the provisions of Paragraph 8.1 and 2 of Article 12 of RI Act after the specified permission users and permission waste management operators obtained the permission. The said users or operators shall be allowed to use the facilities only after they pass the facility inspections.

⁴ Periodic inspection : the periodic inspections that NRA or the registered inspection organization perform, according to the provisions of Paragraph 1 and 2 of Article 12-9 of RI Act, for the structure of the facilities etc. to the specified permission users and permission waste management operators

⁵ On-site inspection : the inspections that officials of NRA who have considerable knowledge and experience about the prevention of radiation hazard (radiation inspectors) enter the place of business of registered certification organization and inspect books, documents, and to question the people concerned, limited to the minimum extent necessary for examination, according to the provisions of Paragraph 1 of Article 4243-3 of the RI Act.

Suggestion 1	Documentary Evidence
	<ul style="list-style-type: none"> • The RI Act. Article 12-2, Article 39, Article 41, Article 41-5, Article 41-11, Article 41-14, and Article 43-3. • The procedures for Conducting on-site inspections based on the Act on the Prevention of Radiation Hazards due to Radioisotopes, etc. (July 3 2013 NRA [amended on April 2 2018]). • 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. • Guide for On-Site Inspections for Registered Certification Organizations etc. (December 13 2017 [amended on March 30 2018]).
	Results of Self-Assessment
Closed on the basis of progress made and confidence in effective completion in due time	

1.7 Provisions for the decommissioning of facilities, the management of radioactive waste, and of spent fuel

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

The funds for the decommissioning of nuclear power plants, [the assurance that the measures to ensure safety will not be impeded due to financing](#), the [appropriate](#) management of spent fuel, and the disposal of high level radioactive waste are ensured by licensees of those nuclear facilities, through the relevant acts and other measures. The NRA requests METI to ensure adequate funding for nuclear safety.

1.8 Competence for safety

To develop and maintain the competence of the NRA Secretariat (S/NRA) personnel, the NRA Establishment Act requires that training programs, including facilities to improve their professional skills, be established, and that financial resources for human resource development be secured (Article 6 of Supplemental Provision). To meet this requirement, the Cabinet Order for Organization of the NRA requires the establishment of a Human Resource Development Center within the NRA (Article 9).

To ensure the competence of licensees, for example, the Reactor Regulation Act requires licensees to [have the necessary technical competence etc. needed to install systems, structures, and components \(hereinafter “SSCs”\)](#), to operate them appropriately, and to take necessary measures to prevent and mitigate severe accidents.

1.9 Provision of technical services

[At the time of the initial mission](#), in Japan, technical services, such as individual dose monitoring, environmental monitoring, and calibration of measuring instruments, [were](#) available mainly from private enterprises as necessary and appropriate. Therefore, the [government evaluated](#) that it sees no need to take special additional measures for these technical services.

However, in the initial mission, the IRRS team identified that 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 were no requirements on the necessary technical quality of the services provided. The NRA responded to the recommendation introduced based on the indication as follows.

Recommendation 2	Contents of Recommendation
	The Government should empower the regulatory body ① to establish requirements for authorization or approval processes for service providers for monitoring of occupational and public exposures, and environmental monitoring in general, and ②verify that these requirements are met by licensees.

Recommendation 2	Basis
	<p>GSR Part 3 requirement 25 para. 3.99 states that: “Employers, as well as self-employed persons, and registrants and licensees shall be responsible for making arrangements for assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that arrangements are made with authorized or approved dosimetry service providers that operate under a quality management system.”</p>
	<p>GSR Part 3 requirement 32 para. 3.135 states that: “The regulatory body shall be responsible, as appropriate, for: ... (i) Verifying compliance with the requirements of these Standards in respect of public exposure in planned exposure situations”</p>
	<p>GSR Part 1 requirement 13 para. 2.41 states that: “Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.</p>
	<p>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; ...</p>
	Response Status
<p>The individual dose measurement is obliged to be implemented by the licensees based on the Reactor Regulation Act and the RI Act. The measurements are roughly classified into the measurement by APD (alarm electron dosimeter) to control exposure dose for individual work unit and the one by passive dosimeter to control exposure dose for a specified period. APD measurements are carried out by the licensees and calibrated by the manufacturers, etc. Passive dosimeter measurements may be carried out by the licensees themselves or be provided by individual dose measurement service providers. In Japan, while the responsibilities related to technical services by the licensees specified in the Reactor Regulation Act and the RI Act have been regulated in compliance with the corresponding IAEA requirements, there are no direct regulatory requirements for the licensees specified in the Reactor Regulation Act and the RI Act, and quality assurance has been left to the voluntary efforts made by the service providers.</p> <p>Environmental radiation monitoring has been implemented by the government or local governments for the purpose of observation of environmental radiation. There are various measurement items and methods, such as spatial radiation dose rate that is directly measured by using measurement equipment and radioactivity measurement that consists of a series of process of sampling, pretreatment, and measurement. Regarding the measurement equipment used for environmental radiation monitoring, in Japan, the National Institute of Advanced Industrial Science and Technology provides national measurement standards, and the system to secure traceability has been established under Japan Calibration Service System (JCSS) based on Measurement Act. The measurement equipment is calibrated with a standard radiation source by the manufacturer at the factory shipping stage, and is also periodically calibrated with a standard radiation source by the nuclear licensees or calibration service providers at the use stage. Additionally, in the case of the stationary measurement equipment such as monitoring station etc., since the calibration cannot be performed by bringing it into the calibration field, checks have been carried out at the site by using a standard radiation source. So far, only a few operators have been certified as JCSS registered operators.</p>	

Recommendation 2	<p>(Response to ①)</p> <p>【Occupational Exposure Monitoring】</p> <p>Since the primary responsibility for ensuring safety must be owned by the operators responsible for the facility and activity that has potential radiation risks, the legal system in Japan requires that the licensees under the Reactor Regulation Act and the RI Act should have the primary responsibility of radiation protection. As occupational exposure monitoring is one of the activities to secure safety performed by facility operators, even in the case where a part of the measurement is outsourced to monitoring service providers, as well as in the case where the licensees implement such monitoring by themselves, the licensees shall bear the responsibility. Therefore, by requiring the appropriate measures such as quality management for the measures related to the monitoring, the technical quality of monitoring will be consistently controlled under the responsibility of the licensees. In addition, the NRA can confirm the activities including the implementation status of this management in the safety review and the inspections. Therefore, while the recommendation requires the regulatory body to directly authorize or certify the monitoring service providers, the NRA decided to achieve specifying the quality control requirements for monitoring in accordance with IAEA safety standards and confirming the status of its compliance by strengthening regulations for licensees under the Reactor Regulation Act and the RI Act.</p> <p>Regarding the Reactor Regulation Act, the NRA has set out to revise the relevant documents (standard review plan of operational safety programs and guides for measures taken for the operational safety) to clarify that the licensees should appropriately perform calibration of radiation measurement equipment, etc. (including the case that they procure such service), and is going to put it in force in April 2020. Regarding the RI Act, the NRA has set out to revise the relevant documents (ordinance for enforcement of the RI Act and its relevant guide) to request in regulations that the licensees use the service provided by individual dose measurement service providers that have quality assurance certification based on the accreditation system described below, or they implement measurement of individual dose with equivalent quality, and is going to formulate such documents within FY2020.</p> <p>Additionally, the NRA established “Technical Study Team on Environmental Radiation Monitoring” consisting of the members of the NRA commissioner, the officials of NRA, and external experts. In this study team, by the study of the technical matters related to quality assurance of individual dose measurement, as mentioned below, the accreditation system for individual dose measurement service providers was established. This system will be positioned as one of the methods to meet the requirement regarding the quality of occupational exposure monitoring in the Reactor Regulation Act and the RI Act by April FY2020.</p> <p>Regarding the accreditation system, as a result of the survey on overseas situations, it was found that, in the U.S., the federal regulations stipulate that the ISO/IEC 17025 certified service providers based on NVLAP (U.S. National Voluntary Laboratory Accreditation Program) have to implement measurement/evaluation of individual dose, and, in Japan, while the said service is provided by individual dose measurement service providers except for certain operators, there is no accreditation system related to quality assurance for an individual dose. Based on the above, the NRA set a policy of creating a new accreditation system for individual dose measurement service providers based on ISO/IEC 17025 in cooperation with Public Interest Incorporated Foundation Japan Accreditation Board (JAB) in reference to NVLAP of U.S. JAB specified ISO/IEC 17025 “General Requirements for the Competence of Testing and Calibration Laboratories” as a reference standard, and formulated necessary additional requirements (guidelines) in July 2018, taking into account the current status of radiation measurement services in Japan and NVLAP that have operational experience in accrediting individual dose measurement service providers as well as general matters in management and technology of quality assurance for the testing specified in ISO/IEC 17025. JAB started accepting the applications for certification in July 2018 and consequently 2 organizations were certified in March 2019.</p> <p>【Public Exposure Monitoring】</p> <p>Regarding public exposure monitoring, after the study, the NRA decided to respond to the recommendation by strengthening the regulations for the licensees under the Reactor Regulation</p>
---------------------	---

<p>Recommendation 2</p>	<p>Act and the RI Act for the same reason as the occupational exposure monitoring described above. Based on this, in the Reactor Regulation Act and the RI Act, the NRA has set out to revise the relevant documents to clarify that the licensees should appropriately perform calibration of radiation measurement equipment etc. (including the case that they procure such service), and is going to formulate them in FY2020.</p> <p>【Environmental Radiation Monitoring】 Environmental radiation monitoring at ordinary times has been carried out by the government (local governments) themselves from the viewpoint of protecting the health and safety of residents in the vicinity of nuclear facilities, thus such monitoring service has not been provided by private or nongovernmental organizations. It has been confirmed that the quality assurance efforts for environmental radiation monitoring by local governments are not inferior internationally and have good results. However, the NRA decided to continuously strengthen the quality assurance efforts of local government under the initiative of the NRA, as a result of the study in “Technical Study Team on Environmental Radiation Monitoring” consisting of the members of the NRA commissioner, the officials of NRA and the external experts.</p> <p>As a result of study on the quality assurance of environmental radiation monitoring in Japan, the study team confirmed the following by October 2017.</p> <ol style="list-style-type: none"> 1) For spatial radiation dose rate measurements using a removable detector and radioactivity concentration measurements not requiring pretreatment, it is important to continue the calibration with secured traceability in a calibration facility or the location where measurement equipment is installed, etc. 2) For spatial radiation dose rate measurement using a monitoring station, considering the necessity to maintain the soundness of the equipment, it is important that the monitoring station administrator steadily carries out a regular function check of the equipment and implements in-situ calibration for some monitoring stations picked up from them to verify validity of function check as before. 3) For radioactivity concentration measurement that requires pretreatment, it is important to encourage a monitoring agency (like local governments) to accept cross-check and proficiency tests by utilizing the framework of cross-check and proficiency tests built in Japan and for the agency to conduct radioactivity concentration measurement in accordance with the concept of ISO17025. <p>Based on the results of the above studies, the concept of quality assurance in environmental radiation monitoring was incorporated into the “Ordinary Radiation Monitoring (supplementary reference materials for Nuclear Emergency Response Guideline)”, and the explanatory meeting for local governments, etc. was held in May 2018 with the aim of disseminating the concept. Additionally, in April 2019, in the form of the government-commissioned project from the NRA, a mechanism in which the external organizations with ISO17025 certification for measurement of radiation and radioactive materials periodically carry out cross-check/proficiency tests for the calibration and measurement by local governments was established.</p> <p>(Response to ②) The state of compliance with the regulatory requirements for occupational exposure monitoring and public exposure monitoring as mentioned above will be confirmed in the nuclear regulatory inspection based on the Reactor Regulation Act and the on-site inspection based on the RI Act, respectively, and the NRA has set out to revise the relevant documents and will formulate them within FY2020.</p>
	<p>Documentary Evidence</p> <ul style="list-style-type: none"> • The Commercial Reactors Ordinance Article 67, 79 • The RI Act Article 20 • The RI Ordinance Article 20 • Ordinary Radiation Monitoring (supplementary reference materials for Nuclear Emergency Response Guideline) (April 4, 2018 Nuclear Regulation Authority, Radiation Monitoring Division)

	Results of Self-Assessment Closed on the basis of progress made and confidence in effective completion in due time
--	--

2 Global nuclear safety regime

2.1 Conclusions

Based on the self-assessment (SARIS) for global nuclear safety regime, it finds that, as shown in [Sections 2.2 and 2.3](#), Japan is a signatory to all the conventions on nuclear safety under IAEA auspices. The NRA evaluated that it has a mechanism in place to share operating and regulatory experiences with the international community and promotes international cooperation to improve nuclear safety globally. Therefore, it concludes that the framework and measures of Japan are, in principle, in accordance with the relevant IAEA safety requirements, with the exception of the following.

As a challenge, the following [was identified](#): in order to further enhance international cooperation and the NRA's contribution to global nuclear safety, the NRA should develop its human resources which are capable of interacting [with](#) international human networks as well as having technical knowledge, contributing to global nuclear safety.

To address this challenge, the NRA implemented [the measures for improvement based on](#) the Action Plan as shown in [Section 2.4](#).

2.2 International obligations and arrangements for international cooperation

Japan is a signatory to all the conventions on nuclear safety under IAEA auspices: the Convention on Nuclear Safety, the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and the Convention on the Physical Protection of Nuclear Material. The NRA promotes international cooperation to improve global nuclear safety through many bilateral and multilateral partnerships.

Japan has also made a written commitment to the IAEA with regard to the Code of Conduct on the Safety and Security of Radioactive Sources, the Supplementary Guidance on the Import and Export of Radioactive Sources, and the Code of Conduct on the Safety of Research Reactors. The NRA ensures that licensees comply with these codes, by enshrining these requirements in the regulations under the Reactor Regulation Act and the [RI Act](#).

However, the NRA [verified](#) the limitation of its contribution to international peer reviews, since its staff has not been able to provide sufficient feedback to other countries' regulatory activities covered by the Convention on Nuclear Safety and other conventions.

To address this challenge, the NRA implemented [the measures for improvement based on the Action Plan \(A1\)](#) as shown in [Section 2.4](#).

2.3 Sharing operating experience and regulatory experience

The NRA has an established mechanism to share operating and regulatory experiences. Under this mechanism, the NRA [collects/organizes information related to the accidents/troubles of nuclear facilities in Japan and overseas, relates them to the tendency of the regulations in other countries, implements screening, and accordingly reflects necessary matters to the regulations. When implementing these, through screening \(holding the Technical Information Committee where it discuss whether regulatory actions are required or not and after receiving advice from the Committee on Examination of Reactor Safety and the Committee on Examination of Nuclear Fuel Safety\) the NRA committee reviews the information and](#) establishes/strengthens the system to identify the lessons obtained from operating experiences.

Japan collects and shares information on operating and regulatory experiences through bilateral information exchanges with countries such as the U.S., France, and the U.K., as well as multilateral corroborations (e.g., IAEA, OECD/NEA⁶, INRA⁷, and Top Regulators' Meeting (TRM)⁸ between Japan, China, and the Republic of Korea). Such information is reflected in regulatory activities.

⁶ OECD/NEA : Organization for Economic Co-operation and Development / Nuclear Energy Agency

⁷ INRA : The International Nuclear Regulators Association

⁸ TRM : Top Regulators' Meeting on Nuclear Safety among China, Japan and Korea

2.4 Action plan

Basis	(B1) The IAEA safety standard states that “The government shall participate in the relevant international arrangements, including international peer reviews,” [GSR Part 1, R14]. However, the NRA has not provided sufficient feedback to other countries’ regulatory activities in the Review Meetings of the Convention of Nuclear Safety and other conventions.
Recommendation	(R1) The NRA needs to expand human resources to contribute fully to international peer reviews and train personnel who have an experience in international networking and possess the required technical knowledge.
Action Plan	(A1) In evaluating the performance of staff for international affairs, safety research, improvement of regulations and guides, and other relevant positions, ① contribution to international activities (in particular for peer review) should be included in such personnel evaluation. In order to establish global human networks, ② the frequency of personnel rotation and the opportunities for working in international organizations should be optimized.
Response Status (A1)	<p>(Response to ①) The NRA advances international human resource development according to the Basic Policy for Human Resource Development for NRA Officials in accordance with the policy that “along with allowing the activities of the NRA to take more international status into consideration than it has done so far; to realize the regulations based on international standards, the staff will make more efforts on acquisition of knowledge on the activities of the overseas regulatory organizations, international organizations such as IAEA, etc., and the safety standards established by IAEA, including improvement of language skill.” For improvement of peer-review abilities of the staff, regarding the 6th Review Meeting for Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management held in 2018, the staff to engage in the peer review was widely invited within the NRA, and 13 members participated in the peer review of other countries involved in the Convention including 1 member who played the vice-chairman of other group. The performance for response to the international conventions which is identified as an independent item that “efforts on improvement of abilities for international affairs” has been evaluated in personnel evaluation conducted on the semiannual basis since FY2016.</p> <p>(Response to ②) The NRA lists the persons who are able to engage in international affairs and gives them special personnel consideration, such as dual posts in order that persons who leave the post associated with international conventions due to personnel rotation can continue to participate in the said international conventions. Additionally, by providing appropriate support such as language training, etc., for the persons to be assigned to the international organization, and opportunities for working in international organization.</p>
Documentary Evidence	• Basic Policy for Human Resource Development for NRA Officials (Materials of Committee as of June 25 2014)
Results of Self-Assessment	Closed

3 Responsibilities and functions of the regulatory body

3.1 Conclusions

Based on the self-assessment (SARIS) for responsibilities and functions of the regulatory body, it finds that, as shown in Sections 3.2 through 3.9, the NRA was established to serve as a regulatory body with effective independence and has undertaken the responsibility of nuclear safety regulation in an integrated manner, through the restructuring of the nuclear safety regulatory organization following the Fukushima Dai-ichi accident. The NRA has greater independence and neutrality, and the NRA's activities are much more open and transparent in communicating with regulated parties in order to reduce public doubt and distrust, compared to the previous situation. Therefore, it concluded that the framework and measures of the NRA are, in principle, in accordance with the relevant IAEA safety requirements, and the following exceptions were identified.

- The NRA does not have sufficient qualified staff to meet the needs of the several specific regulatory activities and therefore needs to ensure sufficient staff to perform its responsibilities.
- The NRA should optimize the frequency and pattern of personnel rotation in consideration of the characteristics of individual posts, based on the NRA's "Basic policy for human resource development" and the "Model career path for NRA personnel." This effort should be combined with training in specialized fields to help personnel effectively acquire the competence necessary for their tasks.
- Safety research of JAEA (Japan Atomic Energy Agency) should be further enhanced for strengthening the technical competence of the regulatory body, and also the cooperation between the NRA and JAEA in terms of human resource development needs to be strengthened.

Additionally, in the initial mission, the recommendations/suggestions related to enhancement of measures for radiation prevention, organizational structure, and allocation of resources, staff, and abilities were provided. Along with handling them after considering their responses, the NRA implemented the measures for improvement based on the Action Plans as shown in Section 3.10.

In the initial mission, the IRRS team noted that: due to the current situation following TEPCO Fukushima Dai-ichi accident, the NRA has oriented its strategy to give first priority to the improvement of nuclear safety regulation, research, and review of applications of nuclear power plants under the NRA standards. While this is important and understandable, the IRRS team is concerned that the NRA may not allocate sufficient priority and resources to its responsibilities in the radiation protection area. The NRA responded to the recommendation introduced based on the indication as follows.

Recommendation 3	Contents of Recommendation
	The NRA should put greater priority and allocate more resources on ①its oversight of the implementation of radiation protection measures by licensees as well as ②its participation in the development of international standards in radiation protection and related research activities in collaboration with NIRS.
	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."
	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."
	Response Status
	(Response to ①) The NRA strengthened the organizational structure in the department responsible for the regulation of radioisotopes by requesting for enhancement of the organizational structure and

Recommendation 3	<p>increase of the fixed number of the employee to the personnel authority. At the time of the IRRS initial mission, while the number of radiation inspectors in the division responsible for enforcement of the RI Act was 12, the number has been increased to 19 as of January 2019. In this way, the oversight system for the licensed operators has been strengthened. Additionally, based on the fact that the fixed number of the radiation inspector has been increased from 22 to 50 by amending the cabinet ordinance for enforcement of the RI Act, the NRA will continue to enhance oversight system for the permission users, etc.</p> <p>(Response to ②)</p> <p>In order to make the regulations for radioisotopes in Japan the latest/the best, considering the proposals from research organizations in response to the themes indicated by the NRA for each fiscal year, the NRA established and started the operation of “Strategic Promotion Project for Radiation Safety Regulatory Study” in FY2017 that promotes surveys and research contributing to improve regulations related to prevention of radiation hazards and radiation protection systematically/effectively. The project consists of “Radiation Safety Regulation Research Promotion Project” and “Radiation Protection Research Network Formation Promotion Project”, and promotes the research that serves as a basis of regulations related to the prevention of radiation hazard, the research for creating knowledge that provides the basis for the development and operation of the regulation, and the research for incorporating the latest international knowledge. In this way, the NRA will promote the construction of the network by relevant research organizations that supports improvement of regulations, etc. Regarding the international activities related to radiation protection, the NRA organized the current status, established new management posts in charge of international affairs, and summarized the basic concept regarding the efforts for the future. Based on this concept, along with making efforts to enhance the involvement in IAEA committees related to development of standards, etc., and fostering junior staff members, the NRA started strengthening international activities such as enhancement of the relationship with the relevant organizations inside and outside of Japan. Additionally, by establishing the opportunity to exchange opinions regularly and continuously between National Institutes for Quantum and Radiological Science and Technology (QST; set up by reorganizing and consolidating NIRS and a part of JAEA), and JAEA, the NRA is facilitating mutual communication and enhancing the collaboration in this way.</p> <p>Regarding “Radiation Safety Regulation Research Strategic Promotion Project” that has been continuously implemented since FY2017, in FY2019, the following themes were set as the prioritized themes; 1) studies on technical issues related to the initial response to a large amount of contamination or a large number of invalids, 2) rationalization and systematization of safety management based on the actual situation of radioisotope and radiation use, and 3) surveys and research on common issues related to the operation of the laws and regulations related to radiation regulation. By newly adopting 4 research studies from the said prioritized themes in “Radiation Safety Regulation Research Strategic Promotion Project” and implementing 14 safety research studies including 2 research studies adopted in FY2017, further resources have been allocated in the field of radiation protection. The selection of research and their progress management is reviewed by the research promotion committee that includes the members of external experts, and the results of the project are also reviewed by external experts through organizing the research evaluation committee.</p>
Documentary Evidence	
<ul style="list-style-type: none"> • The RI Cabinet Order Article 30 	
Results of Self-Assessment	
Closed	

3.2 Organizational structure of the regulatory body and allocation of resources

The NRA, following the procedures required for government organizations, may change its organizational structure according to needs, and create suitable bodies to fulfill its responsibilities in a manner commensurate with the level of radiation risk associated with regulated facilities and activities.

The NRA, after developing priority policies for the next fiscal year, establishes an annual priority plan for its

staff size and allocation and a budget. Based on this annual priority plan, the NRA manages its human and financial resources, anticipating expected changes in task loads and priority, and may increase the number of staff and budget if any shortage is anticipated or streamline when necessary. These procedures are implemented as part of the NRA integrated management system.

On the other hand, in the initial mission, it was indicated that: the current organizational structure of the NRA, its way of planning the annual activities lacks of measures to assess organizational performance and use of resources are not optimal for the NRA to discharge its responsibilities and perform its functions efficiently in accordance with a graded approach. The NRA responded to the recommendation introduced based on the said indication as follows.

Recommendation 4	Contents of Recommendation
	<p>The NRA should ① evaluate the effectiveness of its current organizational structure, ② implement appropriate cross cutting processes, ③strengthen the collection of information from interested parties when planning its annual activities and ④ develop tools to measure its performance and use of resources.</p>
	Basis
	<p>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.”</p>
	Response Status
	<p>The NRA is responsible for a wide variety of tasks, from the safety and security regulations of nuclear power plants, research reactors, reprocessing facilities, nuclear fuel materials fabrication facilities, radioisotope handling facilities, and radiation generator facilities to environmental radiation monitoring, nuclear emergency response, nuclear safety research, etc. The management of the organization is within the framework of the system that governs commonly the administrative organizations such as civil servant system and official document management system etc. (For details, refer to the documentary evidence “Framework for management of the NRA.”)</p> <p>(Response to ①)</p> <p>Regarding evaluation of effectiveness of organizational system, the NRA examines the organization and personnel necessary to conduct its operations effectively and efficiently in the process of annual request for enhancement of organizational structure and increase of the fixed number of employees to the personnel authority, which is made taking into account the result of management review implemented in accordance with the NRA Management Rules and the policy evaluation conducted based on the government Policy Evaluations Act.</p> <p>The NRA has made the following efforts:</p> <ul style="list-style-type: none"> • Considering the indications related to efficiency of the inspection system etc., a “nuclear regulation inspection” will be newly incorporated into the regulatory system. For the enforcement of the new inspection system, the organizational structure was modified in FY 2017 in order to divide the department for the regulation of nuclear power plants and nuclear fuel facilities not by the type of facilities, but by their task such as safety review and inspection. Accordingly, the NRA increased the number of specialized nuclear inspectors, nuclear operation inspectors and their instructors to strengthen the inspection system. • Taking into consideration the indications such as proper allocation of resources for oversight of the implementation of radiation protection measures by licensees, a division responsible for the regulation of radiation (director for safety regulation) and the post of nuclear security officer was newly established, and the number of radiation safety reviewers was increased.

<p>Recommendation 4</p>	<p>(Response to ②) The NRA will make efforts to construct/implement cross-cutting process as follows:</p> <ul style="list-style-type: none"> • Implement hierarchization, systematization, and complementation of the documents related to the management system. • Specify the main operational manuals on the process mentioned above. • Prepare the documents to complement the NRA Management Rules including the standard form of the operational manual. • Standardize the format of main operational manuals at the timing of periodic revisions of management system-related documents. • Add the missing processes and the processes to be conducted in cross-cutting manner. <p>At present, the following works are progressing:</p> <ul style="list-style-type: none"> • Established the Operational Manual Development Rules and the basic model of standard form of Operational Manual in FY2018. • Organized the concept of hierarchical structure of the management system-related documents in FY2018, proceeded confirmation/classification/organization of the existing management system-related documents in FY2019, posted the list of management system-related documents on the portal site of the NRA, and started their centralized management. • Began establishing a common process across the organization to evaluate and review various rules, guides, etc., that are used in each department on a regular basis or when a new need arises, within 2019. In FY2020, the specific procedures for the above-mentioned evaluation/review will be documented. <p>(Response to ③) While the NRA has conventionally collected information from the interested parties, after the initial mission, the following list of the information to be collected was created, and from FY2018, by providing the list to each division when formulating the annual implementation plan, the NRA enhanced the process of information collection from the interested parties.</p> <ul style="list-style-type: none"> • Schedule of applications for authorization/application for inspections from operators • Request for technical evaluation of industrial standard from the regulated parties • Implementation status and technical information of an international cooperation project in overseas related organizations <p>Additionally, when the regulatory system was revised, the NRA solicited public comments based on the Administrative Procedures Law, and collected opinions widely, including the ones from the interested parties, and made allowance for those opinions.</p> <p>(Response to ④) Regarding development of the tool to measure its own performance and utilization of resources, the NRA developed a tool to investigate the workload for the main duties for each staff member and each division per month in order to utilize such data for appropriate allocation of human resources, and started operation of the tool in April 2017. The status of workload of each division shown by using overtime work hours as an indicator is shared in regular executive meetings and used as reference for staffing. The NRA will check these efforts related to effectiveness improvement of work efficiency through internal audit and cross-organizational management review, and will improve them if necessary.</p>
Documentary Evidence	
<ul style="list-style-type: none"> • Framework for management of the NRA • NRA Management Rules • Improvement of the NRA Management System • Annual Priority Plan for FY2019 	
Results of Self-Assessment	
Open	

3.3 Effective independence in the performance of regulatory functions

The NRA Establishment Act requires the NRA Chairman and Commissioners to perform their duties independently (Article 5). The NRA is effectively independent of organizations or agencies responsible for operating or promoting nuclear facilities and activities. Under the Reactor Regulation Act and the Radiation Hazards Prevention Act, the NRA establishes the measures to ensure safety in the use of nuclear energy or centrally administrates the affairs to be implemented in an integrated manner under the NRA Establishment Act, etc., which means that the NRA can perform its functions without undermining its effective independence.

The NRA is also granted authority to intervene with licensees under the Reactor Regulation Act and the RI Act. This authority enables the NRA to order licensees to take necessary measures to prevent a nuclear disaster or radiation hazard (e.g. suspension of the use of facilities), when the NRA decides such actions are necessary including situations of, earthquakes, fire, or other disasters.

3.4 Staffing and competence of the regulatory body

The NRA, following the procedures required for government organizations, may change its organizational structure according to needs. The NRA tries to ensure the required competence of S/NRA personnel is met by recruiting new graduates with the necessary engineering expertise through examinations and interviews, as well as mid-career experts who both meet the recruitment conditions (e.g., job history in the nuclear power industry and associated expertise) and pass intensive interviews. In particular, for highly specialized posts (e.g. Nuclear Safety Inspector, Nuclear Facility Inspector, and Senior Specialist for Nuclear Emergency Preparedness), the competence of the candidates has been determined based on specific requirements such as the years of working experience and completion of the designated training courses. However, the NRA evaluated that it does not have a sufficient number of qualified staff for performing the assigned responsibilities, which may undermine its effective independence.

For human resource development, the NRA has adopted a “Basic policy for human resource development” and a “Model career path for NRA personnel”, and implements programs based on these policies. The NRA develops a training program with reference to IAEA standards and other good practices. Specifically, the NRA clarifies the knowledge and skill levels required for each task and implements adequate training programs. The supervisors of staff are required to provide on-the-job training⁹ and to provide advice on the required trainings.

In the near-term, it was identified that the NRA should implement efficient specialized training programs to enable personnel to acquire the necessary competencies, and ensure suitable job rotations (frequencies, patterns) taking into account various task needs based on “Basic policy for human resource development” and the “Model career path for NRA personnel.”

In the initial mission, the IRRS team observed that: the NRA 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 a sufficient number of qualified staff. Accordingly, the NRA responded to the recommendation introduced based on the said indication as follows.

Recommendation 5	Contents of Recommendation
	<p>The NRA should further develop and implement the activities related to ①the evaluation of competencies, ②execution of training programmes, ③on the job training, ④internal job rotation, and ⑤strengthening 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.</p>

⁹ On-the-Job Training

Recommendation 5	Basis
	<p>GSR Part 1 Requirement 18, para. 4.11 states that “The regulatory body has to have appropriately qualified and competent staff..”</p>
	<p>GSR Part 1 Requirement 18, para. 4.13 states that “A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management ...”</p>
	Response Status
	<p>(Response to ①) In addition to the implementation of ability evaluation as a part of personnel evaluation for the staff, the NRA defined the qualifications that a staff member of the NRA or the NRA Human Resource Development Center who will be appointed to positions that require highly specialized expertise and experience should have, and evaluated the competence of individual staff who has been already engaged in those duties by conducting oral examination, etc., corresponding to each job qualification. The NRA gave them the appropriate job qualifications on the basis of the results of the evaluation by September 2017. For the inspectors of nuclear facilities, the NRA plans to conduct oral examination, etc., by the end of FY 2019 prior to the enforcement of revised Reactor Regulation Act.</p> <p>(Response to ②③) The Basic Policy for Human Resource Development for NRA Officials stipulates that the NRA is going to implement human resource development by utilizing and combining training, OJT, workshop/seminars, assignment of duties/responsibilities, voluntary training by the staff, etc. In addition to the conventional training based on the policy, in May 2016, the NRA started practical training so that inspectors and accident responders can learn the confirmation of reactor start-up and shutdown and the right ways to respond to severe accidents, etc., by utilizing plant simulators. Along with the study to establish the new inspection system, the NRA established a new mechanism, in July 2017, for new inspectors’ development by reference to the inspector development system of US NRC, and started new education and training courses in the NRA Human Resource Development Center in April 2018. The staff who are newly engaged in the inspection affairs will be granted job qualifications by completing these new education and training courses.</p> <p>(Response to ④) As for internal job rotation, the personnel evaluation process related to staff ability and performance evaluation is implemented, and appropriate rotation is carried out after interviews with each division that are conducted taking into account the results of the survey of employee hopes and the status and prospects of the duties.</p> <p>(Response to ⑤) In the safety research, the NRA Basic Policy for Safety Research indicated a policy that the NRA should consider the importance of collaboration with domestic organizations concerned that have research resources such as technical support organizations, universities, and academic societies. The recommendation was that they should use such organizations depending on their technological capabilities, and also actively work on collaboration and cooperation with overseas research institutions and international organizations. Based on the policy, the NRA participates in safety research project hosted by international organizations (OECD/NEA), actively exchanges information with overseas organizations (NRC, IRSN, GRS, etc.), and formulated the Joint Research Implementation Rules, in April 2017, so that the NRA can jointly implement research with domestic technological support organizations, universities, academic societies, etc. After 2017, the NRA has implemented 7 join researches with JAEA, and 5 with universities. In addition, for the purpose of steadily advancing the future nuclear regulations, the NRA implements the subsidy program for Human Resource Development for Nuclear Regulations from FY 2016 in order to widely secure/develop the human resources related to nuclear safety and nuclear regulation. In FY2018, 5 new projects were added to the 13 projects adopted in FY2016, and eventually 18 projects, including the projects in which universities will be the “implementing</p>

IRRS Follow-up Mission to JAPAN 2020

Recommendation 5	<p>organizations”, have been adopted.</p> <p>Also, regarding acquisition, maintenance, and development of human resources, the NRA receives a lot of advice from external experts, etc., in the course of the meetings of the Reactor Safety Examination Committee, the Nuclear Fuel Safety Examination Committee, and reviews of administrative projects¹⁰, and the NRA is going to implement continuous improvements taking the advice into consideration.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> • 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) • Instruction Regarding the Appointment of Positions that Require Highly Specialized Expertise and Experience (Chairman of the NRA, July 2 2019) • Basic Policy for Human Resource Development for NRA Officials (NRA, June 25 2014) • Basic Policy for Safety Research in NRA (NRA, July 6 2016) • Joint Research Implementation Rules (Nuclear Regulatory Agency, April 21 2017)
	Results of Self-Assessment
	Closed

Additionally, in the initial mission, the IRRS team identified concerns regarding the attractiveness of the NRA to recruit and retain suitable numbers of staff to enable it to fulfill its regulatory mandate and responsibilities. The NRA responded to the suggestion introduced based on the said indication as follows.

Suggestion 2	Contents of Proposal
	<p>The NRA should consider developing a strategy for ①attracting new and ②retaining its current technical expertise through seeking to improve the attractiveness of the 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.</p>
	Basis
	<p>GSR Part 1 Requirement 11, para. 2.3v6 states that “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.”</p> <p>GS-G-1.1 para. 4.6 states that “In addition to working in an appropriate legal framework and employing sufficient staff with suitable qualifications and expertise, the effectiveness of the regulatory body will depend also on the status of its staff in comparison with that of the staff 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.”</p>
	Response Status
	<p>(Response to ①②)</p> <p>The NRA provides staff members with the ability to directly influence the licensee’s safety performance and to establish legal requirements that affect national policies through making them engage in new regulatory standards conformity reviews, large-scale domestic law revisions, and associated tasks requiring system development, and also provides them with more responsibilities by expanding the options for regulation duties such as security measures for radioisotopes, etc. In addition to these, the NRA is aiming to secure new technical experts and maintain existing</p>

¹⁰ The efforts made by the whole government where the executive and judicial agencies of the government voluntarily organize the budget implementation state related to the project, etc., for individual projects; review the projects from the viewpoint of necessity, efficiency, effectiveness, etc., promptly after the end of each fiscal year; and reflect the results of the review to budget demands and implement and release the results.

Suggestion 2	<p>technical experts by showing a clear career path to senior staff according to the type of job (such as administrative positions, research positions, etc.) and seeking to improve the attractiveness of the NRA as an employer of choice</p> <p>The NRA strengthened organizational structure by requesting an increase of the fixed number of staff members to the personnel authority, and continuously conducted recruiting of new human resources while developing the organization structure that contributes to secure human resources. As a result, in the achievements of 2018, the NRA newly employed 12 technical experts with practical experience. As for new graduates, 29 personnel including 7 who passed the nuclear engineering staff recruitment examination or research employment selection recruitment examination that the NRA independently conducted were adopted. With regard to maintaining the skills of in-service specialists, the NRA enhanced the training system including refresher training for the experienced staff. For employees with specialized skills that are unlikely to be replaceable, the NRA has taken measures as a special case, after consultation with the National Personnel Authority, such as extension of the appointment period to maintain the ability, from March 2014.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> Track record of adoption of new graduates and experienced workers.
	Results of Self-Assessment
	Closed

3.5 Liaison with advisory bodies and support organizations

Several advisory committees have been legally established within the NRA. The Reactor Safety Examination Committee and the Nuclear Fuel Safety Examination Committee investigate and review safety matters associated with reactors and other nuclear facilities when instructed by the NRA. The Radiation Council reviews the coordination of technical standards for the prevention of radiation hazards, when consulted by other ministries or agencies, and provides its report and opinions related to the matters concerning technical standards for prevention of radiation hazards to the head of the relevant administrative agencies. The NRA appoints external “experts for emergency response” to examine EPR (Emergency Preparedness and Response) matters based on the NRA Establishment Act (Article 22), and these experts may provide advice or support to the NRA on specific issues in an emergency.

In addition to legally constituted advisory committees, the NRA may establish other ad-hoc teams (e.g. a study team), consisting of the NRA members (commissioner and staff) and external experts, for specific issues on nuclear regulations. These external experts may provide advice.

However, the external experts’ advice does not replace the assigned responsibilities to the NRA, and the NRA makes final decisions on regulatory activities (e.g. authorization, change of regulatory framework) taking this advice into account.

The NRA supervises the groups supporting NRA and QST activities within the JAEA, which conducts safety research and provides input to regulations, and QST, which conducts studies and research to support NRA activities.

However, the Department of Regulatory Standards and Research within the NRA (internal TSO) does not have facilities necessary for experiments. The JAEA’s safety research is not sufficient to support the NRA technical competency, even though this is one of the NRA’s most important conditions for performing its duties and its independence, with the cooperation of technical support organizations such as the JAEA and NIRS. Therefore, it was evaluated as necessary to further enhance the safety research of JAEA to ensure technical competence, and also to enhance cooperation between the NRA and JAEA in terms of human resource development.

To address these challenges, the NRA took the measures for improvement based on the Action Plan (A4) shown in Section 3.10.

3.6 Liaison between the regulatory body and authorized parties

The NRA has a “Policy on Ensuring the Operational Transparency of the NRA,” to ensure transparency in communicating with licensees and other interested parties. This will contribute to reducing public doubt and distrust, as well as the enhancement of neutrality and independence. The NRA intends to foster communications with licensees while ensuring high levels of transparency in accordance with this policy.

Review meetings with licensees for authorization are, in principle, open to the public. In addition to those open review meetings, the NRA has a system of “Interview”, where the NRA staff may clarify matters related to the authorization applications, or the licensees may clarify the regulatory standards or regulatory systems. The summary of these interviews as well as the materials used are made available on the NRA website.

Communication related to licensing shall be conducted by any of 3 ways, review meeting, hearing, and interview. Review meetings are intended to discuss or indicate the review related to licensing, etc., where all the relevant materials and recordings used in the meetings except for classified information are open to the public and the meetings are also broadcast live. Hearings are intended to confirm the facts for the preparation of review meetings, where the outline including the matters to be confirmed are prepared and are disclosed together with the relevant materials. Interviews are intended to respond to inquiries to the regulatory system, standards, etc., from the licensees, where their outlines are disclosed together with the relevant materials used in interviews as well as hearings.

In 2014, the NRA launched dialogues with the heads of licensees, open to the public, to deepen mutual understanding. These dialogues focus on the basic policy of the licensees for their activities enhancing safety and their proposals for improvements of the current regulatory systems.

In the initial mission, the IRRS team indicated that: there were 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 2 organizations and promoting their resolution. The NRA responded to the suggestion introduced based on the said indication as follows.

Suggestion 3	Contents of Proposal
	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.
	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 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”.
	SSG-12 para 2.30 states that “The regulatory body should establish a formal management system for dealing with license 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 license 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.”

Suggestion 3	Response Status
	<p>The NRA promotes thorough implementation of administrative operation based on documentation in accordance with the “Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority”, and continuously publishes the minutes that contain the results of the review meeting on conformity to the new regulatory requirements or instructions and agreements in the interview on its website. On this basis, the NRA inquired of licensees whether there is anything to be improved about the communication of matters pointed out at the review meetings, in July 2016. Consequently, it was confirmed that the existing method for the liaison is effective and there is no particular demand for its improvement.</p> <p>In addition to exchange of opinions between CEO of nuclear operators and the NRA commission, the NRA is trying to improve communication with stakeholders by newly establishing the framework of opinion exchange between the Chief Nuclear Officer (CNO) and the NRA commission in 2017, that contributes to smooth introduction of regulations and enhancement/clarification of regulatory standards and reviews for improving predictability. And also, from February 2018, the NRA commissioners visited nuclear facilities to grasp site conditions and conduct exchange of opinions with regulated parties and the local people concerned that desire such exchange of views.</p> <p>From the viewpoint of improving the transparency of safety review, opportunities for closed meetings with licensees are kept to a minimum, and public safety review meetings are held at regular intervals to make sure which response is required from the regulatory side or operator side about unsolved issues. Since April 2019, the NRA works on recording communication in closed meetings (such as hearings and interviews) and publishes the transcription results created by automatic transcription software on the NRA website.</p> <p>The NRA will continue to appropriately respond in the case where a licensee has made a point regarding confirmation of the facts in the minutes, make efforts to increase predictability by clarifying matters that have been pointed out or agreed upon in review meetings, hearings, etc., and promptly publish the recordings of meetings.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> • The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority (Nuclear Regulatory Agency, September 19 2012)
	Results of Self-Assessment
	Closed

3.7 Stability and consistency of regulatory control

Under the Atomic Energy Basic Act which defines the basic policy for the utilization of nuclear energy, the Reactor Regulation Act provides regulations on facilities and activities associated with nuclear energy, and the RI Act governs the use of radioisotopes, etc. The NRA Establishment Act spells out the NRA’s authority and functions as a regulatory body. The NRA defines regulatory criteria to implement these acts in the NRA Ordinances, and standard review plans or guides in the form of NRA directives. The NRA makes these criteria or guides publicly available. The NRA conducts reviews for authorization (e.g. establishment permits, construction plan approval, operational safety programs approval, decommissioning plans approval), regulatory inspections, and other authorizations in accordance with these regulatory criteria and guides. The NRA also publishes the result of its reviews for these authorizations such as an evaluation report that explains the basis for the NRA judgment. Therefore, the NRA ensures stability and consistency of regulatory control.

3.8 Safety-related records

The NRA manages licensees’ applications and other documents as administrative documents based on the Public Records and Archives Management Act. The records of the NRA’s regulatory inspections are developed in accordance with directives and kept together with relevant applications as administrative documents.

In addition, the Reactor Regulation Act and the RI Act require licensees to record necessary matters and keep

these records within the facility. The NRA verifies the creation and retention of these records through operational safety inspections and on-site inspections as needed.

For licensees of nuclear facilities which are required measures for severe accidents, the Reactor Regulation Act requires licensees to conduct periodic safety assessment of continuous improvement, to submit the report to the NRA, and to make that report publicly available.

Therefore, the NRA ensures the retention of safety-related records.

3.9 Communication and consultation with interested parties

The NRA makes decisions in its commissioner meetings, which are open to the public, except for those on nuclear security and other confidential matters. These meetings are broadcast live on the Internet and recorded video is available on the NRA web site. Materials used for such meetings are instantly made available to the public and licensees via the NRA’s website after their start, which gives licensees and the public instant access to the information. Other meetings, such as study groups consisting of external experts are also broadcast live on the Internet, with their materials and minutes published. When making important regulatory decisions, including establishing regulatory criteria and associated guides, the NRA solicits public comments even when the Administrative Procedure Act does not require such public input.

Within this broad range of available public information, the NRA also develops, for interested overseas parties such as international organizations and regulatory authorities, publicly available English reports on such issues as accidents or monitoring. The NRA sends these reports to international organizations and overseas regulatory authorities.

The NRA may ask the opinion of other competent authorities on regulatory decisions if legally required, and otherwise communicate and coordinate with them if thought necessary even though this is not legally required.

For local governments, the NRA participates in meetings with residents or their representatives living near nuclear facilities and provides further explanation on its important decisions such as the new regulatory requirements or decisions to issue permits under new regulatory requirements, based on a request from local government.

For the academic community, the NRA participants in research discussions or as an observer in committees for industrial standards development, and also provides information on regulatory activities.

For the media, the NRA organizes weekly press conferences by the Chairman and regular briefings by the S/NRA twice a week.

In order to ensure transparency of the process related to response to accidents/trouble events, the NRA holds public meetings at any time for information sharing and discussion with operators.

3.10 Action plan

Basis	<p>(B2) The IAEA Safety Standard states that “The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfill its statutory obligation for the regulatory control of facilities and activities.” [GSR Part 1, R3, and para 4.4]. and that “To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities.” [GSR Part 1, para 2.8 and 4.6]. However, the NRA currently does not have sufficient numbers of qualified staff to fulfill these tasks.</p> <p>(B3) The IAEA Safety Standard states that “The government shall make provision 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” [GSR Part 1, para 2.36. (b)] and that “A process shall be</p>
-------	---

IRRS Follow-up Mission to JAPAN 2020

	<p>established to develop and maintain the necessary competence and skills of the staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training program on the basis of an analysis of the necessary competence and skills” [GSR Part 1, para 4.13]. The NRA should optimize training programs and staff rotations to make staff more effectively attain the competence necessary for their tasks.</p>
<p>Recommendation</p>	<p>(R2) The NRA should ensure there is sufficient qualified staff to meet the needs of regulatory activities.</p> <p>(R3) The NRA should optimize the frequency and pattern of personnel rotation in consideration of the characteristics of individual posts based on the NRA’s “Basic policy for human resource development” and the “Model career path for NRA personnel.” This should be combined with specialized training to help personnel achieve maximum efficiency and acquire the competence necessary for their tasks.</p>
<p>Action Plan</p>	<p>(A2) With strengthening its efforts to recruit new graduates and mid-career experts, and with enhancing the attractiveness of its working conditions, the NRA will ensure to have sufficient qualified staff to meet the needs of regulatory activities.</p> <ol style="list-style-type: none"> ① The NRA will acquire staff with administrative experience and those with high expertise, through further extension of their retirement age and intergovernmental exchange of staff. ② The NRA will enhance its attractiveness through (i) sending newly recruited staff for overseas training or education from an early stage, (ii) expanding opportunities to exchange personnel with other organizations (e.g. universities, research institutes, international organizations), and (iii) improving welfare programs (e.g. housing). In the case of cooperation with universities, internships should be further utilized and overall human resource development programs in the field of nuclear safety and regulations should be jointly implemented. ③ In planning the expected needs of regulatory activities, the additional needs of legal experts and inspectors should be considered, since the increase of administrative decisions and the improvement of inspection systems are foreseen, as well as current imminent needs to expand staff engaged in review and other authorization tasks. ④ The NRA will ensure a sufficient number of qualified staff, and optimizes their allocation based on their competence evaluation. This process will take into consideration not only the needs of administrative tasks but also the required training programs, including long-term ones conducted domestically or overseas educational or regulatory institutes. <p>(A3) The NRA will make the following improvements for human resource development, based on the “Basic policy for human resource development” and the “Model career path for NRA personnel.”</p> <ol style="list-style-type: none"> ① Enhancing training programs in each specialized field in the reflecting career path. In particular, strengthening practical training with simulators for field response capabilities. ② Considering improving the frequency of personnel rotation, paying particular attention to individuals’ expertise, in a manner that extends the overall rotation cycle. ③ Managing staff competences and the development of necessary systems for that management. ④ Ensuring a sufficient number of qualified staff, and optimizing the allocation of its staff based on their competence evaluation with the consideration not only of the needs of administrative tasks but with the required training program, including long-term ones conducted in educational or regulatory institutes domestically or overseas (the same as in the last bullet of A2) ⑤ 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 an

IRRS Follow-up Mission to JAPAN 2020

(A3)	<p>emergency preparedness, and regulation for radiation) that require high expertise, in October 2017, due to the introduction of the job qualification system in these 5 fields, the NRA established a system to manage the abilities of the staff. At the same time, by linking job qualifications (fields/levels) and their associated posts, the NRA introduced a system for the qualifications to be reflected in staffing and treatment of the staff.</p> <p>(Response to ④) The NRA continues to improve the abilities of the staff associated with the activities through personnel dispatch to study programs within Japan and overseas, personnel dispatch to international organizations based on Act on Dispatching Staff to International Organizations, and registering NRA staff as visiting researchers to the research institutes in Japan, etc. Regarding 5 fields (nuclear inspections, nuclear safety review, safeguards inspection, emergency preparedness, and regulation for radiation) that require high expertise, in October 2017, due to introduction of job qualification system, the NRA established a system to manage the abilities of the staff. At the same time, by linking job qualifications (fields/levels) and their associated posts, the NRA introduced a system for the qualifications to be reflected in staffing and treatment of the staff.</p> <p>(Response to ⑤) Performance for responses to the international conventions as “efforts on improvement of abilities for international affairs” have been evaluated in the personnel evaluation conducted on a semiannual basis since FY2016.</p> <p>In order to secure human resources required for the work in the NRA, taking the practical needs into consideration, the NRA conducts public recruitment for each post for technical work, clerical work, and research work (4 times in the achievements of FY2018). The NRA employed 29 staff in total in the achievements of FY2019, not only by employing the persons with practical experience that have experience in required operation and abilities, but also by employing new graduates from university by way of implementing employment examinations for nuclear engineers and research work that the NRA independently performs.</p>
Documentary Evidence	<p>A2</p> <ul style="list-style-type: none"> • NRA Organization Chart • Image of Education and Training Courses (FY2018 Annual Report Figure 4-2) <p>A3</p> <ul style="list-style-type: none"> • Procedures related to Development of Staff (September 3, 2014, the NRA Secretariat / the NRA Human Resource Development Center) • Image of Education and Training Courses (FY2018 Annual Report Figure 4-2) • NRA Organization Chart
Results of Self-Assessment	A2 : Closed / A3 : Closed
Basis	<p>(B4) The IAEA Safety Standard states that “The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body, and organizations providing services or expert advice on matters relating to safety. Competence shall be built, in the context of the regulatory framework for safety, by such means as research and development work” [GSR Part 1 R11 & para 2.35] and that “A process shall be established to develop and maintain the necessary competence and skills of the staff of the regulatory body, as an element of knowledge management.” [GSR Part 1, para 4.13]. The regulatory authority’s technical competence is an essential element for performing duties and ensuring independence and needs to be supported by safety research. However, the Department of Regulatory Standards and Research in the NRA, which is an internal TSO¹¹, does not possess facilities for experiments, and safety research of external</p>

¹¹ Technical Support Organization

IRRS Follow-up Mission to JAPAN 2020

	TSOs (JAEA) are not sufficient to contribute to develop and maintain technical competence of regulatory bodies.
Recommendation	(R4) JAEA's safety research should be enhanced in order to develop and maintain technical competence of the regulatory body and the collaboration of safety research between the NRA and JAEA should be strengthened in terms of human resource development.
Action Plan	(A4) The NRA will enhance activities to achieve objectives set forth in "Safety Research by the NRA," with an emphasis on the following aspects: (i) Enhancing fundamental research that contributes to human resource development (ii) Strengthening cooperation between the NRA and JAEA in research fields
Response Status	(Response to ①) The NRA sends its staff to the JAEA as the visiting researchers for the purpose of learning basic research techniques and the JAEA also sends its researchers to the NRA. In addition, the NRA and the JAEA work on improvements of technical competence of researchers through staff dispatch to the IAEA and overseas research institutes. Furthermore, the NRA intends to enhance and intensify research infrastructure in the NRA by accumulating know-how of research staff and by developing various testing facilities that are expected to be widely used and by conducting safety research that corresponds to regulatory needs such as examinations and inspections in flexible manner. Additionally, the NRA also works on the improvement for environment of back offices in the NRA so that staff can concentrate on research and outcome of papers and the NRA technical reports can be produced more smoothly. (Response to ②) As mentioned in Response to Recommendation 5, the NRA enacted Joint Research Implementation Rules in April 2017 in order to jointly implement research with domestic technological support organizations and universities/institutes and implemented 7 joint researches with the JAEA.
Documentary Evidence	
Results of Self-Assessment	Closed

4 Management system of the regulatory body

4.1 Conclusions

Based on the self-assessment (SARIS) for management system of the regulatory body, it finds that, as shown in Section 4.2, the NRA established the rules for a management system with reference to IAEA standards and ISO¹³ 9001 standards and started its implementation in April 2015. Therefore, it concludes that its integrated management system is, in principle, in accordance with the IAEA safety requirements.

However, in the initial mission, the IRRS team provided recommendations/suggestions related to the implementation of an integrated management system, application of graded approach, promotion of safety culture, review of strategic approach, and classification of management system; NRA addressed these issues after considering responses to them and implemented measures for improvement based on the Action Plan shown in Section 4.3.

4.2 Management system of the regulatory body

The NRA established the rules with reference to IAEA standards and ISO¹² 9001 standards and started implementation in April 2015. In implementing its integrated management system, the NRA defines the “NRA’s Mission Statement (core values and guiding principles)” as the basic policy for management and determines a midterm (5-year) goal and priority programs for each fiscal year based on the basic policy. To achieve these goals and programs, the NRA manages resources and tasks, evaluates and improves its activities. Specifically, the NRA implements an integrated management system for each task, namely organizational management, responsibilities, and mandates, resource management (assignment of human resource, human resource development, knowledge management, training program), documentation, communication, procurement, and other administrative tasks. For evaluation and improvement, the NRA conducts internal audits, management of items needed for improvement, self-evaluation on the achievements of tasks, and top management reviews of these results, which will be reflected in the goals and programs for the following fiscal year.

In May 2015, the NRA also developed a “Policy Statement on nuclear safety” to supplement its mission statement as a supplement of the organization policy.

In the initial mission, the IRRS team observed that the NRA has identified in its self-assessment that the establishment of its management system is an area for improvement. Organization of management system documentation does not provide for ensuring appropriate consistency of regulatory approaches. Not all NRA management, regulatory, and supporting processes are documented (e.g. preparation of training and retraining programmes, etc.). There are also processes missing, including the management of organizational changes, the implementation of activities for promoting, enhancing and assessing safety culture, the management of records, conduct of management system reviews, collecting and addressing expectations from interested parties, etc. Application of graded approach in the conduct of regulatory activities and in the development of supporting MS documentation is not consistently applied. The NRA responded to the recommendation introduced based on the said indication as follows.

Recommendation 6	Contents of Recommendation
	The NRA should ③complete, ②document and ①fully implement its integrated management system for all regulatory and supporting processes needed to deliver its mandate. ④Grading of the application of management system should be applied consistently and ⑤generic processes should be fully developed such as control of documents, products, records and management of change. ⑥The effectiveness of the NRA management system should be monitored and measured in a comprehensive way to identify opportunities for improvement.
	Basis
	GSR Part 1 Requirement 19 states that “The regulatory body shall establish, implement, assess, and improve a management system that is aligned with its safety goals and contributes to their

¹² ISO : International Organization for Standardization

Recommendation 6	achievement.
	GS-R-3 para. 2.5 states that “The organization shall be able to demonstrate the effective fulfillment of its management system requirements.”
	GS-R- 3 para. 2.6. states that “The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of: <ul style="list-style-type: none"> • The significance and complexity of each product or activity • The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity • The possible consequences if a product fails or an activity is carried out incorrectly
	GS-R- 3 para. 2.8. states that “The documentation of the management system shall include ... a description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved ...”
	GS-R- 3 para. 6.1 states that “The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement.”
	Response Status
<p>The management of the organization of the NRA is within not only the NRA Establishment Act, but also the framework of the system that commonly governs the administrative organizations such as civil servant system, official document management system, etc. (For details, refer to the documentary evidence “Framework for management of the NRA”)</p> <p>(Response to ①②③④)</p> <p>Hierarchization, systematization, and complementation of management system will be conducted as follows:</p> <ul style="list-style-type: none"> • Classify the management system-related documents into hierarchical structures, and into the processes directly linked to nuclear safety (core process) and administrative management processes (support process). • Prepare documents to complement the NRA Rules for an Integrated Management System including standard forms of the operational manual, the concept of graded approach, etc. • Standardize the format of main operational manuals at the timing of periodic revisions of management system-related documents and apply a graded approach in the documents, taking significance, complexity, potential risk, etc., of the work into consideration. • Properly implement the processes developed by organizing the management system-related documents as mentioned above. <p>At present, the following works have been progressed.</p> <ul style="list-style-type: none"> • Established the Operational Manual Development Rules and the basic standard form of the operational manual in FY2018. • Organized the concept of hierarchical structure of the management system-related documents in FY2018, proceeded in confirmation/classification/organization of the existing management system-related documents in FY2019, posted the list of the management system-related documents on the portal site of the NRA, and started centralized management. <p>(Response to ⑤)</p> <p>The efforts to develop generic processes are as described in the response status of Recommendation 4.</p> <p>(Response to ⑥)</p> <p>The NRA receives advice from external experts on the effectiveness of each measure and project of the NRA in the course of policy evaluations and reviews of administrative projects every fiscal year. For the status of the efforts on matters pointed out in the initial mission, the NRA also</p>	

IRRS Follow-up Mission to JAPAN 2020

Recommendation 6	receives evaluation and advice from the Reactor Safety Examination Committee and the Nuclear Fuel Safety Examination Committee. Additionally, the NRA tries to improve the management system by considering the results of internal audits of the management system, administrative reports on matters requiring improvement, and proposals on operational improvement through management review.
	Documentary Evidence
	<ul style="list-style-type: none"> • Framework for management of the NRA • NRA Management Rules
	Results of Self-Assessment
	Open

Additionally, in the initial mission, the IRRS team identified that 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. The NRA responded to the suggestion introduced based on the indication as follows.

Suggestion 4	Contents of Proposal
	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.
	Basis
	GS-R-3 para. 2.5 states that “The management system shall be used to promote and support a strong safety culture by: <ul style="list-style-type: none"> • Ensuring a common understanding of the key aspects of safety culture within the organization • Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization • Reinforcing a learning and questioning attitude at all levels of the organization • Providing the means by which the organization continually seeks to develop and improve its safety culture
	Response Status
	As part of its efforts to improve the management system, the NRA formulated “Improvement of NRA Management System” in November 2016 and has implemented the following efforts. The NRA is going to foster a safety culture by continuing to implement and improve such efforts. <ul style="list-style-type: none"> • Dialogue between executives and staff members Dialogue between commissioners/executives and staff members started in January 2017. The theme varied with each commissioner/executive, and the dialogue was carried out in small groups to foster safety culture through the transfer of experience and organizational culture of openness that contributes to open-minded discussions. • Promotion of staff support Following the “Statement on Nuclear Safety Culture” developed in 2015, a practical guide was formulated in October 2017 to promote an understanding of the statement. <ul style="list-style-type: none"> - The workshops for consideration of safety were held twice in March and in September 2018 combined with site tours of the TEPCO Fukushima Dai-ichi Nuclear Power Station. - E-learning related to the NRA management system and basic knowledge of safety culture was provided in February 2019. • Promoting the creation of opportunities to take actions “My Statements Card on Nuclear Safety and Security Culture” was distributed to staff members in December 2016 for the purpose of promoting the implementation of the operations in accordance with the “Organizational Philosophy of the NRA”, “Statement on Nuclear Safety Culture”, and “Code of Conduct on Nuclear Security Culture”, etc., and encouraged the staff members to carry it with them every day.

IRRS Follow-up Mission to JAPAN 2020

Suggestion 4	<ul style="list-style-type: none"> Survey of employee awareness and behavior <p>A questionnaire survey was conducted from 2016 to 2018 to comprehend staff awareness and behavior, and the results were compiled. In FY2019, the NRA is going to conduct interviews to identify specific issues and good practices, and enhance the contents of self-assessment of safety culture.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> Improvement of the NRA Management System Statements on Nuclear Safety Culture
	Results of Self-Assessment
Closed	

Furthermore, in the initial mission, the IRRS team identified that the NRA plans to complete development of its management system in several years' time frame. Even though development of management system is recognized as one of the NRA priorities, the work is not organized 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 resource planning. The NRA responded to the suggestion introduced based on the indication as follows.

Suggestion 5	Contents of Proposal
	<p>The NRA Commissioners should ③consider taking a strategic approach to the implementation of the management system ②demonstrating their commitment to the project by ①initiating a specific multi-year management system development plan and by reviewing its implementation on periodic basis.</p>
	Basis
	<p>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.”</p>
	<p>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.”</p>
	<p>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“.</p>
Response Status	
<p>(Response to ①②③)</p> <p>After the initial mission, the NRA established “Roadmap for Improvement of Management System” for the period from the latter half of FY2016 to FY2019 and implemented it while regularly confirming it in management review. For example, the NRA has already realized the following matters:</p> <ul style="list-style-type: none"> Implemented the regular direct exchange of opinions between the commissioners and external experts of above-mentioned policy evaluations, reviews of administrative projects, and the Reactor Safety Examination Committee and the Nuclear Fuel Safety Examination Committee. Incorporated the legal policy evaluation system that was performed separately from management review (the PDCA cycle-based system that tries to improve policies of each governmental agency by conducting a self-evaluation of the policies from the view point of necessity, efficiency, and effectiveness.) into the management system by integrating the viewpoint of evaluation and the classification of policy and project with these of management system. Systematically classified the management system-related documents including hierarchization. Enhanced the activities related to nuclear safety culture such as direct dialogue between the commissioners and staff members, implementation of questionnaire surveys, and e-learning for 	

IRRS Follow-up Mission to JAPAN 2020

Suggestion 5	the staff. <ul style="list-style-type: none"> Introduced an operational improvement system in the management review, such as internal audits for the management system, administrative reports on matters requiring improvement, and proposals on operational improvement, etc. The NRA will formulate a new plan based on the results of IRRS follow-up mission from FY2020.
	Documentary Evidence
	<ul style="list-style-type: none"> Improvement of NRA Management System
	Results of Self-Assessment
Closed on the basis of progress made and confidence in effective completion in due time	

In the initial mission, the IRRS team identified that: the NRA has not developed a comprehensive description of its management system in a single document such as manual. In addition, there are many 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. The NRA responded to the suggestion introduced based on the indication as follows.

Suggestion 6	Contents of Proposal
	The NRA should consider ①developing a hierarchical structure for the management system that is easy to use and which supports effective and consistent implementation of regulatory activities. ②Specific descriptions of each process should be developed in a unified format including requirements, risks, interactions, inputs, process flow, outputs, records and measurement criteria.
	Basis
	GS-R- 3 para. 2.8. states that “The documentation of the management system shall include the following: <ul style="list-style-type: none"> ... A description of the management system ... A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved
	GS-R- 3 para. 2.9. states that “The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable, and available at the point of use.
Response Status	
(Response to ①) The NRA organized the concept of hierarchical structure of the management system in FY2018, proceeded in confirmation/classification/organization of the existing management system-related documents, and implemented hierarchization in FY2019. The NRA posted the list of the management system-related documents on the portal site and started centralized management of the documents.	
(Response to ②) The NRA established the Operational Manual Development Rules and the basic model of standard form of the operational manual in FY2018 and organized the concept of creating a unified operational manual including the items such as work flow diagrams, the risks inherent in the operation, and the preventive measures for such risks. The NRA continues to develop the relevant documents in stages, such as implementing form standardization at the timing of periodic revisions of management system-related documents.	

Suggestion 6	Documentary Evidence
	Results of Self-Assessment
	Open

4.3 Action Plan

Basis	(B5)The IAEA Safety Standard states that “A management system shall be established, implemented, assessed and continually improved” [GS-R-3, para 2.1.] Since the NRA’s integrated management system has just been established, the NRA needs to improve it continuously through the implementation of the PDCA cycle.
Recommendation	(R5) Issues identified for the integrated management system in the course of self-assessment should be autonomously resolved through the implementation of the PDCA cycle on the NRA management system.
Action Plan	(A5) Although the NRA’s integrated management system has been established, it has not fully matured. The NRA will implement internal audits and management reviews and identify any new issues. These issues, as well as those already identified during the preparation for IRRS, will be addressed in continuous improvement of the integrated management system.
Response Status (A5)	This Action Plan is implemented as a part of the response to Recommendation 6.
Documentary Evidence	
Results of Self- Assessment	Closed

5 Authorization

5.1 Conclusions

Based on the self-assessment (SARIS) for authorization, it finds that, the Reactor Regulation Act and the Radiation Hazards Prevention Act provide the legal framework for authorizations appropriately. The requirements, formats, and contents of applications and criteria for the review are well developed, tailored for each authorization stage of each type of facility and activity, and based on a graded approach according to the risk associated with the facilities and activities. Therefore, it identified that the framework and measures for authorizations are, in principle, in accordance with relevant IAEA safety requirements, except in the following circumstances:

- Quality assurance programs should be required for the establishment or equivalent stage.
- An initial decommissioning plan should be developed at the time of establishment and be updated periodically during the lifetime of operations.
- The dismantling plan of the authorized facilities should be reviewed when that dismantling work may result in releasing radioactive materials with possible exposure beyond the dose limit to the public (1 mSv/year) at the site boarder.

Additionally, in the Initial Mission, the IRRS team provided the recommendations/suggestions related to improvement of aging management, inclusion of results in radiation facility inspections to authorization process, consideration for decommissioning in all life stages of the facilities, etc. The NRA considered and addressed responses to them and implemented the measures for improvement based on the Action Plans as shown in Section 5.9.

5.2 Generic issues

The NRA performs nuclear safety regulatory functions in an integrated manner, as described in Section 1.6. The Reactor Regulation Act, which provides safety regulations for nuclear facilities and activities, and the RI Act, which provides safety regulations for the handling of radioisotopes, etc., enable the NRA to make final regulatory decisions, even in cases when the NRA is legally required to hear the opinions of other government agencies.

- Facilities and activities subject to authorization under the Reactor Regulation Act
 - Refining of nuclear source material or nuclear fuel material
 - Fabrication and enrichment of nuclear fuel material
 - Installation and operation of reactors
 - Interim storage of spent fuel
 - Reprocessing of spent fuel
 - Waste management of nuclear fuel material or material contaminated by nuclear fuel material
 - Use of nuclear source material or nuclear fuel material as designated in terms of nuclide and amount
 - Transportation of nuclear fuel material or material contaminated by other nuclear fuel material
- Facilities and activities subject to authorization under the RI Act
 - Use of radioisotopes as designated in terms of nuclide and amount
 - Selling or renting of radioisotopes
 - Waste management of radioisotopes

The Reactor Regulation Act and the RI Act require the applicants for authorization to submit materials and documents demonstrating the safety of regulated facilities or activities in order to support their applications. However, the submitted materials and documents may differ depending on the type of facility or activity, based on a graded approach.

The NRA Ordinances specifically require a licensee's quality assurance program in their applications for construction plans or operational safety programs of nuclear facilities, but they are not required for applications for establishment permits.

To address this challenge, the NRA implemented the improvement measures etc., based on the Action Plan (A6) as shown in Section 5.9.

5.3 Authorization of nuclear power plants

5.3.1 Authorization of nuclear power plants

The Reactor Regulation Act provides the regulatory framework, which obliges licensees to submit applications with supporting documents to show the compliance with safety requirements at each stage of progress, for installation, modification, use, or operation of nuclear power reactor facilities. That act further obliges applicants to undergo reviews and inspections by the NRA, and to have its authorization (permit, approval, or confirmation) before installation, modification, use, or operation of their facilities.

The requirements related to authorization, format of the application for authorization, and appended documents are defined by the Cabinet Order or the NRA Ordinances under the Reactor Regulation Act. The NRA develops and publishes various guides explaining requirements and procedures for these applications.

In the initial mission, the IRRS team noted that ageing management at NPP is to be addressed by licensees and examined by the NRA under 3 regulatory processes which may be concurrent: change in Operational Safety Programs for plants operating beyond 30 years, reports 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. The NRA responded to the suggestion introduced based on the indication as follows.

Suggestion 7	Contents of Proposal
	The NRA should consider enhancing the interfaces and overall coherence of the existing 3 regulatory processes related to NPP aging management
	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.”
	Response Status
	The regulatory process for aging nuclear power plants includes an Aging Management Technical Evaluation System, Operation Period Extension Authorization System, and Periodic Safety Assessment of Continuous Improvement System.
	The Aging Management Technical Evaluation System requires the licensees to perform deterioration status evaluation, assuming long-term operation, of equipment and structures that are important for safety before the plant operation has passed 30 years and every 10 years thereafter, and to formulate a long-term maintenance management policy taking the evaluation results into consideration and including it in their Operational Safety Programs. The implementation status of the maintenance plan that embodied the policy is confirmed through the safety inspections, etc.
	The Operation Period Extension Authorization System specifies the operation period which nuclear power plant can be allowed as 40 years from the start of operation and grants an extension of operation period up to 20 years at maximum only once in the case that the licensee obtains authorization by the end of the operation period after conducting special inspections and safety review based on the results of deterioration status and taking the results of the special inspection into consideration.
	The Periodic Safety Assessment of Continuous Improvement System is the system that encourages voluntary efforts on improvement of safety of facilities by requiring the licensees to perform comprehensive evaluation regarding the efforts for both hardware and software for each facility, including voluntary efforts by licensees themselves, and to contribute social evaluation through publication of the results.

Suggestion 7	<p>Among these, for example, the deterioration status evaluation required in the case of obtaining the approval for the extension of operation period based on the Operation Period Extension Authorization System is substantially same as the deterioration status evaluation of the 40th year required in the Aging Management Technical Evaluation System. However, since the NRA Ordinance Concerning the Installation and Operation of Commercial Power Reactors redundantly requires the licensees to submit similar document in each application, the procedures between regulatory processes were not optimized.</p> <p>The NRA conducted a study to improve the interface and consistency of the existing processes related to aging countermeasures for nuclear power plants, and, following the results of the study, amended the Commercial Reactors Ordinance in August 2017. In the amended regulations, when deterioration status evaluation based on the Operation Period Extension Authorization System and the one based on the Aging Management Technical Evaluation System are integrally performed and the documents related to the results of either of the systems have already been submitted in the applications, it is not necessary to submit it twice. 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 Periodic Safety Assessment of Continuous Improvement of Commercial Nuclear Reactors in March 2017, so that the results of the Aging Management Technical Evaluation System can be utilized for the mid-long term assessment relating to aging of nuclear facilities that have been operating over 30 years.</p>
Documentary Evidence	
<ul style="list-style-type: none"> • The Commercial Reactors Ordinance Article 113. • Operational Guide for the Periodic Safety Assessment of Continuous Improvement of Commercial Nuclear Reactors (established by NRA on November 27 2013, amended on March 29 2017) 	
Results of Self-Assessment	
Closed	

5.3.2 Staffing of the operating organization

Regarding installation of commercial nuclear power reactors, the Reactor Regulation Act requires licensees to have the technical competence, etc., necessary to install SSCs, to operate them appropriately, and to take required measures to prevent and mitigate severe accidents in order to ensure the competence of licensees.

The Reactor Regulation Act provides a qualification system for “Chief engineer of reactors” (Article 41) and requires licensees to appoint a supervisor for safety of reactor operations from those who are qualified as a “Chief engineer of reactors” and have work experience commensurate with NRA ordinances (Article 43-3-26). That act also requires licensees to take safety measures for the operation of nuclear power reactors (according to Article 43-3-22). In implementing such measures, the Commercial Reactors Ordinance obliges licensees (i) to employ operational staff with the required knowledge, (ii) to have the required number of staff for reactor operations, and (iii) to have supervisors with the necessary knowledge, skills, and experience (Article 87). That ordinance also requires the licensees to have an NRA confirmation in advance for the licensees’ procedures and implementation systems that judge the conformity of these supervisors’ ability to the NRA’s criteria. (Article 92). That Ordinance requires operational safety programs to include the assigned tasks (scope and description) for a “Chief engineer of reactors”, its mandates and the organizational position in supervising operational safety. The Act requires licensees to have an NRA approval of operational safety programs.

Additionally, while the NRA required licensees to receive NRA approval of operational safety programs before operating facilities, it requires approval before starting installation construction of the facilities pursuant to Article 43-3-24 of the amended Act (scheduled to enact on April 1 2020).

As described above, the framework under the Reactor Regulation Act and its ordinance require licensees of nuclear power reactors to allocate competent managers and a sufficient number of qualified personnel

for the safe operation of nuclear power plants.

5.3.3 Operational limits and conditions

The Reactor Regulation Act requires licensees to develop and receive an NRA approval of operational safety programs [before starting installation construction of the facilities](#) in accordance with Article 92 of the Commercial Reactors Ordinance ([scheduled to enact on April 1 2020](#)) as shown in [Section 5.3.2](#), and to maintain the compliance of the operational activities to these programs in paragraph 1 of [the same Article-1-9](#). The [Standards Review Plan on operational safety programs](#) specifies that it requires operational safety programs to include operational limits and conditions and that the plan requires licensees to define the limits of operations, according to the operating state, for SSCs important to safety and those coping with severe accidents. [The Reactor Regulation Act also requires the licensees for nuclear power plants and their employees comply with the operational safety program \(Article 43-3-24\)](#). As described above, the regulatory framework obliges licensees of nuclear power reactors to conduct operations in compliance with the defined operational limits and conditions.

5.3.4 Qualification and training of personnel

As described in [Section 5.3.2](#), the Reactor Regulation Act provides a qualification system for a “Chief engineer of reactors” and requires licensees to appoint a supervisor for the safety of reactor operations from those who are qualified as a “Chief engineer of reactors” and have work experience commensurate with NRA ordinances.

The Commercial Reactors Ordinance requires [licensees](#) to establish a quality assurance program in accordance with the operational safety program, to implement the program (plan, implement, evaluate, and improve operational safety activities), and to continuously improve the quality assurance program (Article 69). That ordinance also requires operational safety programs to include a quality assurance program (in Article 92 of [the same Ordinance](#)), and its [Standards Review Plan of operational safety programs](#) quotes the industrial code “Rules of Quality Assurance for Safety of Nuclear Power Plants (JEAC4111-2009¹³)” (Japan Electric Association) as the basis or the equivalent and specifies as required criteria, and JEAC4111-2009 calls for defining competence management, necessary education and training programs, and evaluation of such measures. As described above, the regulatory framework obliges licensees to manage its competences.

5.3.5 Management of modification

The Commercial Reactors Ordinance requires licensees to take necessary measures, etc., [appropriately](#) (e.g. development of a plan for maintenance and management, its implementation) for facility modification (Article 81), [etc.](#), and the NRA confirms these licensees’ measures in the approval of operational safety programs.

The Reactor Regulation Act requires licensees either to obtain the NRA’s permit for the modification of an establishment, or to notify to the NRA only in cases where such modifications will evidently not affect the conformity to the regulatory requirements (Article 43- 3-8).

That act requires licensees either to obtain the NRA’s approval for a construction plan or to notify the NRA of such a plan, before starting construction (Article 43-3-9, 43-3-10 of [the Act](#)). In the case that licensees plan to modify construction plans after the NRA’s approval, licensees shall again seek NRA approval or notify the NRA of the changes ([Article 43-3-9 of the Act](#)).

That act requires licensees to undergo NRA preservice inspections for modified facilities to enable the NRA to confirm that all modifications comply with the approved construction plans and other requirements, and to receive NRA confirmation before beginning operations (Article 43- 3-11). Licensees are required to [attach](#) the documents on maintenance, replacement, or other modifications as annexes to the applications for preservice inspections.

¹³ Incorporated association Japan Electric Association, the industrial code “Rules of Quality Assurance for Safety of Nuclear Power Plants (JEAC4111-2009)”

As described above, the regulatory framework obliges licensees to manage facility modifications.

It was identified that the dismantling plan of the authorized facilities should be reviewed when that dismantling work may result in releasing radioactive materials with possible exposure beyond the dose limit to the public (1 mSv/year) at the site boarder.

To address this challenge, the NRA implemented the measures for improvement, etc., based on the Action Plan (A8) as shown in Section 5.9.

5.3.6 Commissioning

The Reactor Regulation Act specifies licensees to pass a preservice inspection conducted by the NRA before use of the facilities for commissioning (Article 43-3-11). The following inspections are conducted for commissioning:

- ① When ready to start criticality operations, regulatory inspections for the performance and function of SSCs (i.e. reactors, cooling systems for reactors, instrumentation and control systems, and generators) required for criticality operations
- ② When completing all the approved construction, regulatory inspections for the overall performance of facilities in power operations

As specified in Article 43-3.24, the Reactor Regulation Act requires licensees to specify operation safety programs regulations related to operation, control, etc., of operation of nuclear power reactor facilities and to obtain approval by the NRA before starting facility construction as shown in Section 5.3.2 (scheduled to enact April 1 2020).

5.3.7 Operating procedures

The Commercial Reactors Ordinance requires licensees to establish necessary operational documentation as follows:

- To establish operational manuals, work procedures, and other operational safety documents in accordance with the operational safety program, and to comply with these documents (Article 76).
- To establish necessary plans and work procedures in the event of extensive damage or severe accidents (Articles 85, 86 of the Act).
- To establish measures to be taken in an emergency shutdown; and, specifically in the event of an emergency shutdown, to establish a plan to identify the cause, to evaluate damage, and to confirm that the restart of operation will not cause any further troubles. Licensees are required to observe these plans or procedures (Article 87 of the Act).

As described above, licensees are required to establish and comply with operational manuals both under normal operations and in the event of accidents.

5.3.8 Maintenance programs

The Commercial Reactors Ordinance requires licensees to establish a maintenance management policy (1) to ensure that the performance of a nuclear power reactor facility is maintained according to the permitted establishment plan and the approved construction plan; (2) to set up maintenance management targets under that policy; (3) to set up a plan to implement maintenance management to achieve these targets; and (4) implement maintenance management as planned (Article 81). In addition, Article 92 of the ordinance requires operational safety programs to specify the maintenance management for the facilities in a Standards Review Plan of operational safety programs, and its Standards Review Plan quotes the industrial standard “Code of maintenance and inspections for nuclear power plants (JEAC4209-2007¹⁶)” as one of the acceptable standards for these requirements for licensing.

As described above, licensees are required to establish and implement maintenance programs.

5.4 Authorization of research reactors

The [requirements and procedures](#) of authorization for research reactors are basically the same as those for nuclear power plants, but the requirements in terms of contents and levels differ based on a graded approach [according to the risk](#) associated with the [facilities and activities](#).

The Reactor Regulation Act requires licensees of research reactors to appoint a supervisor for safety of reactor operations from those who are qualified as a “Chief engineer of reactors” [just as in the case of nuclear power plants shown in Section 5.3.2](#) (Article 40) and have work experiences commensurate with NRA ordinances. The NRA’s approval for welding methods of the designated research reactors is required for welding parties, not for licensees of research reactors.

5.5 Authorization of fuel cycle facilities

The [requirements](#) and procedures of authorization for fuel cycle facilities are basically the same as those for nuclear power plants, but the requirements in terms of contents and levels differ based on a graded approach [according to the risk](#) associated with [the facilities and activities](#).

The Reactor Regulation Act requires [licensees](#) of fuel cycle facilities to appoint a supervisor for safety of facility operations from those who are qualified as a “Chief engineer of nuclear fuel”, who is certified under a qualification system of the Act [besides “Chief engineer of reactors” shown in Section 5.3.2](#). The NRA’s approval for welding methods of the designated fuel cycle facilities is required for welding parties, not for licensees.

5.6 Authorization of waste management facilities

[The requirements procedures of authorization for waste management facilities in Reactor Regulation Act are basically the same as those for nuclear power plants](#), but the requirements in terms of contents and levels differ based on a graded approach [according to the risk](#) associated with [the facilities and activities](#).

At present, for buried disposals, only near surface disposals (disposals in a trench or pit) are implemented in Japan, and the NRA regulates these facilities and activities.

With regard to radioactive waste originating from nuclear power plants but is not suitable for near surface disposals, and waste from facilities other than nuclear power plants (e.g. research facilities), currently there are no projects for such disposals foreseen in the near future. Therefore, the NRA [has](#) not developed any regulatory requirements for the disposal of [this](#) waste. However, since the number of decommissioned plants is expected to increase and certain waste will not be allowed for near surface disposal because of exceeding the limit of radioactivity concentration designated for that disposal, the NRA is developing regulatory requirements for intermediate depth disposal¹⁴. [It was identified that](#) the NRA needs to start deliberations on the regulatory requirements for the disposal of radioactive waste coming from research institutes, etc., as the JAEA is advancing its program to build such disposal facilities.

5.7 Authorization of radiation sources¹⁵ facilities and activities

[The RI Act](#) requires relevant organizations to receive NRA authorization before the use of radioisotopes and radiation generating apparatuses. Required authorizations differ according to the level of the risk associated with that use. The act requires the relevant operators using the designated radioisotopes (nuclides and amount) to obtain an NRA permit and its confirmation via inspections at several different stages. Operators using radioisotopes below the designated level shall notify the NRA if those do not apply to exemptions. The act prohibits the possession of radioisotopes without NRA permission or prior notification to the NRA.

¹⁴ It is expected that the degree of the waste from nuclear reactor should be, in order make the volume and concentration suitable for total volume of radiation, the concentration of long half-life radionuclide, etc., deeper than underground disposal and shallower than geological disposal. While the approach of such disposal in Japan had been called as “subsurface disposal”, the same approach is internationally called as “Intermediate depth disposal”. Thus, the name was changed to “Intermediate depth disposal”. Accordingly, this report uses the integrated expression Intermediate depth disposal.

¹⁵ In this section, “radiation sources” indicates the generator of radioisotopes and radioactive rays.

The RI Act also stipulates that applicants for a permit or inspection shall submit necessary documents to the NRA to confirm the safety and other required matters, and that ordinance stipulates formats of the documents and attachments. The NRA develops and publishes various guides explaining requirements and application procedures related to these authorizations,

In confirming the required compliance of these authorized operators, the Act (1) provides a qualification system for a Radiation Protection Supervisor to persons who have passed the examination prepared by the NRA or a Registered Examination Body (by the NRA approval) (Article 35), (2) requires authorized operators to make an appointed Radiation Protection Supervisor to supervise radiation protection measures (Article 34), and (3) requires any persons in the facility to follow the instructions of the Radiation Protection Supervisor to comply with all legal requirements and for the implementation of the Radiation Hazards Prevention Program (Article 36).

In the initial mission, the IRRS team identified that 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. The NRA responded to the recommendation introduced based on the indication as follows.

Recommendation 7	Contents of Recommendation
	The NRA should incorporate the findings of the facility inspection into the review and assessment and the authorization process for radiation sources.
	Basis
	GSR Part 1 Requirement 25 states that “The regulatory body shall review and assess relevant information.....to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization...”
	Response Status
	<p>In Japan, in order to allocate limited administrative resources effectively, the Registered Organization System has been adopted as a basic policy, based on the “Reform Implementation Plan for Governmental Engagement with Public Interest Corporations (cabinet decision, March 29, 2002) and the “Three-Year Plan for Promoting Regulatory Reform/Private Opening” (cabinet decision, March 19, 2004), so that the government delegates the authority of administrative action such as implementation of inspections to the registered organization. In the case of administrative actions such as routine and less discretionary inspections, the government registers organizations that are determined to have certain technical capabilities based on the laws as the registered organization and delegates the authority to the organizations. Thus, the authority to take administrative actions such as inspections, etc., shall be entrusted to the registered organizations, and the registered organizations conduct the inspections as national agencies. While the government does not conduct the inspections by the registration, at the same time, it shall newly have the authority for oversight of the registered organizations. Based on the above-mentioned cabinet decisions, the NRA adopted the Registered Organization System in the regulations based on the RI Act, and in the case of administrative actions such as routine and less discretionary, the registered organizations are conducting the actions.</p> <p>The pass/fail judgment in the facility inspection is conducted to confirm that the installation of the facility is carried out in line with the permission given by the government; therefore the content of the inspection is routine and extremely less discretionary. For this reason, based on the above-mentioned cabinet decisions, the government decided to adopt the registered organization system by amending the RI Act (amended in 2004). The government registered the organizations that have been recognized as having certain technical capabilities, etc., pursuant to the Act, and delegates the authority of pass/fail judgment of facility inspections to the organizations. In this way, the registered organizations conduct the pass/fail judgment of facility inspection as national</p>

Recommendation 7	<p>agencies. Along with the delegation of the authority to the organizations, the NRA obtains the authority to approve the operational rules of, give an order of operational improvement to, and oversight by conducting on-site inspections of the registered organizations. For this reason, even after the delegation of the authority, the NRA can be properly involved in a series of regulation processes related to the decision of starting the use of the facilities, by exercising oversight authority.</p> <p>In addition to this, the NRA revised the Standard Review Plan for Operational Rules of the registered organization in December 2017, and required them 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. This ensures that the results of the facility inspections have been included more properly in a series of regulation processes including subsequent regulations.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> • The RI Act, Article 12-2, Article 12-8, Article 41-5, Article 43-3 • The RI Ordinance, Article 14-16 • 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.
	Results of Self-Assessment
Closed	

5.8 Authorization of decommissioning activities

The Reactor Regulation Act provides the framework for decommissioning activities. It requires licensees (1) to submit applications for authorization with documents to explain safety and other requirements, (2) to undergo NRA reviews or inspections, (3) to obtain NRA authorization (approval or confirmation), according to the stage of decommissioning. Licensees are required to receive confirmation of the completion of each stage, before moving to the next stage.

The requirements for decommissioning are basically the same for all the nuclear facilities, but the items and the levels of requirements differ depending on the types of nuclear facilities, based on a graded approach according to the risk associated with the facilities and activities.

The Reactor Regulation Act requires licensees to develop and obtain NRA approval of decommissioning plans before they take action in decommissioning. However, licensees are not required to develop an initial decommissioning plan at the time of establishment, or to update such plans periodically during operations.

The RI Act requires the licensees to notify their decommissioning plans to the NRA in the case of abolition of all use of radioisotopes, radiation generating apparatus, etc., which are approved. Additionally, at the time of completion of the decommissioning plan, the licensees are required to report that effect to the NRA without delay.

In the initial mission, the IRRS team noted that: in the case of non-nuclear facilities authorized under the RI Act the regulator does not provide a formal confirmation to the operator regarding completion of decommissioning and release from further responsibility. In the 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 the NRA has no clearly defined criteria for the release of sites at the end of decommissioning, consistent with GSR Part 6 requirements 5 and 15. Lack of criteria results in the NRA not being able to complete the process of termination of authorization. The NRA responded to the recommendation introduced based on the indication as follows.

Recommendation 8	Contents of Recommendation
	<p>The NRA should establish ①requirements relating to consideration of decommissioning during all life stages of nuclear and radiation facilities, and ②criteria for the release of sites at the end of decommissioning.</p>

Recommendation 8	Basis
	<p>GSR Part 6 Requirement 5, states that “The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility’s lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met.”</p>
	<p>GSR Part 6 Requirement 5, para 3.3 states that “The responsibilities of the regulatory body shall include: ... Establishing requirements and criteria for termination of the authorization for decommissioning and especially when facilities and/or sites are released with restrictions on their future use”</p>
	<p>GSR Part 6 Requirement 15, para 9.2 states that the regulatory body shall review the final decommissioning report and shall evaluate the end state to ensure that all regulatory requirements and end-state criteria, as specified in the final decommissioning plan and in the authorization for decommissioning, have been met. On the basis of this review and evaluation, the regulatory body shall decide on the termination of the authorization for decommissioning and on the release of the facility and/or the site from regulatory control.</p>
	<p>GSR Part 6 Requirement 15, states that “On the completion of decommissioning actions, the licensee shall demonstrate that the end-state criteria as specified in the final decommissioning plan and any additional regulatory requirements have been met. The regulatory body shall verify compliance with the end-state criteria and shall decide on termination of the authorization for decommissioning.”</p>
	Response Status
<p>【Nuclear Safety】 (Response to ①) The NRA considered the initial decommissioning plan, and decided to add legal regulatory requirements and newly required the licensees for nuclear power plants, research reactors, refining facilities, fuel fabrication plants, spent fuel interim storage, reprocessing facilities, radioactive waste disposal or storage activity and usage facilities (the users that use nuclear fuel materials specified by the Cabinet Order) to formulate a decommissioning measures implementation policy to initial decommissioning plan and publish it when the licensee intends to initiate the business or the operation of the reactor. For this reason, the NRA amended the Nuclear Reactor Regulation Act and relevant regulations, and put it in force in October 2018. The amended Act obliges the licensees to include the expected amount of material contaminated by nuclear fuel materials to be disposed of, estimation of the costs required for decommissioning and its way of financing etc., and the matters required for implementation of decommissioning into the decommissioning measures implementation policy, and to officially announce without delay when the licensee amended the policy. The NRA also developed the operational guide that shows the basic concept regarding preparation and publishing of the policy.</p> <p>(Response to ②) Regarding the site release criteria, the “Study Team on the Radiation Protection Standards of Waste Disposal” consisting of the members of the NRA commissioner, the officials of Nuclear Regulatory Agency, and the external experts was established and the site release criteria for nuclear facilities were studied in the study team. The NRA is going to formulate the site release criteria (dose criteria for representative individuals after site release) for nuclear facilities in 2019, considering the results of the study and the concept of the radiation protection standard after completion of the regulated period of near surface disposals, and compile a technical document in FY2021, regarding measurement methods upon the site release.</p>	

Recommendation 8	<p>【Radiation Safety】</p> <p>(Response to ①) Regarding RI facilities, the implementation of transfer and disposal of RI and RI contaminated objects, and removal of the contamination has been required to have a permission of the termination of use. On the other hand, the amount and scope of these transfers, disposals, and decontamination are smaller than those of nuclear facilities, and in practice, the Japan Radioisotope Association, a public interest incorporated foundation, has centralized control over collection and disposal of RI, etc., and has a proven record to complete the activities in Japan. For this reason, based on the graded approach taking the difference of radiation risk with that of nuclear facilities derived from the easiness of decommissioning into consideration, the NRA decided not to require consideration related to decommissioning at the stage of installation and utilization of RI facilities.</p> <p>(Response to ②) The site release criteria for RI facilities is operated in accordance with the same criteria as for the decommissioning, and since the site release is smoothly implemented using current criteria, the NRA decided not to specify any new regulations for site release of RI facilities. The status of decommissioning has been confirmed by the on-site inspections to be conducted just prior to the completion of the decommissioning or the completion report of the decommissioning plan that is legally required to submit to the NRA. Also note that, at the time when the notification of the termination of use is received by the NRA, the corresponding permission of the licensee becomes invalid, however the licensee still undertakes obligations as a “revoked permission user” until the decommissioning is completed.</p>
	<p>Documentary Evidence</p>
	<ul style="list-style-type: none"> • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors, Article 12-5-2, Article 22-7-3, Article 43-3, Article 43-3-33, Article 43-26-4, Article 50-4-3., Article 51-24-3, Article 57-4) • The Commercial Reactors Ordinance Article 115-2 to 4. • Operation guide related to preparation of decommissioning measures implementation policy (November 22 of 2017, NRA) • The RI Act, Article 27, 28 • The RI Ordinance Article 26
	<p>Results of Self-Assessment</p> <p>Closed on the basis of progress made and confidence in effective completion in due time</p>

5.9 Action Plan

<p>Basis</p>	<p>(B6) The IAEA Safety Standard states that “A quality assurance program shall be implemented for all activities that may influence safety or the derivation of parameters for the design basis for the site.” [NS-R-3¹⁶ paragraph 6.6.] and that “The design organization shall establish and implement a management system for ensuring that all safety requirements established for the design of the plant are considered and implemented in all phases of the design process and that they are met in the final design.” [SSR 2/1¹⁷ R2, paragraph 3.2.]</p> <p>Under the current system, at the basic design stage, while a quality assurance program is required and reviewed in terms of the technical competence of licensees, these reviews do not apply to quality assurance programs during the basic design stage including the evaluation of site characteristics.</p> <p>(B7) The IAEA Safety Standard states that “Management systems to provide for the assurance of quality shall be applied to all safety-related activities, systems, and components throughout all the steps of the development and operation of a disposal facility.” [SSR-5¹⁸ R25] In the design/construction stage of a waste disposal facility, development and implementation of quality assurance programs are not set as a regulatory requirement.</p>
<p>Recommendation</p>	<p>(R6) The NRA should consider requiring licensees to institute quality assurance programs during the establishment permit procedure or equivalent stage.</p>
<p>Action Plan</p>	<p>(A6) The NRA will consider adding requirements① to plan and implement quality assurance programs at the establishment permit or equivalent stage, and ② to review these implementations.</p> <p>In considering these actions for nuclear facilities other than nuclear power plants, the measures to be taken for nuclear power plants and the facility specific features will be taken into account.</p>
<p>Response Status (A6)</p>	<p>(Response to ①) The NRA established “Study Team for Review of Inspection System” that comprises of a commissioner of the NRA, the officials of the NRA, and the external experts to discuss regulations related to establishment of quality assurance plans and studied about the direction and the contents for review of the system with the participation of the nuclear licensees in a public place. As a result of the studies, the NRA amended the Reactor Regulation Act in order to monitor overall safety activities by the licensees from the establishment approved to the completion of decommissioning; it newly established requirement that the applicants for nuclear facility installation can be approved only after it is recognized that their quality management system concerning activities for ensuring safety of the nuclear facility comply with the standards specified by the ordinance at the stage of the establishment permit application. For the future, in “NRA ordinance on the standard for quality management system concerning activities for ensuring safety of nuclear facilities” that will be specified by the enforcement of the amended Act, April 2020, The NRA will require establishment/implementation of quality assurance plan.</p> <p>(Response to ②) As the implementation status of the quality assurance plan at the stage of basic design, the NRA has started the amendment work of the relevant documents (operation guides on application for installation [modification] permit) by requiring a description in the attachment to the establishment permit application and verifying the attachment in the</p>

¹⁶ NS-R-3 : Site Evaluation for Nuclear Installations, Safety Standard Series No. NS-R-3

¹⁷ SSR-2/1 : Safety of Nuclear Power Plants: Design

¹⁸ SSR-5 : Disposal of Radioactive Waste, Safety Standard Series No. SSR-5

IRRS Follow-up Mission to JAPAN 2020

(A6)	examination of the establishment permit, etc., and will enact in April 2020. After that, the proposal for the guide has been established with the policy to verify it in the nuclear regulatory inspection. The NRA will determine its detail contents after trial operation of new regulatory inspection system.
Documentary Evidence	<ul style="list-style-type: none"> • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors Article 13, 14, 23, 24, 43-3-5, 43-3-6, 43-4, 43-5, 51-2, 51-3).
Results of Self-Assessment	Closed on the basis of progress made and confidence in effective completion in due time
Basis	(B8) The IAEA Safety Standard states that “The licensee shall prepare and submit to the regulatory body an initial decommissioning plan, and the decommissioning plan shall be updated by the licensee, reviewed by the regulatory body periodically and maintained throughout the lifetime of the facility.” [GSR Part 6 ¹⁹ R10, paragraph 7.4. and paragraph 7.5, (WS-R-5 ²⁰ paragraph 5.6. and paragraph 5.7)] Under the current system, however, licensees are not required to develop and update decommissioning plans as staged in the above.”
Recommendation	(R7) The NRA should consider developing a regulatory framework for licensees to develop an initial decommissioning plan at the establishment or equivalent stage, and to update such plans periodically throughout the lifetime of the facility.
Action Plan	<p>(A7) The NRA will require ① the establishment and periodic updating of the decommissioning at plan throughout the lifetime of an existing facility, in ② the implementation of licensees’ periodic safety assessment of continuous improvement for nuclear power plants, reprocessing facilities and fuel fabrication facilities.</p> <p>In considering these actions for nuclear facilities other than nuclear power plants, the measures to be taken for nuclear power plants and the facility specific features will be taken into account.</p>
Response Status (A7)	<p>(Response to ① and ②)</p> <p>This Action Plan has been implemented as a part of specification of the requirements to consider decommissioning at all the stages of service period of nuclear facilities in the response to Recommendation 8.</p> <p>While establishment/announcement of the decommissioning measures implementation policy is intended to contribute to a smooth transition to the decommissioning stage, the periodic safety assessment of continuous improvement is the one to improve safety for the nuclear facilities during operation. Therefore, as a result of consideration, the NRA amended the Reactor Regulation Act by changing the original Action Plan. In October 2018, not as a part of the periodic safety assessment of continuous improvement but separately, the NRA newly required the establishment/announcement of the decommissioning measures implementation policy.</p> <p>Additionally, after announcement of the decommissioning measures implementation policy, the NRA requires licensees to review the entire policy every 5 years.</p>
Documentary Evidence	<ul style="list-style-type: none"> • Operation guide related to preparation of decommissioning measures implementation policy (November 22 of 2017, NRA) • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors Article 12-5-2, 22-7-3, 43-3, 43-3-33, 43-26-4, 50-4-3, 51-24-3, 57-4)

¹⁹ GSR Part6 : Decommissioning of Facilities, Safety Standards Series No. GSR Part6

²⁰ WS-R-5 : Decommissioning of Facilities Using Radioactive Material, Safety Standard Series No. WS-R-5

IRRS Follow-up Mission to JAPAN 2020

Results of Self-Assessment	Closed
Basis	(B9)The IAEA Safety Standard states that “the regulatory body shall review and assess relevant information to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization 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.” [GSR Part 1 R25] and “The decommissioning plan shall be supported by an appropriate safety assessment covering the planned decommissioning activities and abnormal events that may occur during decommissioning.” [GSR Part 6 ¹⁹ paragraph 5.2., (WS-R-5 paragraph 5.2.)]. However, while the plan for permanently decommissioning a nuclear power plant is set as the scope of review and assessment, the safety of dismantling work of individual SSCs is not covered in the review and assessment.
Recommendation	(R8) The dismantling plan of the authorized SSCs should be reviewed when that dismantling work may result in releasing radioactive materials with possible exposure beyond the dose limit to the public (1 mSv/year) at the site boarder.
Action Plan	(A8)③The dismantling plan of the authorized SSCs will be reviewed by the NRA, when ① that dismantling work may result in releasing radioactive materials with possible exposure beyond the dose limit to the public (1 mSv/year) at the site boarder. ②The NRA will require SSCs to implement the exposure assessment to the public for the work, etc.
Response Status (A8)	<p>(Response to ①) The licensees can temporarily designate or release controlled areas in their site for the work such as construction in accordance with their operational safety programs. Actually, when implementing dismantling/removal of a part of equipment of nuclear facilities, the NRA verified the implementation of appropriate radiation control to avoid the radiation effect on the surroundings of the sites by maintenance of safety function of the buildings and establishment/release of the controlled areas under operational safety programs.</p> <p>(Response to②and③) In the amended Reactors Regulation Act, the NRA requires the construction for establishment/modification of nuclear facilities to be implemented after NRA approval regarding its design, construction method, construction plan, etc., before starting construction, except for one that does not impair disaster prevention. The NRA requires to include the description such as the considerations for construction, etc., in the construction plan and to clarify implementation of the description related to radiation control when dismantling work may result in releasing radioactive materials with possible exposure beyond the dose limit to the public (1 mSv/year) at the site boarder. Then it started amendment work of the relevant documents (procedure guide for construction plan) and will enact in April 2020.</p> <p>Additionally, in the case of implementing work for dismantling/removal of a part of equipment of nuclear facilities, etc., the NRA continues to verify proper implementation of dose control in the examination of operational safety program approval and operational safety inspections, etc.</p>
Documentary Evidence	<ul style="list-style-type: none"> • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors Article 16-2, Article 27, Article 43-3-9, Article 43-8, Article 45, Article 51-7)
Results of Self-Assessment	Closed on the basis of progress made and confidence in effective completion in due time

6 Review and assessment

6.1 Conclusions

Based on the self-assessment (SARIS) for review and assessment, it finds that, as shown in 6.2, the Reactor Regulation Act and the Radiation Hazards Prevention Act provide the legal framework requiring licensees to conduct safety assessment for each authorization stage of regulated facilities and activities, and under which the NRA conducts its review and assessment on the licensees' applications before authorization. This legal framework is well developed with consideration of a graded approach [according to the risk associated with the facilities and activities](#). Therefore, it [identified](#) that the framework and measures for review and assessment are, in principle, in accordance with the relevant IAEA safety requirements, except in the following circumstance.

- The standard review plans [and guide](#) for authorization of nuclear power plants should be enhanced to address this challenge.

[To address this, in the initial mission, the NRA verified the compatibility of feedback process of operation experience, provided proposals related to the human factor, the organizational factor related to plant designing, and enhancement of systematic consideration for human error. Along with coping with each response after studying, the NRA will implement improvement measures, etc., based on the Action Plans as shown in Section 6.3.](#)

6.2 Generic issues

6.2.1 Management of review and assessment

The Reactor Regulation Act and [the RI Act](#), with their subordinate ordinances, require the submission of applications and necessary appendices that explain the safety and other measures for all facilities and activities governed by these acts. The items included in these documents differ, depending on the types of facilities and activities, based on a graded approach.

The NRA develops and publishes its ordinances, standard review plan, and other guides. These define the items to be reviewed to verify application compliance to the relevant requirements, so that applicants understand the required application information in advance. In conducting a review, if the NRA identifies unclear explanations in any submitted documents, it requires applicants to provide supplementary information to ensure the accuracy and sufficiency of the information for review and assessment.

6.2.2 Organization and technical resources and bases for review and assessment

The NRA may change its resource allocations and organizational structure according to the needs and importance of the tasks and may formulate other suitable organizations to fulfill its review and assessment responsibilities effectively in a manner commensurate with the level of radiation risk associated with regulated facilities and activities. At present, the NRA has a shortage of staff to implement review and assessments.

[To address this challenge, the NRA implemented the improvement measures, etc., based on the Action Plan \(A2\) as shown in Section 3.10.](#)

The NRA supervises the groups within JAEA which support NRA activities. These include conducting safety research and providing technical support to evaluate the effectiveness of safety measures in the licensees' applications. [In the initial mission, the IRRS team observed that 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. The NRA responded to the suggestion introduced based on the indication as follows.](#)

Suggestion 8	Contents of Proposal
	<p>The NRA should consider reviewing its current operating experience feedback process to to: ① determine whether its criteria allow the reporting of enough safety significant events; ②ensure lessons learned from these events, including return to service from extended shutdowns, are taken into account by the licensees and ③actually result in appropriate and timely measures at the facilities.</p>
	Basis
	<p>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 other 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.”</p>
	<p>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.”</p>
	<p>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. ...”</p>
Response Status	
<p>(Response to ①)</p> <p>The NRA conducted a survey on criteria of legal reporting events of each country and examined the response at the Technical Information Committee established in Nuclear Regulatory Agency. As a result of the survey, it was confirmed that, in other countries, the events that are subject to the legal reporting such as reactor trip occurred more compared to the case of Japan, in addition, the events such as “minor LCO deviation events” and “malfunctions of engineering safety facilities (unintended actions)” that are not subject to legal reporting in Japan are treated as events subject to the legal reporting in other countries, thus there were differences in the number of legal reporting events. On the other hand, in Japan, the licensees have voluntarily registered events not subject to the legal reporting on the nuclear facility information disclosure library site²¹ and have continued to make efforts to reflect operational experience in information to be shared bringing transparency of the information. Taking such status into consideration, in October 2017, the NRA clarified the criteria and rules for collecting information on the operational experience feedback process. Specifically, the scope of the information collection by the NRA has been expanded. For example, for information on nuclear power plant and fuel cycle facilities of Japan Nuclear Fuel</p>	

²¹ Library site for nuclear facility information (NUCIA information): “NUCIA, Nuclear Information Archives” is the library site for nuclear facility information to widely share the information related to operation of domestic nuclear power plants and nuclear fuel cycle facilities managed by Japan Nuclear Safety Institute (JANSI). (NUCIA, Nuclear Information Archives) The information managed by the site are divided into 3 sections as follows: 1) Trouble information: to be reported to the Government pursuant to law. 2) the information not to be reported but the information related to safety (in the case of damage or its sign in the important devices for safety and in the permanent facilities to cope with severe accidents etc., in the case of violence in safety regulation programs, in the case of deviation from operational limits, in the case of nuclear reactor shutdown due to malfunction, in the case of power change of the nuclear reactor over 5 %, in the case of occurrence of fire, in the case of occurrence of flooding within nuclear facilities, and in the case of possibilities of occurrence of serious effects that cannot be considered in designing/operation by work/operation) the one that need to take the measure to prevent reoccurrence from the viewpoint of prevention prior to occurrence of troubles, and 3) other information: various kinds of information released on the websites by the licensees from the viewpoint of improvement of transparency, although it is not required to share such information between the nuclear operators etc. such as incipient fire, malfunction of fire alarm, entry of fire engines, ambulances due to occurrence of injured persons not attributable to nuclear facilities.

IRRS Follow-up Mission to JAPAN 2020

Suggestion 8	<p>Ltd., in addition to the conventional legal reporting events, “maintenance quality information” shared in the nuclear facility information disclosure library site is newly subject to the screening, and the Fuel Incident Notification and Analysis System (FINAS) and the Incident Reporting System for Research Reactors (IRSRR) are also added in the scope of the information collection. Additionally, from FY2017, in order to further improve the completeness of the information collection, the NRA also made the events of violation of the Operational Safety Program (including observation) and the ones of the deviation from operational limits that are described in the safety inspection report of Nuclear Regulatory Agency for all the licensees of nuclear facilities in Japan subject to the screening.</p> <p>(Response to ②)</p> <p>In the operational experience feedback process of Nuclear Regulatory Agency, the collected domestic and overseas operational experience information is analyzed and screened several times and the screening 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. Also, the information on overseas regulatory trends collected by the NRA and knowledge gained from regulatory experience, safety research, and academic investigations and research are also presented to these review committees. For the matters that need regulatory response including lessons learned from the experience of restart of the facilities from shutdown condition, the corresponding countermeasures are deliberated in the NRA committee and become regulatory requirements as needed. The NRA shall require all the licensees, including the ones that restart operation of nuclear facilities after a long-term shutdown, to respond to the events that require regulation response in this way. The countermeasures are considered on the basis of the survey of the licensees and vary depending on the significance, urgency, etc., of the event, and cover a broad range of measures such as addition/changes of regulations, confirmation of the status by subsequent safety inspections, etc. The recent cases are as follows: addition of regulatory requirements related to High Energy Arcing Fault (HEAF) derived from domestic events (August 2017), addition of regulatory requirements, etc., related to open phase condition (OPC) based on the events in US (July 2014 and June 2019), confirmation of the operator’s countermeasures by inspection concerning steam void problem of residual heat removal system (RHR) based on the events in US (July 2018), and directions for reconfirmation of manufacturing records of pressure vessels to all the commercial nuclear reactor operators derived from carbon segregation problems in pressure vessels in France (August 2016). Additionally, even the information screened out is disclosed on the website of the NRA, and the information is exchanged with licensees through regular information exchange between the NRA and JANSI. Since FY2018, the NRA also started the studies regarding the method for information exchange with fuel cycle operators and research and test reactor operators.</p> <p>(Response to ③)</p> <p>The NRA shall confirm the response status in the nuclear facilities in the nuclear regulatory inspections.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> • The Latest Findings Reflection Process • The Technical Information Committee
	Results of Self-Assessment
	Closed

In the initial mission, the IRRS team identified that the 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. The NRA responded to the suggestion introduced based on the indication as follows.

Suggestion 9	Contents of Proposal
	The NRA should consider reviewing the regulatory requirements for all nuclear facilities to ensure that ①submissions by licensees give full systematic consideration to human and organizational

<p>Suggestion 9</p>	<p>factors and human errors in the design of the plant, and ②the sufficiency of qualified and experienced NRA resource to assess this.</p>
	<p>Basis</p> <p>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>
	<p>GSR Part 4 Requirement 11, states that “The Human interactions with the facility or activity shall be addressed in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required in response to anticipated operational occurrences and accidents, ensure an adequate level of safety.”</p>
	<p>Response Status</p> <p>(Response to ①)</p> <p>The NRA established “Study Team on Consideration of Human and Organizational Factors for the Regulations” consisting of the members of the NRA commissioner, the officials of the Nuclear Regulatory Agency, and external experts. In the study team, the NRA decided to formulate 2 types of guides (a guide related to safety culture and one related to cause analysis) to be used in safety reviews and inspections related to the licensee’s efforts for safety culture and cause analysis of incompliance events, and incorporate the outcome into the regulatory requirement. In developing both guides, the contents of GSR Part2 that is safety requirement regarding leadership and management for safety established by the IAEA in February 2016 will be reflected in the guides</p> <p>In the guide on safety culture, the items related to the demonstration of leadership on fostering and maintaining sound safety culture, efforts on fostering and maintaining of sound safety culture, evaluation and improvement of the state related to safety culture, and the abilities to be held within the organization related to safety culture will be incorporated for the purpose of setting sound safety culture in place as an organizational culture by fostering and maintaining the safety culture. In the guide on cause analysis, the items related to the implementation system of cause analysis and the implementation contents of cause analysis will be incorporated for the purpose of ensuring that the analysis is properly performed and the knowledge obtained is accurately reflected in the organization. As for design and operation of nuclear reactor control room, etc., based on the consideration of ergonomic factors, the NRA considers to formulate the guide to be used to confirm its appropriateness in safety review for installment license, etc.</p> <p>The NRA is going to ensure, by establishing and amending relevant ordinances, that the considerations of human and organizational factors in plant design are included in the documents to be submitted by the licensees by the starting of the new inspection system in FY2020. It is planned that the guides on safety culture and cause analysis will be formulated by November 2019, while ensuring the consistency with contents of ordinances, etc., to be established or amended, as a review/inspection guide in application of the ordinance on the development of the system required for quality management related to safety activities in nuclear facilities considering the results of trial operation of the new inspection system. A trial version of these guides was prepared and released in 2018. In addition to the above, regarding the evaluation of appropriateness of the measures taken by the operators to prevent incorrect operation, the NRA intends to compile the draft of a guide (the evaluation guide on reactor control room, etc., based on the consideration of human and organizational factors), within 2020, that is to be used for the safety reviews by the NRA. In developing the guide, the requirements for the consideration of human and organizational factors for the reactor control rooms, etc., are organized, and the DS492 that is the safety guide on the considerations of ergonomic factors related to nuclear power plants being considered by IAEA will be consulted.</p>

Suggestion 9	(Response to ②) In the recruitment guidance for experienced employees, specific research outlines of the subjects of the research related to human factors that the applicants will be in charge of after adoption are listed, and the recruitment activities are carried out by making it easier for applicants to imagine the duties.
	Documentary Evidence
	Results of Self-Assessment
	Closed on the basis of progress made and confidence in effective completion in due time

6.3 Action Plan

Basis	(B10) The IAEA Safety Standard states that “The regulatory body shall inform applicants of the objectives, principles, and associated criteria for safety on which its requirements, judgments and decisions are based” [GSR Part 1 paragraph 4.26] and that “The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization” [GSR Part 1 paragraph 4.34]. Though the standard review plan and guides for the review of application for authorization of nuclear power plants are published, they should be further enhanced.
Recommendation	(R9) The standard review plan and guides for the authorization for commercial nuclear power plants should be enhanced.
Action Plan	(A9) Considering the progress of on-going compliance reviews and the priority in expected applications, the NRA will enhance standard review plans for nuclear power plants.
Response Status (A9)	This Action Plan is implemented as a part of response to Recommendation 11.
Documentary Evidence	
Results of Self-Assessment	Closed

7 Inspection

7.1 Conclusions

Based on the self-assessment (SARIS) for regulatory inspections, it founds that, as shown in [Section 7.2](#), the Reactor Regulation Act provides the legal framework for various types of regulatory inspections, (e.g. preservice, welding, fuel assembly, periodic facility, operational safety, and on-site inspections for nuclear facilities), and under which these inspections are structured to confirm the compliance of facilities and activities to the relevant requirements, based on a graded approach. Therefore, it [identified](#) that the framework and measures for regulatory inspections [that](#) are, in principle, in accordance with relevant IAEA safety requirements, except in the following circumstances under the Reactor Regulation Act.

- Regulatory inspections should be improved so that they do not substitute for the control, supervision, and verification activities conducted by the authorized party itself. For confirmation of waste disposal facilities and waste packages, it should be improved in order not to merely act as a substitute for licensees' own confirmation.
- The scope of regulatory inspections should cover all safety activities of licensees.
- The inspection approach should be more effective by applying risk-informed²² and performance based²³ inspections.
- The inspection framework should be simplified, flexible, and effective by streamlining the scope of various regulatory inspections [and monitoring](#).
- Competency of inspectors should be further enhanced in accordance with the improvement of the framework.

[Additionally, in the Initial Mission, the IRRS team provided the recommendations/suggestions related to improvement/simplification of the inspection system and improvement of training/retraining of the inspectors. Along with handling each issue after considering responses to them, the NRA will implement improvement measures for improvement, etc., based on the Action Plans as shown in \[Section 7.3\]\(#\).](#)

7.2 Generic issues

7.2.1 Inspection approaches, methods and plans

The Reactor Regulation Act defines the regulatory inspections of nuclear power plants at various stages: namely construction, operation, and decommissioning stages

At the construction stage, the act stipulates preservice inspections, fuel assembly inspections, and welding safety management reviews. In conducting the preservice inspections, the NRA verifies the compliance of the facility with the approved construction plan and relevant technical standards in each step of construction. In conducting the fuel assembly inspections for domestic fabricating parties, the NRA verifies the compliance of the fuel assembly with the approved design and the relevant technical standards at each step of fabrication; and for imported assemblies, their compliance with the relevant technical standards. In conducting the welding safety management review, that act requires licensees to implement their own inspection on welding, and the NRA then verifies the implementation system of the licensees' inspection.

At the operation stage, the act stipulates periodic facility inspections, operational safety inspections, and periodic safety management reviews. In conducting the periodic facility inspections, the NRA inspects the items specified by the Commercial Reactors Ordinance during the period of planned shutdown for periodic maintenance. In conducting the periodic safety management reviews, the act requires licensees to implement their own inspections in the maintenance cycle period (covering the periods of both operation and planned shutdown). The NRA verifies the implementation system of the licensees' inspection. In conducting operational safety inspection, the NRA reviews the compliance of licensees' operational activities with the approved operational safety programs. The NRA conducts operational safety inspections quarterly and additional ones as required by the Commercial Reactors Ordinance (e.g. implementing an inspection at the timing of emergency drill or others) ([Commercial Reactors Ordinance](#)

²² risk informed : including risk inform (implementation method of inspection)

²³ performance base : based on operation performance (implementation method of inspection)

Article 93-2-2).

At the decommissioning stage, the act stipulates periodic facility inspections and operational safety inspections. At the completion of decommissioning, the NRA is required to confirm such completion. The NRA conducts periodic facility inspections for the items specified by the Commercial Reactors Ordinance not later than 9 months from the completion date of the previous periodic facility inspection. The NRA conducts operational safety inspections similar to that in the operational stage, but the frequency may be set to quarterly or less frequently depending on the progress of decommissioning work and other conditions. In confirming the completion of the decommissioning, the NRA verifies the compliance of the final conditions with the defined criteria.

As described above, the NRA inspects facilities and activities through programmed inspections, where the items and the timing for inspections are legally defined. During programmed inspections, the NRA may have free access to the site and may conduct inspections on specific items without prior notification.

In addition, the Reactor Regulation Act allows the NRA to conduct on-site inspections of licensees, suppliers for SSCs, and other related parties, at the detailed design, construction, operation, and decommissioning stages as necessary for the enforcement of law (Article 68). On-site inspections are regarded as reactive inspections, and the NRA may undertake such inspections at short notice, denying licensees the chance to prepare for the inspections. It may have the same effects as an unannounced inspection.

Inspections of facilities and activities other than nuclear power plants are basically the same as those for nuclear power plants, but the scope and methods of inspection differ according to the risk associated with the facilities and activities, based on a graded approach. For welding inspections of nuclear fuel cycle facilities, the NRA inspects welding parties, not licensees. This differs from inspections of nuclear power plants.

In the self-assessment, the NRA identified the challenges (see Section 7.1) of the above-mentioned framework/plan of the inspections for the nuclear facilities. To address these challenges, the NRA implemented the measures for improvement based on the Action Plan (A10) as shown in Section 7.3.

The RI Act requires designated applicants for specified use and waste management of radioisotopes to undergo facility inspections during the construction stage, and subsequent periodic inspections and periodic confirmations during the operational stage. In addition, the NRA may conduct on-site inspection at any authorized operator's subject.

7.2.2 Inspection processes and practices

NRA inspectors develop the inspection records and reports based on these results and report them to the responsible NRA directors in accordance with the organization's directive.

When the inspectors identify nonconformance situations during a facility inspection, they shall record the facts, explain the situation to licensees, and ask them to initial the report. If noncompliance is found during an inspection where the NRA makes a pass/fail judgment, the inspection is suspended. The licensee is asked to make a report on the corrective action of the noncompliance, and the inspection may be resumed only after that report is confirmed as appropriate.

The results of operational safety inspections are reviewed and shared within the NRA, sent to the licensees and made available to the public. When inspectors find activities not in compliance with approved operational safety programs, they will inspect these items at the next inspection to **monitor and** confirm that corrective actions have been taken to prevent recurrences.

The regulatory framework provides a step-by-step approach at each stage, confirming compliance with the authorization at the previous stage. Specifically, at the establishment stage, the compliance of basic designs and siting conditions with the relevant requirements is confirmed. Subsequently at the stage of construction, the compliance of such plans with the approved establishment permit is confirmed and then the compliance of the SSCs with the approved construction plans is confirmed in preservice

inspections.

In the self-assessment, the NRA identified the above-mentioned challenges (see Section 7.1). To address these challenges, the NRA implemented the measures for improvement based on the Action Plan (A10) as shown in Section 7.3.

7.2.3 Inspectors

The Reactor Regulation Act and the RI Act requires licensees to undergo regulatory inspections with legally designated scope for all inspections, and grants authority to certified NRA inspectors (Article 67-2 and Article 43, respectively). For regulatory inspections under the Radiation Hazards Prevention Act, Registered Inspection Bodies may conduct facility inspections before use, and periodic inspections/confirmations during use (Articles 41-15 to 41-18)

The nuclear operational safety inspectors, nuclear facility inspectors and radiation inspectors are appointed from those who have a minimum number of years of practical experience, have completed an NRA approved training course, and are equipped with the expertise necessary for such tasks.

In the self-assessment, the NRA identified the above-mentioned challenges (see Section 7.1). To address these challenges, the NRA implemented the measures for improvement etc., based on the Action Plan (A10) as shown in Section 7.3.

In the initial mission, the IRRS team observed that:

- 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 the NRA and Licensee. The NRA, for example of fuel cycle facilities, currently undertakes inspection of all primary welding of nuclear facilities, while also confirming the qualification of welders undertaking the welding. This situation might jeopardize 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.

The NRA responded to the recommendation introduced based on the indication as follows.

Recommendation 9	Contents of Recommendation
	<p>The government should improve and simplify the inspection framework to: ① Increase NRA flexibility to provide for efficient, performance-based, less prescriptive, and risk-informed regulation of nuclear and radiation safety; ② Ensure NRA inspectors have formal rights for free access to all facilities and activities at any time; ③ Allow NRA decisions about reactive inspections to be made at the lowest possible level. ④ 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>
	Basis
	<p>GSR Part 1 Requirement 2 paragraph 2.5 states “the government shall promulgate laws and statutes to make provision for an effective governmental, legal, and regulatory framework for safety. This framework for safety shall set out the following: ... (10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded</p>

IRRS Follow-up Mission to JAPAN 2020

<p>Recommendation 9</p>	<p>approach; ...”</p>
	<p>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>
	<p>GSR Part 1 Requirement 28 states that “Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.</p>
	<p>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>
	<p>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>
	<p>GSR Part 1 Requirement 29 Paragraph 4.53 States “In conducting inspections, the regulatory body shall consider a number of aspects, including: - Structures, systems, components, and materials important to safety; - Management systems; - Operational activities and procedures; - Records of operational activities and results of monitoring; - Liaison with contractors and other service providers; - Competence of staff; - Safety culture; - Liaison with the relevant organization for joint inspections, where necessary.”</p>
	<p>GSR Part 3 Requirement 2 paragraph 2.14 states “The government shall ensure that adequate arrangements are in place for the protection of people and the environment, both now and in the future, against harmful effects of ionizing radiation, without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks. This shall include arrangements for the protection of people of present and future generations and populations remote from present facilities and activities.”</p>
<p>Response Status</p>	
<p>(Response to ①②) The NRA established “Study Team on Inspection Reform” consisting of the members of the NRA commissioner, the officials of Nuclear Regulatory Agency and the external experts. In the study team, the NRA studied the direction and the contents of the reform to make the inspection system more effective by strengthening the oversight and evaluation system for the efforts to secure safety by the licensees. In the study, the system design proposal was compiled by incorporating reactor oversight programs being operated in the United States as much as possible while considering the IAEA safety standards, the cases in overseas regulatory organizations, and current situation of safety activities by the licensees. The NRA considered revisions of the Reactor Regulation Act on the basis of compiled system design proposal. As for the conformity of nuclear facilities to safety standards, the NRA obliged the licensees to voluntarily perform inspections and clarified that the licensees have primary responsibility for securing safety. It was decided that the subdivided inspections related to nuclear facilities and safety activities that have been conducted by the NRA will be integrated into the nuclear regulatory inspection and establish a system so that the NRA</p>	

Recommendation
9

oversees and evaluates the implementation status of the measures to be taken by the licensees pursuant to law, by setting the inspection samples depending on the risks without any restrictions on timing and target. In this process, legal authority of free access has been given to the NRA inspectors. Specifically, preservice inspections, fuel assembly inspections, and welding safety management reviews being conducted at the construction stage will be abolished, and the operator's preservice inspection will be in service. The licensees will be obliged to verify the conformity to the safety standards by themselves including the inspections on welding parts and fuel assembly. The NRA also stipulates that nuclear power plant should only be used after the licensees of reactor operation conducted the operator's preservice inspection and has received confirmation from the NRA saying that the nuclear power plant meets the acceptance criteria. In addition, periodic facility inspections, periodic safety management review, operational safety inspections, and physical protection inspections at the operating stage will be abolished, and it was decided that by integrating inspections into the other inspection items, the NRA will seamlessly monitor and oversee the activities of the licensees after design approval until the completion of decommissioning.

The NRA has newly established a process to conduct comprehensive evaluation after evaluating significance of individual matters based on the results of nuclear regulatory inspections as shown in Figure 1. The NRA is going to take appropriate measures when the comprehensive evaluation shows that such measures are necessary, and conduct efficient and performance-based regulations that reflect the results of the evaluation to the subsequent nuclear regulatory inspections. In addition, in response to the revision of the law, along with progressing studies to establish and amend the relevant rules, in order to secure transparency and predictability of system operation, the NRA continues the studies to formulate operational guides, etc., that clarify the process and standards, and recording methods of the result of oversight/evaluation and its basis etc. Along with the incorporation of reactor oversight process, the NRA set out to formulate inspection guides required for operating the process safety performance indicators, evaluation guide related to evaluation/operation, etc., of significance on the matters pointed out in inspections and establish a system to perform comprehensive evaluation of licensees. The basic concept for using risk information and reflecting the experience of securing safety as well as the scope and extent to apply it will be documented as an administrative policy of the NRA.

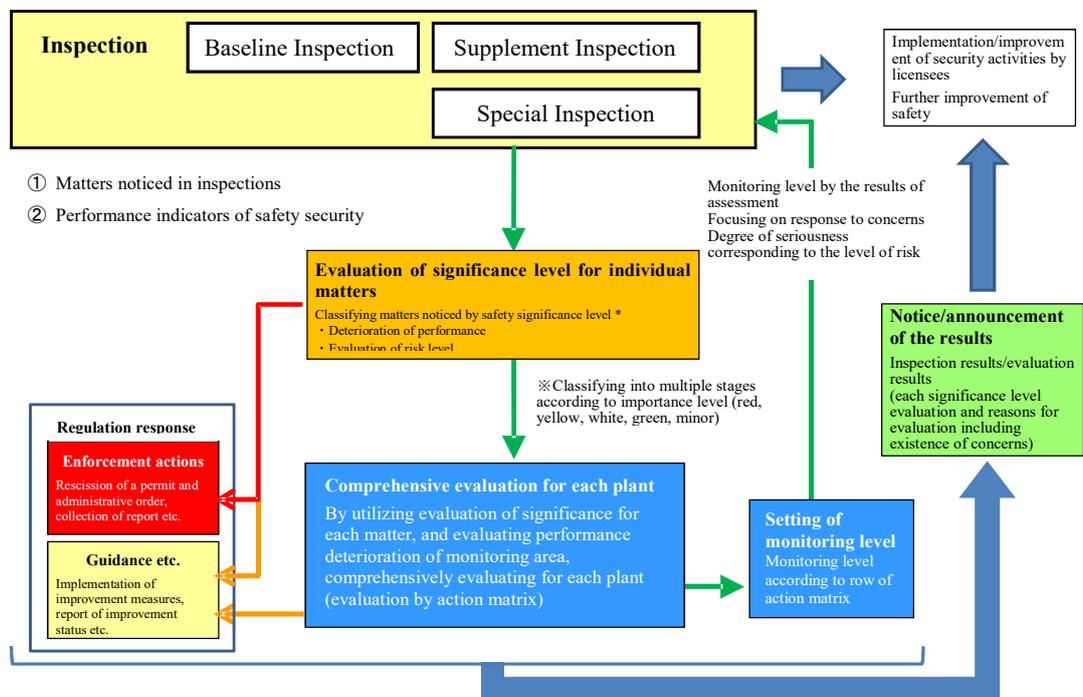


Figure 1. Process for comprehensive evaluation in new regulation system

Recommendation 9	<p>(Response to ③) Based on the above-mentioned efforts, the NRA is studying the evaluation method of significance of the matters pointed out in inspections, evaluation method of severity of legal violations, etc., determination method of the contents of countermeasures, determination method of the extent of accident and trouble events, and decision-making process of determination of countermeasures. Additionally, by using the guide for the initial response on occurrence of accidents and criteria for judging necessity of reactive inspection, the NRA will consider the process so that such decision is made at lower level.</p> <p>(Response ④) With regard to the new inspection system that integrates conventional subdivided inspections, the NRA will develop the new inspection system as a systemized inspection program after extracting issues through trial operation and fixing the extracted issues. In developing the inspection program, the NRA is going to apply a graded approach, to all facilities and activities, that varies inspection items to be conducted, the number of samples of basic inspections and amount of time for inspections according to the significance derived from the scale and the characteristics of the facility, condition of nuclear facilities such as commissioning phase, decommissioning phase, etc., as well as the type of facility operations, etc. The NRA will also prepare the inspection items in advance for the operator that performed initial response to the accident, develop a system that enables the inspectors to immediately start responding to the inspection, and will formulate the procedures for transition to special inspection to verify subsequent response by the operator. The trial operation of the new inspection system started in October 2018, and the NRA is aiming to start the practical operation in FY2020 after extracting the problems and fixing the extracted problems through the trial operation. At the same time, in consideration of the increase in workload in the future, the NRA enhanced the organizational structure of the departments in charge of nuclear facility inspection and development of inspectors.</p> <p>To promote the study and the preparation of new inspection system, the NRA dispatched a total of 11 staff members to US NRC over a period of about 2 years, in a phased manner, for the purpose of enhancing effectiveness of the activities. Along with improving the understanding of the inspection system of US in this way, the NRA is also addressing making the study effective and efficient by inviting the experienced experts in the area of inspection from US NRC to receive advice on the challenges taking the status of study for inspection system reform, status of on-site inspection, etc., into consideration.</p>
	<p>Documentary Evidence</p> <ul style="list-style-type: none"> • List of relevant regulations/guides etc. • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors Article 61-2-2) • Enforcement Guide (for trial operation)
	<p>Results of Self-Assessment</p> <p>Closed on the basis of progress made and confidence in effective completion in due time</p>

In the initial mission, the IRRS team observed that: the initial training provided to NRA inspectors is very limited in time. There is no retraining programme in place. The NRA responded to the suggestion introduced based on the indication as follows.

Suggestion 10	<p>Contents of Proposal</p> <p>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>
	<p>Basis</p> <p>GSR Part 1 Requirement 18 Paragraph 4.13 states 4.13. “A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training program on the basis of an analysis of the necessary competence and skills. The training program</p>

IRRS Follow-up Mission to JAPAN 2020

Suggestion 10	shall cover principles, approach, 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.”
	Response Status
	In addition to the conventional training, etc., based on the Basic Policy for Human Resource Development for NRA Officials, the NRA started practical training in May 2016 that the inspectors and the accident responders can learn the confirmation of reactor start-up and shutdown operations and the right ways to respond to serious accidents, etc., by using the plant simulator. Along with the study to establish a new inspection system, the NRA established a new mechanism in July 2017 for new inspector development by referencing the inspector development system of US NRC, and started new education/training curriculum in April 2018. The curriculum will be conducted on a two-year basis with a wide range of content such as technical knowledge of nuclear facilities, inspection method, safety assessment, comprehensive evaluation, etc. The NRA also decided to introduce a training system for updating nuclear inspection qualification and be in the process of study to initiate it in FY2020. In addition, for the staff who have already been engaged in duties as inspector, the NRA will assign qualifications by conducting oral examination etc. after providing training to acquire new inspection method by the end of 2019.
	Documentary Evidence
	• Basic Policy for Human Resource Development for NRA Officials (NRA, June 25 2014)
	Results of Self-Assessment
Closed on the basis of progress made and confidence in effective completion in due time	

7.3 Action Plan

Basis	<p>(B11)The IAEA Safety Standard states that “Regulatory inspection cannot diminish the prime responsibility for safety of the authorized party, and cannot substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party.” [GSR Part 1 paragraph 4.49] Concerning preservice inspections, fuel assembly inspections, and welding inspections, the Reactor Regulation Act requires only NRA regulatory inspections, and does not stipulate the licensees’ responsibilities for conducting their own inspections to verify compliance with regulatory requirements.</p> <p>(B12)The IAEA Safety Standard states that “Regulatory inspections shall cover all areas of responsibility of the regulatory body.” [GSR Part 1 paragraph 4.52.] Currently, however, part of the licensees’ safety activities (e.g. Compliance of welding standards [except for nuclear power plants] and of fuel assemblies with the relevant requirements) are not within the scope of regulatory inspections.</p> <p>(B13) The IAEA Safety Standard states that “The manner, extent, and frequency of inspections shall be in accordance with a graded approach.” [GSR Part 1 paragraph 4.52.] The current inspection method should be more efficient and effective in accordance with a graded approach.</p> <p>(B14) The IAEA Safety Standard states that “Regulatory inspection cannot diminish the prime responsibility for safety of the authorized party, and cannot substitute for the control, supervision, and verification activities conducted under the responsibility of the authorized party.” [GSR Part 1 paragraph 4.49] For confirmation of waste disposal facilities and waste packages, the Reactor Regulation Act requires only NRA regulatory inspections, and does not stipulate the licensees’ responsibilities for conducting their own inspections to verify the compliance with regulatory requirements.</p>
Recommendation	(R10) The framework for regulatory inspections should be improved so that they do not substitute for the control, supervision, and verification activities conducted under the responsibility of the authorized party.

IRRS Follow-up Mission to JAPAN 2020

	<p>(R11) The scope of regulatory inspections should cover all the licensees' safety activities</p> <p>(R12) Regulatory inspections should be more risk-informed and more performance-based</p> <p>(R13) The inspection framework should be simplified, flexible, and effective by streamlining the scope of various regulatory inspections.</p> <p>(R14) For confirmation of waste disposal facilities and waste packages, the NRA should consider improvements in order not to substitute the licensees' own confirmation</p>
<p>Action Plan</p>	<p>(A10)The NRA will take measures to improve the framework for regulatory inspections, with reference to overseas frameworks</p> <ol style="list-style-type: none"> ① Not to substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party ② To formulate a more flexible framework by integrating the existing regulatory inspections ③ To ensure effectiveness and efficiency ④ To enhance inspectors' competency in accordance with an improved framework ⑤ For confirmation of waste disposal facilities and waste packages, the NRA considers improving the regulatory frame work in order not to substitute the licensees' own confirmation
<p>Response Status (A10)</p>	<p>(Response to ①②③) In this Action Plan, the NRA implements enhancement of responsibilities of the licensees, improvement of flexibility of inspection/monitoring by integration of inspections and securing of effectiveness and efficiency as a part of response to Recommendation 9.</p> <p>(Response ④) The NRA implemented the competence improvement of inspections as a response to Recommendation 5 and Suggestion 10.</p> <p>(Response to ⑤) Regarding the review of inspection/monitoring system related to verification of facilities for waste disposal facilities and verification of waste packages, the NRA requires licensees to verify compliance with standards in the relevant regulations, monitors the activities of the nuclear operators by nuclear regulatory inspection, and, based on the results of them, considers the inspection guides and the guide for verification procedures in order to develop the system that allows each process of waste disposal to proceed. In October 2018, the NRA started the new inspection system for trial operation and aims at working on the inspection process; starting practical use in FY2020 through identifying and arranging the issues, etc.</p>
<p>Documentary Evidence</p>	
<p>Results of Self-Assessment</p>	<p>Closed on the basis of progress made and confidence in effective completion in due time</p>

8 Enforcement

8.1 Conclusions

Based on the self-assessment (SARIS) for enforcement, it finds that, as shown in [Section 8.2](#), the Reactor Regulation Act and the [RI Act](#) clearly provide for the use of enforcement actions, the conditions for such enforcement actions, and allow the NRA to decide on these enforcement actions. Therefore, it concluded that the framework and measures for enforcement are, in principle, in accordance with relevant IAEA safety requirements.

However, in the initial mission, the recommendation related to establishment of regulations to cope with the standard of enforcement policy, process, and corrective actions was provided. The NRA addressed these issues after considering their responses.

8.2 Generic issues

The Reactor Regulation Act and the [RI Act](#) stipulate requirements for enforcement, and the NRA decides on the necessity of enforcement actions, according to the level of any violation or noncompliance to legal requirements.

For example, if the NRA finds a violation against the operational safety programs in nuclear power plants, the NRA may decide on a disposition ranging from administrative guidance, an order to modify operational safety programs under that act ([Article 43-3-24](#), paragraph 3), rescission of an establishment permit, or order to stop operations under the act ([Article 43-3-20](#), paragraph 2).

For a power-generating nuclear reactor facility, the Reactor Regulation Act stipulates the following enforcement actions. For other nuclear facilities, that act stipulates basically the same provisions.

- [Reactor Regulation Act](#)
 - Order to return the certificate for chief engineer of reactors ([Article 41](#))
 - Order to change the notification on an establishment permit *etc.* ([Article 43-3-8](#))
 - Order to change the notification on a construction plan *etc.* ([Article 43-3-10](#))
 - Rescissions of an establishment permit *or suspension of operation* ([Article 43-3-20](#))
 - Order of halt the use of facility ([Article 43-3-23-1](#))
 - [Order for corrective measures for protective measures](#) ([Article 43-3-23](#))
 - Order to change the operational safety program ([Article 43-3-24](#))
 - Order to dismiss the chief engineer of reactors ([Article 43-3-26](#))
 - Order to change the physical protection program ([Article 43-3-27](#))
 - Order to dismiss the physical protection manager ([Article 43-3-28](#))
 - Order to change the periodic safety assessment of continuous improvement ([Article 43-3-29](#))
 - Rescission of the design certificate ([Article 43-3-30](#))
 - Rescission of the designation of design certificates for specific SSCs ([Article 43-3-31](#))
 - Order to take measures for decommissioning ([Article 43-3-34](#))
 - Order to take necessary measures for previous licensees ([Article 43-3-35](#))
 - Order for suspension *etc.* of disposal ([Article 58](#))
 - Order for suspension *etc.* of transport ([Article 59](#))
 - Order to take emergency measures ([Article 64](#))
 - Request for report ([Article 67](#))
 - On-site inspection ([Article 68](#))

For facilities that use radioisotopes *etc.*, the Radiation Hazards Prevention Act stipulates the following enforcement actions.

- [RI Act](#)
 - Rescission of certificates ([Article 12-7](#))
 - Order to compel facilities to follow required standards ([Article 14](#))
 - Order to take measures necessary for preventing radiation hazards in case of noncompliance with technical standard for use ([Article 15](#) paragraph 2)
 - Order to take measures necessary for preventing radiation hazards in case of noncompliance with technical standard for storage ([Article 16](#) paragraph 2)

- Order to take measures necessary for preventing radiation hazards in case of noncompliance with technical standard concerning transport inside the site (Article 17 paragraph 2)
- Order to take measures necessary for preventing radiation hazards in case of noncompliance with technical standard concerning transport outside the site (Article 18 paragraph 4)
- Order to take measures necessary for preventing radiation hazards in case of noncompliance with technical standard concerning waste management (Article 19 paragraph 3)
- Order to change the Radiation Hazards Prevention Program (Article 21 paragraph 2) Rescission of permission (Article 26)
- Order to take measures necessary for preventing radiation hazards in cases where inappropriate decommissioning measures were taken (Article 28 paragraph 6)
- Order to take measures in an emergency (Article 33 paragraph 3)
- Order to return the certificates of the Radiation Protection Supervisor (Article 35 paragraph 6)
- Order to dismiss the Radiation Protection Supervisor (Article 38)

The Reactor Regulation Act and the RI Act stipulate that the commission of the NRA implements enforcement, and does not specifically allow inspectors to execute these enforcement actions.

The Reactor Regulation Act stipulates conditions for suspension of activities and operation of nuclear facilities. In the case of nuclear power plants, for example, the act stipulates the following in order to take enforcement actions such as halt, modify, or transfer; designate the operational conditions; or other measures necessary for safety (Article 43-3-23).

- When the NRA confirms noncompliance with establishment permit standards as required in the NRA ordinance;
- When the NRA confirms the noncompliance with the technical standards of commercial nuclear reactors as required in the NRA ordinance
- When the NRA finds that the situation violates required measures for safety specified in the [Commercial Reactors Ordinance](#), in activities related to maintenance of [power reactor](#) facilities, operation of [power reactor](#) facilities, or transport, storage of nuclear fuel material, or materials contaminated by nuclear fuel material.

The NRA may amend the regulatory requirements, considering the risk and urgency of the findings, when it identifies a new risk which had not been foreseen in the previous authorization process. With the modified requirements, etc., the NRA may order the suspension of [use of the facilities](#) or other activities [for facilities that are not certified](#) to be in compliance with these modified requirements (application of back fitting).

In the initial mission, the IRRS team observed that: 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. NRA inspectors have no power to enforce corrective actions if there is an imminent likelihood of safety significant event. They are required to defer to NRA headquarters. This situation probably endures for inspectors at all licensed facilities in Japan. The NRA responded to the recommendation introduced based on the indication as follows.

Recommendation 10	Contents of Recommendation
	The NRA should establish ① a documented enforcement policy with criteria and processes for determining graded sanctions or penalties for noncompliance, and ② a provision for processing orders to minimize the decision time for corrective actions if there is imminent likelihood of safety significant event.
	Basis
	GSR Part 1 Requirement 30 states that “The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to noncompliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.”
	GSR Part 1 Requirement 31 states that “In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.”

Recommendation 10	<p>GSR Part 1 Requirement 31, para. 4.58 states that “The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events.”</p>
	<p>Response Status</p> <p>(Response to ①) The NRA established “Study Team on Inspection Reform” consisting of members of the NRA commission, officials of Nuclear Regulatory Agency, and external experts. In this study team, the NRA started establishing “Enforcement Guide.” The guide line provides the basic concepts and processes in order for the NRA to evaluate severity level of the violation and determine necessary actions in cases of violation of the Reactor Regulation Act including intentional misconduct and events affecting the regulatory activities of the NRA. The countermeasure process consists of identification of violations, evaluation of violations, and actions for violations. For the violations identified through nuclear regulation inspections or allegations from the licensees, the severity level will be evaluated in accordance with the enforcement guide taking the following elements into consideration 1)whether the violations resulted in affecting actual safety, 2)whether the violations are likely to make an impact on actual safety, 3)whether the violations made impact on implementation of regulatory oversight functions of the NRA, 4)whether the violations are caused by intentional misconduct by the licensee. In addition, if the identified violation is accompanied by a performance defect of the licensee, the NRA evaluates “significance” in accordance with another guide formulated separately and determines “severity” by reference to the results of the evaluation. The identified violation will be identified as a measure such as implementation order or administrative direction based on the Reactor Regulation Act including rescission of permission and an order to suspend the operation depending on the severity level, and the measure will be enforced accordingly. The trial operation of new inspection system started in October 2018, and the NRA is aiming to incorporate the process into the inspection process after fixing problems extracted during the trial operation by the commencement of practical operation of new inspection system in FY2020.</p> <p>(Response to ②) The NRA formulated the Countermeasure Guideline for Nuclear Regulatory Inspections as a way to minimize the time to determine corrective actions.</p>
	<p>Documentary Evidence</p>
	<ul style="list-style-type: none"> • Enforcement Guide (for trial operation)
	<p>Results of Self-Assessment</p>
	<p>Closed on the basis of progress made and confidence in effective completion in due time</p>

9 Regulations and guides

9.1 Conclusions

Based on the self-assessment (SARIS) for regulations and guides, it finds that, as shown in [Sections 9.2 through 9.8](#), the NRA develops and publishes regulations and guides for various stages (e.g. design, construction, operation, decommissioning) for different types of facilities and activities in various NRA ordinances and directives. The NRA develops regulatory requirements (NRA ordinances) basically as performance-based and develops standard review plans and other supplementary guides. The NRA also establishes a system to utilize voluntary consensus standards, such as [Atomic Energy Society of Japan](#), the [Japan Society of Mechanical Engineers](#), and [Japan Electric Association](#), etc. These new regulatory requirements, which were introduced incorporating lessons learned from the Fukushima Dai-ichi accident and with reference to IAEA safety standards, are also applicable to existing nuclear facilities.

New regulatory requirements for nuclear power reactors significantly strengthened the requirements for natural hazards (e.g. earthquakes and tsunamis) and human induced events and introduced measures to tackle severe accidents (beyond design basis accidents). The measures for severe accidents include the prevention of core damage, prevention of containment function failure, and further mitigation measures even in the case of the release of radioactive materials outside the plant. These requirements are in accordance with SSR-2/1, except in the situation mentioned below.

Therefore, it [was identified](#) that the framework and measures for regulations and guides are, in principle, in accordance with the relevant IAEA safety requirements, excepting the followings.

- Site characteristics applied for the establishment permit or equivalent authorization should be reassessed during the lifetime of the nuclear installation. Currently, only seismic and tsunami hazards are reassessed in the guide for periodic safety assessment of continuous improvement.
- The potential risk of nuclear installation to the outside of its site should be assessed based on the investigations of the site characteristics covering sufficient areas outside the nuclear installations.
- The regulatory framework for decommissioning is, in principle, well developed. However, the specific criteria for confirming the completion of decommissioning (site release) of nuclear facilities and methods to confirm compliance with these criteria should be developed, including the cases when the remediation work is needed on the site.
- Measures to facilitate decommissioning and management of radioactive waste should be considered starting at the design phase.
- The regulatory standards for disposal facilities and waste packages should be amended so as to be performance-based requirements
- A standard review plan for operational safety programs should be clarified to cover the method of closing of waste disposal facilities (e.g. backfilling, sealing, and capping) as well as that of monitoring and surveillance after closure.
- The NRA should expedite its work to develop a regulatory standard for [intermediate depth](#) disposal facility. In addition, in response to the progress of the projects to install a disposal facility of radioactive waste originating from research institutes, etc., a regulatory standard for such facilities also should be developed.
- The NRA should consider establishing a mechanism to identify, collect, and evaluate new findings on radiation protection (e.g. the ICRP²⁴ recommendations in 2007) in order to reflect such findings in the regulatory activities adequately. The NRA also needs to consider the action to respond to new criteria for lens of eyes applicable to occupational exposure as introduced in the IAEA safety standard.

Additionally, in the initial mission, [the recommendation was provided for the improvement of the process to evaluate and review the regulations and guide](#). The NRA addressed this issue after considering responses to it and implemented the measures [for improvement based on](#) the Action Plans as shown in [Section 9.9](#).

9.2 Generic issues

The NRA ordinances and related directives for the Reactor Regulation Act and the RI Act. stipulate the regulatory criteria (e.g. technical standards) and procedures (e.g. format for applications). When developing

²⁴ICRP : International Commission on Radiological Protection

or amending NRA ordinances or associated directives, the NRA may establish a 'study team' of NRA and external experts to develop a draft of these requirements, solicit public comments, and decide on these documents. Additionally, regarding public comments, after providing approaches by the NRA for the comments received, the NRA reflects application of the comments when necessary. Furthermore, upon establishment of the new regulatory requirements in 2013, the NRA conducted a hearing of opinions from the licensees in public places several times.

These processes are broadcasted and the relevant materials and recorded videos, except for confidential matters, are opened. The basic approach and determination criteria as the basis of the regulations, etc., and information on the changes to the regulation framework, except for those on nuclear security and other confidential matters, are all opened. Thus, the NRA has made the regulations determined by the NRA available to the interested parties and the public.

In order to ensure consistency with international standards, the NRA participates in all the IAEA safety standards committees, and collects information and analyzes the differences in safety standards and the respective regulations and guides in preparing for these committee meetings. The NRA tries to reflect state-of-the-art knowledge in its regulations and guides, by having a single department within the NRA responsible both for safety research and the regulations/guides. This enables it to incorporate the latest research findings into the regulations/guides.

Additionally, the NRA collects/organizes and screens information related to the accidents/troubles to nuclear facilities overseas and in Japan, and information related to overseas regulation trend, and reflects the regulation of the matters required. Through screening and holding the Technical Information Committee where the necessity of regulatory response is discussed, receiving advice, etc., from Reactor Safety Examination Committee and the Nuclear Fuel Safety Examination Committee and examining in the NRA, the NRA establishes/enhances the system to analyze and specify the lessons obtained from operation experience and regulation experience.

Since mechanism to identify, collect, and evaluate new radiation protection findings (e.g. the ICRP recommendations in 2007) in order to reflect such findings in the regulatory activities adequately, was not sufficiently in place, in order to smoothly incorporate state-of-art knowledge to domestic laws and regulations, the NRA started enhancing functions of the radiation council established within the NRA. While the former radiation council had reported on consistency of the technical standards concerning prevention of radiation hazards based on consultation for radiation protection requested from the relevant administrative bodies; the "Act on Technical Standards for Prevention of Radiation Hazard" that specified the establishment of the council was partly amended so that the council shall conduct study and deliberation voluntarily and provide the functions to express its opinions to the heads of the relevant administrative bodies as necessary.

The NRA makes this information, such as the basic approach for safety and criteria in formulating regulations/ guide or important modifications of regulatory framework, available to the public and licensees via the NRA web site. Information from NRA commissioner meeting and study teams developing or modifying regulations and guides is broadcasted via the internet. All relevant documents and video recordings are also available on the NRA web site.

In the initial mission, the IRRS team observed that: 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. 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. The NRA responded to the recommendation introduced based on the indication as follows.

Recommendation 11	Contents of Recommendation
	<p>The NRA should: ①improve and document its process for regularly evaluating and reviewing regulations and guides and as the emerging need arises; ②supplement the regulations with guidance documents where necessary; and ③ improve its guidance on Periodic Safety Assessment of Continuous Improvement.</p>
	Basis
	<p>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, technical standards, and of relevant experience “</p>
	<p>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>
	<p>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>
	<p>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>
	<p>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 endorsed by the regulatory body or in the authorization.”</p>
	<p>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>
	<p>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>
	<p>SSG-25 para. 2.18 states that “The steps of the review should be carried out in 4 phases, which may overlap or be further subdivided as appropriate....”</p>
	Response Status
	<p>【Nuclear Safety】 (Response to ①) To evaluate and review the ordinances and guides on a regular basis or when a new need arises, the NRA will revise NRA Rules for an Integrated Management System, will stipulate the evaluation and review process as a common process across the organization, and put the specific procedure in writing in FY2020. On the occasion, the following efforts currently being enforced will be considered.</p> <p>In November 2016, the NRA developed the “Latest Findings Reflection Process” that clarifies the basic policy, screening methods, prioritization scheme, and systems for properly evaluating and</p>

Recommendation
11

reviewing standard ordinances, interpretation of regulations, guides, etc., and specified the policy to conduct review in order. Additionally, the guidelines and internal rules of the former organizations (former Nuclear and Industrial Safety Agency and Nuclear Safety Commission) will be subject to the review and the reflecting process of international knowledge, such as knowledge given by the IAEA and OECD/NEA, will also be included.

The process consists of 3 stages: collection/arrangement, screening, and reflection in regulations. In this process, the latest findings are basically reflected to the regulations on an as-needed basis but taking the importance of the latest findings related to safety and urgency derived from it into consideration, the NRA also determined to review the matters with less importance and emergency every 5 years, in principle. The scope of information collection shall include trouble information, regulation experience, trends in overseas regulation, safety researches, international standards, information on academic meetings, etc. After organizing this information, from the viewpoint of safety of nuclear facilities and potential to require regulatory response, the NRA performs multiple screenings and reflects extracted information from the screenings into the regulations. For reflection of regulatory standards to the regulation, the Technical Information Committee meeting which is the framework to study the necessity of regulatory response is held, and after receiving advice, etc., from Reactor Safety Examination Committee and the Nuclear Fuel Safety Examination Committee, the matter is deliberated in the NRA committee meeting and be reflected to the regulations as needed.

In addition to this, the NRA formulated the process to re-examine the regulatory standards as the “Flow of Re-examination of Regulatory Standards Based on the Safety Review Experience” considering the experience such as the awareness of staff members in charge of safety review that was gained through the safety reviews on conformity to the new regulatory requirements carried out so far. In accordance with this flow, the matters related to the regulatory standards to be reviewed were extracted and reported. Specifically, regarding the matter on the regulatory standard for fire protection from the matter extracted, the NRA decided to amend a part of regulatory standard for fire protection and put it in force.

In the amendments of these regulatory standards, transitional measures are basically applied to provide the licensees with time to be familiar with the amended regulatory standards. Currently, the applications to amend the installment license of the facility in order to conform to the amended regulatory standards have been submitted from licensees to the NRA; the NRA is conducting safety reviews in a strict and an appropriate manner.

Additionally, in relation to the safety review guide, in the safety reviews on conformity to the new regulatory requirements, the NRA had addressed the reviews by preparing individual operational documents regarding the review system and the specific procedure for the reviews so far. The NRA newly organized and systematized individual operational documents, reorganized the processes as a “Flow of Safety Review” for each facility, and reviews them every year. Regarding the inspections, relevant ordinances plan to be developed considering the results of the trial operation, and the improvement process to review and re-exam the ordinances will also be specified and be documented after commencement of practical operation.

(Response to ②)

As a periodic review of regulatory requirements and guides, the NRA carried out the revision of the ordinances, etc. (see Documentary Evidence).

(Response to ③)

As for improvement of guidance related to the periodic safety assessment of continuous improvement, it was decided to perform reassessment of all site characteristics that were the basis of the permission for the activity in the facilities where the implementation of the periodic safety assessment is being required (nuclear power plants, reprocessing plants, and fuel fabrication plants), and to add volcanoes and external fires in the “Operational Guide for the Periodic Safety Assessment of Continuous Improvement” in addition to earthquakes and tsunamis, as evaluation targets of site characteristics that affect risks in the facility. As for nuclear power plants, in March

Recommendation 11	<p>2017, the corresponding operational guide was amended and all site characteristics became subject to the periodic safety assessment and the compliance with the safety elements described in SSG-25, including the element of performance certificate of equipment, was clarified. For uranium fuel fabrication plants, in March 2019, an operational guide for the periodic safety assessment was newly formulated, and all site characteristics are subject to the assessment. While at the same time, the conventional guide covering fuel fabrication plants and reprocessing plants was amended and newly formulated as the “Operational Guide for the Periodic Safety Assessment of Continuous Improvement of Fuel fabrication Plant (other than uranium fuel fabrication plant) and Reprocessing Plant”, and the guide will be reviewed in order.</p> <p>【Radiation safety】</p> <p>(Response to ①)</p> <p>To evaluate and review the ordinances and guides on a regular basis or when a new need arises, the NRA will revise the NRA Rules for an Integrated Management System and will stipulate the evaluation and review process as a common process across the organization, and put the specific procedure in writing in FY2020. On that occasion, the procedure for evaluation/review of the ordinances related to the RI Act, the guides, etc., will also be organized in consideration of the effects of ensuring consistency with the procedures, etc., related to nuclear safety.</p> <p>(Response to ②)</p> <p>Regarding the RI Act, in December of 2017, the “Viewpoint of Standard Review Plan of the Operational Rules for Design Certification and the Operational Rules of for Periodic Training for Registered Certification Organization, etc.”, “Interpretation on Reporting of the Accidents etc. to the NRA According to Article 28-3 of Ordinance for Enforcement of the RI Act Based on the Provisions of Article 31-2 of the RI Act”, “Guide Related to the Matters to be Specified in the Radiation Hazard Prevention Program”, and “On-site Inspection Guide for Registered Certification Organization, etc.” were released.</p> <p>(Response to ③)</p> <p>The periodic safety assessment of continuous improvement is excluded from the object.</p>
Documentary Evidence	
<ul style="list-style-type: none"> • The Latest Findings Reflection Process • List of 76 Latest Findings • List of Correspondence Relations between Reviewed Regulatory Requirements and Guides • Operational Guide for the Periodic Safety Assessment of Continuous Improvement of Commercial Nuclear Reactors (established by NRA on November 27 2013, amended on March 29 2017) • 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. • Interpretation of Accident Reports, etc. to NRA • Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program • On-site Inspection Guide for Registered Certification Organization, etc. 	
Results of Self-Assessment	
Closed on the basis of progress made and confidence in effective completion in due time	

9.3 Regulations and guides for nuclear power plants

Based on the self-assessment (SARIS) for regulations and guides of nuclear power plants, it finds that these regulations and guides are, in principle, in accordance with relevant IAEA safety requirements, but the following are considered separately.

- Site characteristics applied for the establishment permit or equivalent authorization should be reassessed during the lifetime of the nuclear installation. Currently, only the characteristics of seismic and tsunami hazards are reassessed in the guide for periodic safety assessment of continuous improvement.
- The potential risk of nuclear installation to the outside of its site should be assessed based on the

investigations of the site characteristics covering sufficient areas outside the nuclear installations.

- Measures to facilitate decommissioning and management of radioactive waste should be considered starting at the design phase.

Specific criteria to confirm the completion of decommissioning (site release) of nuclear facilities and methods to confirm compliance with the criteria should be developed, including the conditions after remediation of the site.

To address these challenges, the NRA implemented the measures for improvement, etc., based on the Action Plan (A11, A12, A13, and A14) as shown in Section 9.9.

9.4 Regulations and guides for research reactors

Based on the self-assessment (SARIS) for regulations and guides of research reactors, it found that these regulations and guides are, in principle, in accordance with relevant IAEA safety requirements, but the challenges identified that for nuclear power (Section 9.2) may be applicable to research reactors. These exceptions should be addressed, taking into account the unique features of research reactors on a graded approach according to the risk associated with the facilities and activities.

To address this challenge, the NRA implemented the measures for improvement based on the Action Plan (A11) as shown in Section 9.9.

9.5 Regulations and guides for Fuel cycle facilities

Based on the self-assessment (SARIS) for regulations and guides of fuel cycle facilities, it was identified that these regulations and guides are, in principle, in accordance with relevant IAEA safety requirements, but the exceptions identified for nuclear power (Section 9.2) may also be applicable to fuel cycle facilities. These challenges should be addressed taking into account the unique features of fuel cycle facilities on a graded approach according to the risk associated with the facilities and activities.

To address this challenge, the NRA implemented the measures for improvement based on the Action Plan (A11) as shown in Section 9.9.

9.6 Regulations and guides for waste management facilities

Based on the self-assessment (SARIS) for regulations and guides of waste management facilities, it finds that these regulations and guides are, in principle, in accordance with relevant IAEA safety requirements, but the following are considered as challenges.

- The regulatory standards for disposal facilities and waste packages should be amended so as to be performance-based requirements.
- A standard review plan for operational safety programs should be clarified concerning the method of closing of waste disposal facilities (e.g. backfilling, sealing, and capping) as well as that of monitoring and surveillance after closure.
- The NRA will complete the development of a regulatory standard for intermediate depth disposal and consider establishing regulatory standards for the disposal of radioactive waste from research institutes.

To address these challenges, the NRA implemented the measures for improvement etc., based on the Action Plan (A15, A16, and A17) as shown in Section 9.9.

9.7 Regulations and guides for radiation sources¹⁵ applications

(See “11.5 Code of conduct on the safety and security of radioactive sources”).

9.8 Regulations and guides for decommissioning activities

The regulations for decommissioning are included in those for respective facilities. For example, the regulations for decommissioning of nuclear power reactors are stipulated in the Commercial Reactors Ordinance (Articles 105 through 122) based on the Reactor Regulation Act (based on Article 43-3-33 and

43-3-34).

The regulations and guides corresponding to authorization and inspection described in [Section 5.8](#) are as shown in Table 18 and Table 19 in the Appendix

9.9 Action Plan

Basis	(B15) The IAEA Safety Standard stipulates that “Site characteristics that may affect the safety of the nuclear installation shall be investigated and assessed. These characteristics shall be monitored over the lifetime of the nuclear installation.” [NS-R-3 ¹⁶ paragraph 2.4., paragraph 5.1.] Under the current system, however, licensees are required to monitor only weather and volcanic conditions, and to reassess only earthquake and tsunami hazards.
Recommendation	(R15) Site characteristics which were applied for an establishment permit or equivalent authorization should be reassessed during the lifetime of a nuclear installation. However, currently, in conducting periodic safety assessment of continuous improvement, only seismic and tsunami hazards are required for reassessment
Action Plan	<p>(A11)①In the case of nuclear facilities which are legally required to conduct periodic safety assessment of continuous improvement (e.g. nuclear power, reprocessing, and fabrication facilities), the NRA will include all site characteristics that may affect the risk of nuclear facilities as items to be reassessed every 5 years in that safety assessment, in addition to those already required (e.g. earthquakes and tsunami hazards).</p> <p>②For research reactors, the NRA will consider adding reassessment of site characteristics in periodic safety review (every 10 years).</p> <p>Action plans for nuclear fuel cycle facilities and research reactors should take into account the unique features of these facilities on a graded approach, as well as the progress of the Action Plan for nuclear power plants.</p>
Response Status (A11)	<p>(Response to ①) In this Action Plan, the NRA implements improvements on the characteristics of the site by making them the object of re-evaluation for periodic safety assessment of continuous improvement in commercial nuclear reactors, reprocessing and fabrication facilities as a part of response to Recommendation 11.</p> <p>(Response to ②) Regarding the re-evaluation of the characteristics of the site in research reactors, the NRA will evaluate the characteristics of the site including the external hazards in periodic safety review and will amend the standard review plan of relevant operational safety programs and establish the guide documents related to implementation of periodic safety review within 2019.</p>
Documentary Evidence	<ul style="list-style-type: none"> • The Guideline for a Safety Improvement Evaluation of Uranium Fabrication Facilities (March 6 of 2019)
Results of Self-Assessment	Closed
Basis	(B16) The IAEA Safety Standard stipulates that “The combined effects of the site and the installation shall be such that the radiological risk to the population associated with accident conditions is acceptably low.” [NS- R-3 ¹⁶ para 2.27.] The new regulatory requirements for nuclear power only set limits to the dose at the site border in design basis accidents and the amount of release in the case of controlled release of radioactive materials for preventing a containment function failure.

IRRS Follow-up Mission to JAPAN 2020

Recommendation	(R16) The potential risk of nuclear installation to the outside of its site should be assessed based on the investigations of the site characteristics covering sufficient areas outside the nuclear installations
Action Plan	(A12) The NRA will start deliberations and preparations for including an assessment of the potential risk of nuclear installation to the outside of its site, in periodic safety assessment of continuous improvement. When applying probabilistic risk assessment (PRA), the scope of external hazards and its applicability should be well considered, based on the maturity of the methodologies.
Response Status (A12)	<p>The Operational Guide on periodic safety assessment of continuous improvement of commercial power reactors will be amended to require licensees of those reactors to conduct Level 3 PRA in the future.</p> <p>In order to judge the validity of the Level 3 PRA, since November 2016 the NRA has been promoting safety studies related to consistent risk evaluation by Level 1 PRA (core damage), Level 2 PRA (containment failure and release of radioactive materials to the atmosphere) and Level 3 PRA (impacts on the public in the vicinity of the facility) of commercial power reactor facilities in order to enable the NRA to verify the validity of the results of Level 3 PRA submitted by licensees of commercial power reactors. In addition, development of Level 3PRA methods will be encouraged for the licensees of commercial power reactors of nuclear reactors.</p>
Documentary Evidence	
Results of Self-Assessment	Closed

Basis	<p>(B17) The IAEA Safety Standard states that “On the completion of decommissioning actions, the licensee shall demonstrate that the end-state criteria as specified in the final decommissioning plan and any additional regulatory requirements have been met. The regulatory body shall verify compliance with the end-state criteria and shall decide on termination of the authorization for decommissioning.” [GSR Part 6¹⁹ R15, (WR-S-5²⁰ paragraph 9.1. and paragraph 9.2)] and that “The regulatory body shall establish or adopt regulations and guidelines to specify the principles, requirements, and associated criteria for safety upon which its regulatory judgments, decisions, and actions are based.” [GSR Part 1 R32] However, the specific criteria for confirming the completion of decommissioning (site release) of nuclear facilities and the method to confirm the compliance with the criteria have not been developed.</p> <p>(B18) The IAEA Safety Standard states that “The national government shall establish restrictions on entry to an area left with residual radioactive materials; to restore the area and, after the restoration measures on the area left with residual radioactive materials are completed, regularly investigate the condition of the restored area and, if appropriate, change or lift the restriction.” [GSR Part 3 paragraph 5.10. and paragraph 5.15] However, in the case where an area requiring remedial action exists at the decommissioning stage, a standard review plan and a confirmation method for the completion of decommissioning have not yet been developed.</p>
Recommendation	<p>(R17) The criteria for confirming the completion of decommissioning (site release) of nuclear facilities and method to confirm compliance with these criteria should be developed.</p> <p>(R18) The above criteria should also consider the conditions where a contaminated area requiring remediation exists on the site at the decommissioning stage (see Section 11.3 Remediation safety requirements for regulatory authorities).</p>

IRRS Follow-up Mission to JAPAN 2020

Action Plan	<p>(A13) The NRA will consider developing ①specific criteria for confirming the completion of decommissioning (site release) of nuclear facilities and ②the method to confirm the compliance with the criteria. This also covers ③the conditions where a contaminated area requiring remediation exists on the site at the decommissioning stage.</p> <p>Action plans for nuclear fuel cycle facilities and research reactors should take into account the unique features of these facilities on a graded approach, as well as the progress of the Action Plan for commercial nuclear power plants.</p>
Response Status (A13)	<p>(Response to ①) The NRA implements development of specific criteria for site release as a part of response to Recommendation 9.</p> <p>(Response to ②) The NRA is considering specifying about the activities by the licensees to prove the compliance with the criteria in the examination criteria plan for the decommissioning, to confirm in nuclear regulation inspection that the licensees respond by the permitted contents, and the NRA is verifying the contents of the confirmation are verified in the pilot trial of the new inspection system.</p> <p>(Response to ③) The requirement related to remediation of contaminated area means to require compliance with site release criteria (the representative individual radiation dose criteria, etc., after release of the site). As mentioned in Response status of Recommendation 8, the draft for site release criteria (the representative person radiation dose criteria, etc., after release of the site) will be reviewed by the commission of discussed by the NRA within FY2019 and determined (summarizing “approach of site release criteria”, and incorporating the criteria into standard review plan for decommissioning plan). Additionally, by FY2020, the NRA will complete survey and consideration regarding the measurement method upon site release that is required to determine compliance with site release criteria and develop the technical documents within FY2021.</p>
Documentary Evidence	
Results of Self-Assessment	Closed on the basis of progress made and confidence in effective completion in due time
Basis	<p>(B19) The IAEA Safety Standard states that “Measures to facilitate decommissioning and control the generation volume of radioactive waste have to be considered from the design phase.” [GSR Part5 R8, paragraph 4.6.-4.7., SSR-2/1¹⁷ R12, NS-R-5²⁵ paragraph 6.35.-6.36., NS-R-4²⁶ para 6.50.] Under the current system, however, this requirement is not included in the regulatory requirements for nuclear facilities.</p>
Recommendation	<p>(R19) Measures to facilitate decommissioning and control the volume of radioactive waste should be considered from the design phase.</p>
Action Plan	<p>(A14) Based on the experience of the decommissioning of existing nuclear power reactors, the NRA will revise the installation permission standard and technical standard (NRA ordinances) for newly built nuclear power reactors so that measures to facilitate decommissioning and control the volume of radioactive waste should be included from the design phase.</p> <p>Action plans for nuclear fuel cycle facilities and research reactors should take into account the unique features of these facilities on a graded approach, as well as the progress of the</p>

²⁵ NS-R-5 : Safety of Nuclear Fuel Cycle Facilities, Safety Standards Series No. NS-R-5

²⁶ NS-R-4 : Safety of Research Reactors, Safety Standards Series No. NS-R-4

IRRS Follow-up Mission to JAPAN 2020

	Action Plan for nuclear power plants.
Response Status (A14)	<p>Until 2018 the NRA conducted surveys on the specific cases related to the design that takes overseas trend in regulatory requirements and the design that takes decommissioning in domestic commercial nuclear power plants into consideration. In this Action Plan, based on the idea for design considering decommissioning and minimizing the volume of radioactive waste, on the premise of ensuring safety, the NRA intended to establish technical standards to consider decommissioning and minimizing the volume of radioactive waste at the stage of facility design. However, taking the overseas regulatory requirements obtained by the surveys, the decommissioning measures implementation policy, trend in act amendment, etc., related to inspection system, etc., into consideration, the NRA changed this Action Plan from establishment of technical standards and determined to promote voluntary implementation by the licensees without specifying it as a regulatory requirement of installation approval standards, etc.</p> <p>More specifically, within FY2019, the NRA will develop and release the technical documents considering decommissioning and minimizing the volume of radioactive waste. Through incorporating descriptions related to the consideration into the decommissioning measures implementation policy and operation guide related to the new inspection system, the NRA determined to implement them. For the future, regarding research reactors and nuclear fuel cycle facilities, by researching domestic and overseas difficult cases in decommissioning and the detailed examples of the design that contributes to decommissioning, etc. (including minimization of the volume of radioactive waste, together with the ones for commercial nuclear reactors), the NRA will release them as the technical documents within FY2019.</p>
Documentary Evidence	
Results of Self-Assessment	Closed on the basis of progress made and confidence in effective completion in due time
Basis	(B20) The IAEA Safety Standard states that “Waste packages and unpackaged waste accepted for emplacement in a disposal facility shall conform to criteria that are fully consistent with, and are derived from, the safety case for the disposal facility in operation and after closure.” [SSR-5 ¹⁸ R20] However, currently, the required standards for waste disposal facilities and waste packages have not been amended for many years and allow only one technical specification
Recommendation	(R20) The regulatory standards for disposal facilities and waste packages should be amended so as to be performance-based requirements.
Action Plan	(A15) Before accepting applications for new construction or modification of the facilities for near surface disposal or intermediate depth disposal, the NRA will amend the relevant regulations (The NRA ordinance and its notification) so as to be performance-based requirements.
Response Status (A15)	In “Study Team on the regulations for radioactive waste associated with decommissioning “that is comprised of a commissioner of the NRA, the officials of the NRA and the external experts, the NRA developed “Approach to regulations related to waste disposal within nuclear reactor etc.” By taking the approach of ALARA presented by “Study Team on Radiation Protection Standards for Waste Disposal” that has separately studied radiation protection standards for waste disposal and the details of the discussion of policy to incorporate dose constraint into consideration, the NRA established the framework of regulation standards, etc., of intermediate depth disposal that incorporate design process demand based on approach of ALARA and dose constraint. In this framework, along with studying technical standards for waste disposal facilities and waste packages for intermediate depth disposal, the NRA abolished the existing detailed specifications for near surface

IRRS Follow-up Mission to JAPAN 2020

(A15)	<p>disposal and waste packages and provided the results of the studies in order to clarify requirements.</p> <p>In this Action Plan, regarding the facilities for near surface disposal, the NRA clarifies requirements in performance-based language such as “The waste disposal facilities for near surface disposal should have the function to prevent leakage of radioactive materials from the limited area of the waste disposal site at least until completion of disposal in the method to install the facility to partition circumference or to integratedly solidify radioactive waste”. Regarding waste packages, the NRA clarifies requirements in performance-based language such as “radioactive materials should not easily scatter/leak even in case of considering waste packages would be dropped from the expected maximum height during handling the waste packages until they are settled in waste disposal site.” The NRA amended each “the NRA Ordinance on Standards for the Location, Structure and Equipment of Category 2 Waste Disposal Facilities (hereinafter the “Category 2 Waste Disposal Permit Ordinance”)” and “the NRA Ordinance on Activity of Category 2 Waste Disposal of Nuclear Fuel Material and Materials Contaminated by Nuclear Fuel Material (hereinafter the “Category 2 Waste Disposal Ordinance”)” in October 2019.</p>
Documentary Evidence	
Results of Self-Assessment	Closed on the basis of progress made and confidence in effective completion in due time
Basis	<p>(B21) The IAEA Safety Standard states that “Plans for closure, including the transition from active management of the facility, shall be well defined and practicable, so that closure can be carried out safely at an appropriate time. [SSR-5¹⁸ R19] “Before construction activities commence, there has to be sufficient evidence that the performance of the backfilling, sealing and capping will function as intended to meet the design requirements.” [SSR-5¹⁸ par4.38] and that “This (monitoring) program shall be designed to collect and update information necessary for the purposes of protection and safety.”[SSR-5¹⁸ R21] The NRA plans to confirm the method of closing of waste disposal facilities (e.g. backfilling, sealing, and capping) as well as that of monitoring and surveillance programs after closure through the modification of operational safety programs. However, a standard review plan has not yet been prepared.</p>
Recommendation	<p>(R21) A standard review plan for operational safety programs should be implemented for closing of waste disposal facilities as well as monitoring and surveillance after closure.</p>
Action Plan	<p>(A16) Before waste disposal facilities to move to the stage of closure, the NRA will develop a standard review plan for relevant operational safety programs.</p>
Response Status (A16)	<p>The NRA identifies that the new regulatory requirements include regulatory requirements on monitoring and surveillance at the stage of closure and after closure of waste disposal facilities and verifies these actions are stage-managed in the examination related to the permission for the activity. Additionally, regarding the facilities that have already been permitted, the NRA verifies that the stage management based on permission is specified in an operational safety program. While the NRA considered amendment of standard review plans of operational safety programs and specification of the detailed matters on “monitoring and surveillance at the stage of closure and after closure of waste disposal facilities”, as they depend upon methods for disposal and materials to be disposed of, the Action Plan has been changed to review each waste disposal facility not to specify common and detailed standard review plans.</p>
Documentary Evidence	<p>The interpretation of the regulations regarding the location, structure, and equipment standards of Category 2 waste disposal facilities Article 13.</p>
Results of Self-Assessment	Closed

IRRS Follow-up Mission to JAPAN 2020

Basis	(B22) The IAEA Safety Standard states that “The regulatory body shall establish or adopt regulations and guidelines to specify the principles, requirements, and associated criteria for safety upon which its regulatory judgments, decisions, and actions are based.” [GSR Part 1 R32] The regulatory standard for intermediate depth disposal is currently being developed but has not yet been established. The project for building a buried disposal for radioactive waste from research institutes, etc., is progressing , but its regulatory standards have not yet been established.
Recommendation	(R22) A regulatory standard for intermediate depth disposal should be established. The NRA should consider developing regulatory standards for the disposal of radioactive waste from research institutes.
Action Plan	(A17) The NRA should ① expedite its work to develop a regulatory standard for intermediate depth disposal facility. In addition, ② in response to the progress of the projects to install a disposal facility of radioactive waste from research institutes, a regulatory standard for such facilities also should be developed.
Response Status (A17)	<p>(Response to ①) In this Action Plan, the NRA studied the draft standard related to intermediate depth disposal in “Study Team on regulations of radioactive waste associated with decommissioning” that is comprised of a commissioner of the NRA, officials of the NRA, and external experts and developed “approach to the regulations on disposal of waste in the nuclear reactors etc. By taking the approach of ALARA presented by “Study Team on Radiation Protection Standards for Waste Disposal” that has separately studied radiation protection standards for waste disposal and the details of the discussion of policy to incorporate dose constraint into consideration, the NRA established the standards, etc., for intermediate depth disposal which incorporate the design process demand based on the approach to ALARA and dose constraint. The Ordinances and guides relative to Category 2 Waste Disposal will be provided by the end of FY2019.</p> <p>(Response to ②) Regarding the studies of development of the standard related to waste generated by research facilities, etc., the NRA studied in “Study Team on regulations on radioactive waste associated with decommissioning” as well. In the developed “approach to regulations on waste disposal within nuclear reactors, etc.,” the NRA provided the approach to design requirements and management requirements required to ensure safety under regulatory control and after release of regulatory control including the premise of the studies for regulatory requirements. Additionally, in order to rationalize the regulations related to radioactive waste, the NRA amended the RI Act so that, by regarding RI waste which nuclear waste disposal licensees can treat and dispose as waste under the Reactor Regulation Act, the NRA can reasonably regulate such RI waste by the Reactor Regulation Act. In the amendments of regulations related to the Reactor Regulation Act, the restriction on the plant or site that generates waste is partly removed from the technical standard of waste, etc. The amendments include specifying the RI waste accepted by the licensees of waste disposal activity under the Reactors Regulation Act as the objects of the technical standards. The NRA will ask for public comments related to the amendments of these regulations in 2019 and develop amendments by the end of FY2019. Additionally, the NRA also continues the studies for development of the draft amendments of the regulations related to clearance in order to make specific RI waste as the objects of clearance. Within FY2019, the NRA will ask for public comments on the amendments for the relevant operation regulations within FY2019.</p>
Documentary Evidence	<ul style="list-style-type: none"> • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (the Act on Prevention of Radiation Hazards due to Radioisotopes, etc. (the RI Act, etc.) Article 33-2)
Results of Self-Assessment	Closed on the basis of progress made and confidence in effective completion in due time

IRRS Follow-up Mission to JAPAN 2020

(A19)	Regulation Act and the RI Act and their smooth implementation, taking the contents of the advice into consideration.
Documentary Evidence	A19 • Principles of radiation protection measures of the crystalline lens of the eye (advice)
Results of Self-Assessment	A18 : Closed / A19 : Closed

10 Emergency preparedness and response

10.1 Conclusions

Based on the self-assessment (SARIS) for emergency preparedness and response, it **found** that, as shown in [Sections 10.2 through 10.5](#), that the regulatory framework is well-established to regulate licensees' emergency preparedness and response. Therefore, it **was identified** that the framework and measures for emergency preparedness and response are, in principle, in accordance with relevant IAEA safety requirements, except in the following areas:

- EALs ²⁷ for nuclear facilities other than nuclear power plants should be developed.
- As the dose limit of occupational exposure in emergency is changed and that the associated radiation protection measures are strengthened, a preparatory work should be completed for the implementation of this system.
- The NRA should consider developing rules for the conditions or parameters for judging EALs²⁷, which are included in licensee's EPR plan, in order to avoid possible confusion in a nuclear emergency.
- The NRA should consider having regulatory measures for an EPR²⁸ development over operators regulated under the [RI Act](#).

To address these challenges, the NRA will implement the Action Plans as shown in [Section 10.6](#)

Additionally, in the initial mission, the recommendations/suggestions were provided regarding establishment of a set of emergency action levels for nuclear facilities, guidance on identification of the emergency action levels, and consideration of requirements for emergency workers. The NRA addressed these issues after considering response to them and implemented the measures for improvement on the initial mission based on the Action Plans as shown in [Section 10.6](#).

10.2 General EPR²⁸ Regulatory Requirements

The Nuclear Emergency Act requires licensees to develop a "Nuclear operator's EPR²⁸ plan" for each site, to update that plan annually, and to consult with the government, local governments, and other related parties when developing or modifying that plan. The act requires licensees to conduct emergency exercises and to report the result to the NRA. The NRA may order licensees to change their exercise or other measures if it finds that their emergency procedures are not sufficient to prevent or mitigate a nuclear emergency. Thus, the NRA is authorized to supervise the planning, implementation, and improvement of the licensees' EPR plans.

The [RI Act](#) requires authorized operators to give notice of an accident (e.g. the theft or disappearance of radioisotopes), to take necessary measures (e.g. first response notification) in emergency situations such as an earthquake or fire, to develop a Radiation Hazards Prevention Program, to include measures covering emergency situations and disasters (e.g. earthquakes, fires) and other dangerous conditions, and to submit that to the NRA.

However, it **was identified** that authorized operators under the [RI Act](#) are not required to develop their own EPR plans and so that the NRA will consider asking authorized operators for specific EPR measures.

In the initial mission, the IRRS team identified that 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. The NRA responded to the recommendation introduced based on the indication as follows.

²⁷ EAL : Emergency Action Level

²⁸ EPR : Emergency Preparedness and Response

Recommendation 12	Contents of Recommendation
	<p>The NRA and other authorities having jurisdiction for radiation sources should develop a single set of requirements and guidance for ④ EPR in relation to radiation sources including requirements related to ① emergency plans, arrangements for ② timely notification and response, and ③ quality assurance programme using graded approach.</p>
	Basis
	<p>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. [...]”</p>
	<p>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...]. [...]”</p>
	<p>In addition, the following paragraphs provide basis for this recommendation: GS-R-2, paras. 3.6, 3.10, 3.11, 3.15, 3.16, 4.1, 4.9, 4.19, 4.24, 4.37, 4.38, 4.51, 4.70, 4.83, 4.84, 5.2, 5.13</p>
	Response Status
<p>(Response to ①)</p> <p>The NRA established the “Study Team on the Regulation of the Usage Facilities of Radioisotopes, etc.” consisting of the members of the NRA commissioner, the officials of the Nuclear Regulatory Agency, and the external experts. In this study team, the NRA studied improvement and enhancement of the emergency measures for the RI usage facilities on the basis of a graded approach that provides regulatory requirements in stages depending on the risk level of radioisotopes. Based on the results of the studies and the fact that the hazard assessment conducted in accordance with IAEA safety standard for all the licensed RI facilities showed a result that the hazard classification of these RI facilities was III or less, the NRA amended the RI Act to make the report to the NRA, etc., from the licensee in the event of emergency situation legally mandatory. They also stipulated the matters to be specified in the Radiation Hazards Prevention Program in the NRA Ordinance for Enforcement of the Act on Regulation of Radioisotopes, etc., and put the ordinance in force in April 2018. Specifically, based on IAEA safety requirements, the NRA specified “the facilities that could cause severe deterministic effects” as RI operators that need proactive measures and require to develop the determination criteria related to the emergency measures and procedure related to the response, to implement arrangement of organization/equipment and training and to collaborate with off-site responding agencies (fire management agency, police agencies, and medical agencies), taking consistency with the requirements into consideration, and the NRA decided to add regulatory requirement that requires the licensees to specify the details of the emergency measures including the ones above-mentioned in the Radiation Hazards Prevention Program and submit the program to the NRA.</p>	
<p>(Response to ②)</p> <p>Regardless of the type and quantity of radioisotopes, the NRA required RI operators (except for the operator related to approved device with certificated label) to specify the information provision procedures to outside of the facilities upon taking emergency measures in the Radiation Hazards Prevention Program. The NRA also developed the guideline required for smooth collaboration with off-site responding agencies in an emergency for the operators that are not subject to requirements of proactive measures as well.</p>	
<p>(Response to ③)</p> <p>Regarding quality assurance activities, the NRA clarified by the law revision that all the licensees have the responsibilities to take necessary measures such as improvement of operations, etc., taking the latest findings into consideration. In addition, considering the results of the hazard assessment for RI facilities in Japan and graded approach depending on the risk level associated with handling of radioisotopes, etc., for specified permission users and permission waste management operators, the NRA stipulated in the NRA Ordinance for Enforcement of the RI Act</p>	

Recommendation 12	<p>that only the implementation system and recording of activities required for operational improvement among the quality assurance activities needs to be described in the Radiation Hazards Prevention Program, and put the amended ordinance in force in April 2018. From April 1 2018, from the perspective of graded approach only for specified permission users, the reporting method at the occurrence of large-scale natural disasters was re-examined, and a system that allows the operators being required to take proactive measures for emergencies to mutually confirm the situation was established.</p> <p>(Response to ④) The NRA established the requirements to prepare for and respond to emergency situations and the guidance including the requirements related to operation improvement activities (guide related to the matters to be specified in the Radiation Hazards Prevention Program) in December 2017.</p>
	Documentary Evidence
	<ul style="list-style-type: none"> • Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (The RI Act, Article 31-2, Article 38-4) • The RI Ordinance Article 21 • Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program
	Results of Self-Assessment
	Closed

Suggestion 11	Contents of Proposal
	<p>NRA should consider strengthening its plans and procedures to consistently respond to emergencies related to radiation sources.</p>
	Basis
	<p>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. [...]”</p>
	<p>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...]. [...]”</p>
	<p>In addition, the following paragraphs provide basis for this recommendation: GS-R-2, paras. 3.6, 3.10, 3.11, 3.15, 3.16, 4.1, 4.9, 4.19, 4.24, 4.37, 4.38, 4.51, 4.70, 4.83, 4.84, 5.2, 5.13</p>
	Response Status
	<p>As a measure of the NRA in the case of accident or trouble including emergency situations regarding radiation source in RI facilities, the NRA studied the specific response and its procedures on information transmission to the outside and check the status of the site by classifying RI facilities depending on the potential risks. Based on the results of the studies, the NRA organized a response system for the occurrence of the events along with developing the instruction manual in April 2019.</p>
Documentary Evidence	
Results of Self-Assessment	
Closed	

10.3 Functional regulatory requirements

10.3.1 Establishing emergency management and operations

For nuclear facilities, the NRA guide “Viewpoints in reviewing the nuclear operator’s EPR plan” clarifies the allocation of EPR staff and secondary personnel, requirements for an operator’s emergency response center. The NRA confirms the compliance of such EPR plans to these requirements.

The Radiation Hazards Prevention Act requires the authorized operators to stipulate measures to be taken in emergency situations in their Radiation Hazards Prevention Program, and to take necessary measures to prevent radiation hazards under the supervision of qualified radiation personnel (e.g. a Radiation Protection Supervisor).

Thus, the NRA ensures that the authorized operators can take prompt action in a site emergency.

10.3.2 Identifying, notifying, and activating

For nuclear facilities, the Nuclear Emergency Act requires licensees to promptly notify an emergency situation to the relevant parties if they find the ambient dose rate around the site border exceeding 5mSv/h or other significant events as defined by the NRA Ordinance (e.g. loss of cooling water which requires ECCS) (Article 10). This is in accordance with requirements for the notification timing in the appendix VI of GS-G-2.1.²⁹ Licensees are also required to prepare notification procedures in their EPR plan.

The RI Act requires authorized operators to notify fire fighters, police stations, the NRA and other concerned parties in the event of serious incidents such as earthquakes, fire, or leakage of radioactive materials.

10.3.3 Taking mitigation actions

For nuclear facilities, the “Order for nuclear operator’s EPR plan” based on the Nuclear Emergency Act (Article 7) requires licensees to include the assigned tasks for EPR staff and EPR organizational structure in their EPR plan.

The RI Act requires licensee and registrant to undertake first response measures such as the use of firefighting equipment to prevent the spread of fires, measures to prevent the spread of contamination, and its removal in the event of leakage. Authorized operators are required to include measures to tackle emergencies such as fires or earthquakes in their Radiation Hazard Prevention Program.

10.3.4 Taking urgent protective action

For nuclear facilities, the NRA EPR Guide, which is quoted in the Nuclear Emergency Act, sets the OIL³⁰ (Operational Intervention Level) as the criteria in taking protective actions to protect the public. This OIL is, in principle, in accordance with the relevant IAEA standard.

For authorized operators under the RI Act, criteria such as the OIL³⁰ is not defined, taking into account a graded approach since the inventory is significantly smaller compared with nuclear facilities. However, in an emergency (e.g. earthquakes, fire), licensee and registrant are required to take necessary actions including warnings, prevention of contaminated spread, remediation of contaminated areas, and prohibition of entering the site.

10.3.5 Providing information and issuing instructions

The Nuclear Emergency Act requires nuclear facilities licensees to notify the government, local governments or other related parties promptly in the event of emergencies (See Section 10.3.2). Based on the “Basic Plan for Emergency Preparedness”, the government and local governments notify the public and may institute protective measures.

In emergencies, the RI Act requires authorized operators to take actions such as alert persons to prohibit entrance to the site; notify the police, fire department, and coast guard; and promptly notify the NRA. After such notification, the NRA or other related parties may provide information to the public.

²⁹ GS-G-2.1 : Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide, No. GS-G-2.1

³⁰ OIL : Operational Intervention Level

In the initial mission, the IRRS team identified that although a regulatory framework for EPR at NPPs was extensively revised and enhanced after the accident at Fukushima Dai-ichi NPP, there are still issues which remain to be addressed. There is need for the 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 judgment 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. The NRA responded to the recommendation and suggestion introduced based on the indication as follows.

Recommendation 13	Contents of Recommendation
	<p>The NRA should establish: ①complete set of Emergency Action Levels for nuclear facilities other than NPPs and ②associated guidance to promptly define Emergency Action Levels for all nuclear operators; ③verification process that licensees participate in provision of information to the public within emergency planning zones around nuclear facilities at the preparedness stage.</p>
	Basis
	<p>GS-R-2 para. 4.19. states that “The operator of a facility or practice in threat Category I, II, III, or IV shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency, and determination of the appropriate level of response. This shall include a system for classifying all potential nuclear and radiological emergencies [...]”</p>
	<p>GS-R-2 para. 4.54 states that “For facilities in threat Category I or II arrangements shall be made, before and during operations, to provide information on response to a nuclear or radiological emergency to.... population groups ... within the precautionary actions zone and the urgent protective action planning zone. [...] and the effectiveness of this public information programme shall be periodically assessed.”</p>
	<p>In addition, the following paragraphs provide basis for this recommendation: GS-R-2, paras. 4.23, 4.25,</p>
	Response Status
<p>(Response to ①)</p> <p>The NRA held meetings of the “Study Team on Nuclear Emergency Preparedness Measures” consisting of members of the NRA commission, the officials of Nuclear Regulatory Agency, and external experts, and studied the priority zone for nuclear emergency preparedness of nuclear facilities other than nuclear power plants (precautionary action zone [PAZ], urgent protective action planning zone [UPZ] and emergency action level [EAL]). In this study, as a result of performing hazard assessment on reprocessing, fuel fabrication, research reactors, spent fuel storage, waste disposal/management, and usage facilities, it was evaluated that occurrence of the events that could cause severe deterministic effects requiring urgent or early protective actions outside the site were not expected in any type of facility. And, based on the results of the evaluation, the necessity of PAZ and UPZ is set individually. As for EAL, the NRA organized concepts of EAL for individual facilities, and decided to prepare EALs depending on the characteristics of each facility even if the hazard classification is the same. Based on the results of these studies, the NRA amended the NRA EPR guide in July 2017 after a series of exchange of opinions with the licensees, etc., that actually operate EAL. For nuclear fuel facilities, etc., the NRA added conditions or parameters for judging EAL for Alert, Site Emergency, and General Emergency for each facility.</p> <p>(Response to ②)</p> <p>For nuclear power plants, based on the result of the Nuclear Energy Disaster Prevention Drill conducted in FY2016, an appropriate timing of EAL activation was examined and organized, and it was decided to optimize EAL activation considering the burden on evacuation of those who need care in emergencies that occurs in connection with transition to the implementation phase of protective action due to activation of EAL of Site Emergency, etc. The NRA determined to</p>	

Recommendation 13	<p>implement the optimization by reviewing the EAL setting items. In addition, the descriptions related to Site Emergency and General Emergency have been modified, and for facilities that have not conformed to the new regulation standard, the same EAL as that for Fukushima Dai-ichi Nuclear Power Plant Station, unit No.1 to 4 was applied. And for Alert of all the facilities, the requirements for natural disasters such as earthquake/tsunami, etc., were re-examined, and the consequent revisions were reflected. In addition, along with the amendments of the relevant regulations of the Act on Special Measures Concerning Nuclear Emergency Preparedness, the NRA amended, in July 2017, the Explanations of Criteria for Determining Emergency Categories in NRA EPR Guide, in order to modify the descriptions related to nuclear power plant and to add descriptions related to nuclear fuel facility, that provides the licensees, etc., with instructions to properly establish a Nuclear Operator Emergency Action Plan, appropriately determine the emergency classification, and notify the situation in the event of the occurrence of abnormalities etc. in the facilities.</p> <p>(Response to ③) Regarding the provision of information to the public within emergency plan area around the nuclear facilities, the NRA amended, in September 2017, the "Viewpoints in reviewing the nuclear operator's EPR plan" that specifies the viewpoints to be reviewed and the points to be noted for the reviewing when the NRA receives the legal notification of Nuclear Operator Emergency Action Plan from the licensees in order to add the description that the NRA confirms the implementation status of information provision to the public under normal conditions when receiving the legal notification of the Nuclear Operator Emergency Action Plan from the licensees.</p>
Documentary Evidence	
<ul style="list-style-type: none"> • NRA EPR Guide (October 1 of 2018 NRA) Table 2 8 and 9 • 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 14 of 2012, Ordinance of Ministry of Education, Culture, Sports, Science and Technology, Ministry of Economy, Trade and Industry No.2) Article 7, para 1, item 1(ix) and (x) Article 14, para 1 (ix) and (x) • Oder 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 14 of 2012, Ordinance of Ministry of Education, Culture, Sports, Science and Technology, Ministry of Economy, Trade and Industry No.4) Article 7, para 1, Item 1, item 1(ix) and (x), Article 14, para 1 (ix) and (x) • Explanations of Criteria for Determining the Emergency Categories in NRA EPR Guide (July 5 of 2017 NRA) No.8 and 9 • Viewpoints in reviewing the nuclear operator's EPR plan (September of 2017 NRA) p10 Ordinance for Nuclear Operator Emergency Action Plan etc. related to Article 2, para.1, item 17 	
Results of Self-Assessment	
Closed	

10.3.6 Protecting emergency workers

Under the framework of the Reactor Regulation Act, the RI Act and other acts aimed at protecting employees, the dose limit for occupational exposure during an emergency response is set as 100 mSv in effective dose, 300 mSv for the eyes in equivalent dose, and 1 Sv for skin in equivalent dose.

The related ordinances were revised in April 2016 to allow for an increase of those dose limits (e.g. 250 mSv in effective dose), provided that radiation workers have received the necessary training, that they fully intend to undertake emergency work after being informed of the possibility of exposure and the high possibility that radioactive material could be released beyond the site's boundaries.

In the initial mission, the IRRS team observed that: since the TEPCO Fukushima Dai-ichi 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 April 1 2016. The NRA responded to the suggestion introduced based on the indication as follows.

Suggestion 12	Contents of Proposal
	The Government should consider ensuring that the relevant authorities establish consistent requirements for categories of emergency workers performing similar tasks
	Basis
	GS-R-2 para. 4.58. states that “Those called upon to respond at a facility in threat Category I, II, or III or within the precautionary action zone or the urgent protective action planning zone shall be designated as emergency workers. [...] In addition, the radiation specialists ..., radiation protection officers, and radiological assessors ... who may respond to emergencies involving practices or other hazards in threat Category IV shall be considered emergency workers. [...]”
	In addition, the following paragraphs provide basis for this recommendation: GS-R-2, paras. 4.62, 4.63
	Response Status
	The Radiation Council discussed raising of radiation dose limits taking the situation at the time of the accident at the TEPCO Fukushima Dai-ichi Nuclear Power Station (activities of operators, police officers, firefighters, officials of self-defense officials, etc.) into consideration, and made inquiries about the necessity of the raising to the relevant authorities. As a result, in August 2015, only the dose limit of radiation workers and nuclear safety inspectors to be engaged in emergency work to avoid reaching a catastrophic situations was raised to 250mSv. Such raising was not be applied to other emergency workers due to the difference of their tasks and the dose limits for them remained as 100mSv.
	Additionally, it was confirmed that, in the case of occurrence of emergency work, countermeasures have been taken by operators so that the accident can be settled by the operators, and emergency workers other than the operators and nuclear safety inspectors are not expected to enter into the sites. This confirmed that consistent requirements are still applied depending on the duties of the emergency workers. Moreover, the operators designate the workers to be engaged in the emergency work in the nuclear facilities in advance according to the specified requirements and provide necessary education/training etc. to the designated workers.
	Documentary Evidence
<ul style="list-style-type: none"> • Categorization of Emergency Workers • Ordinance on Prevention of Ionizing Radiation Hazards (Article 7, 2. exceptional emergency dose limit) • Radiation Hazard Prevention for Staff -National Personnel Authority’s Rules 10-5 (Article 4-2,3 Dose limit) • The Notification to Establish Dose Limits in Accordance with the Provisions of NRA Ordinance on Activity of Refining Nuclear Source or Nuclear Fuel Materials (Article 7 Dose limits for radiation workers engaged in emergency work) 	
Results of Self-Assessment	
Closed	

10.3.7 Assessing the initial phase

Nuclear operators are required to assess emergency situations in accordance with the NRA EPR guide, and to then notify the appropriate emergency category to the government, local governments and other related parties. The NRA EPR guide also defines the EALs (Emergency Action Level).

Licensees and registrants under the Radiation Hazards Prevention Act are required to alert competent authorities to accidents and other emergency situations.

However, the EALs are defined only for nuclear power facilities. EALs for nuclear facilities other than nuclear power plants should be developed and included in the NRA EPR guides.

The NRA should consider developing rules for the conditions or parameters for judging EALs, to be included in licensee’s EPR plan, to avoid possible confusion in a nuclear emergency.

To address this challenge, the NRA implemented the improvement measures etc., based on the Action Plan (A20, 22) as shown in Section 10.6.

10.3.8 Managing the medical response

The “Basic Plan for Emergency Preparedness” and the “Nuclear Emergency Preparedness Manual” describe the necessary medical responses of licensees and local governments, which are, in principle, in accordance with the requirements in 4.78 and 4.79 of GS-R-2.³¹

10.4 Regulatory requirements for infrastructure

The NRA regulates licensees’ on-site emergency preparedness and response from the viewpoint of nuclear safety and radiation protection.

Licensees are required to include the employment of their EPR staff in an emergency and procedures to change these allocations in their EPR plan. The NRA verifies the effectiveness of these measures through licensees’ emergency exercises.

The Nuclear Emergency Act requires the following measures and the NRA verifies their effectiveness by reviewing the plan and the result of a licensees’ exercise.

- Coordination between licensees and organizations to support emergency work
- Development of an emergency response plan
- Supporting logistical measures and the facilities used in an emergency
- An education and training program

The NRA verifies the effectiveness of a licensees’ quality assurance program by periodic reviews of plans and procedures and review of improvements in emergency response plans.

10.5 Role of regulatory body during response

The Nuclear Emergency Act provides that in a nuclear emergency, the NRA is assigned (a) to provide advice to licensees, coordinate with involved parties, evaluate of the situation, impact analysis, etc., (b) to provide information, advice, and instructions to local governments, (c) to assist the prime minister in deciding emergency response measures.

The RI Act stipulates that during an emergency at an authorized operator’s facility, the NRA may issue an order for authorized operators to transfer materials, to remediate contamination or leaks, or to undertake other necessary measures. The NRA provides advice or support to authorized or related parties as necessary

10.6 Action Plan

Basis	(B25) The IAEA Safety Standard states that “the operator shall make arrangements for determination of the appropriate level of response to a nuclear or radiological emergency in accordance with international standards that classify potential radiological emergencies.” [GS-R-2 ³¹ para 4.19.] Currently, however, the NRA has established emergency action levels (EALs ²⁷) only for power reactors, not for RI facilities ³² .
-------	---

³¹ GS-R-2 : Preparedness and Response for a Nuclear or Radiological Emergency, Safety Standards Series No.GS-R-2

³² "RI facilities: in this section means facilities that are regulated by the Reactor Regulation Act. RI is abbreviation for radioisotope.

IRRS Follow-up Mission to JAPAN 2020

Recommendation	(R25) EALs ²⁷ for nuclear facilities other than nuclear power should be developed.
Action Plan	(A20) The NRA will develop EALs ²⁷ for nuclear facilities other than nuclear power plants and include these EALs in the NRA EPR guide.
Response Status (A20)	This Action Plan is implemented as a part of response to Recommendation 13.
Documentary Evidence	
Results of Self-Assessment	Closed

Basis	(B26) The IAEA Safety Standard states that “response organizations and employers shall ensure that emergency workers who undertake actions in which the doses received might exceed 50 mSv do so voluntarily; that they have been clearly and comprehensively informed in advance of the associated health risks, as well as of available measures for protection and safety; and that they are, to the extent possible, trained in actions that they may be required to take.” [GSR Part 3 para 4.17.] The related regulations were revised and other necessary regulations were coordinated in August 2015.
Recommendation	(R26) Steady implementation of the system relating to the increase of the dose limit for emergency workers at nuclear facilities and the associated arrangements for radiation protection should be ensured.
Action Plan	(A21) The proper implementation should be ensured for the new system of radiation protection for emergency workers (e.g. increase of effective dose limit from 100 mSv to 250 mSv), for which plans will be enacted in April 2016. This also includes the modification of licensees’ operational safety program.
Response Status (A21)	Based on the plan, the NRA responded to the modification of licensees’ operational safety programme by the end of April 2016.
Documentary Evidence	
Results of Self-Assessment	Closed

Basis	(B27) The IAEA Safety Standard states that “the operators of facilities shall make arrangements to assess promptly abnormal conditions at facilities, exposures, and releases of radioactive material and so on, and also that these assessments shall be used for emergency classification and recommendations for urgent protective actions to be taken off the site.” [GS-R-2 ³¹ para 4.70.] Currently, licensees include these arrangements in their EPR plan and submit it to the NRA. However, the contents of these arrangements differ among licensees.
Recommendation	(R27) The contents of licensees’ documents explaining the conditions or parameters for judging EALs ²⁷ should be clearly defined in order to avoid possible confusion in nuclear emergency.
Action Plan	The NRA should consider defining the conditions or parameters for judging EALs ²⁷ .
Response Status (A22)	This Action Plan is implemented as a part of response to Recommendation 13.
Documentary Evidence	

IRRS Follow-up Mission to JAPAN 2020

Results of Self-Assessment	Closed
Basis	<p>(B28) The IAEA Safety Standard states that “the operator of a facility shall establish a quality assurance program, in accordance with international standards, to ensure a high degree of availability and reliability of emergency preparedness.” [GS-R-2³¹ para 5.37.] Currently, however, authorized operators under the Radiation Hazards Prevention Act are not required to develop such quality assurance program.</p> <p>(B29) The IAEA Safety Standards state that each organization responsible for response to emergencies shall prepare plans for performing their assigned functions in the event of an emergency. Currently, however, the operators who are regulated by the RI Act are not required to prepare such emergency plans. [GS-R-2³¹ para 5.19.]</p>
Recommendation	(R28) The NRA will consider requesting specific measure for EPR ³²⁰ to the authorized operators under the RI Act.
Action Plan	(A23) The NRA will consider requesting licensees and registrants under the RI Act to include an EPR plan and quality assurance program in their Radiation Hazards Prevention Program or other means, considering the risk level of the inventory of radioisotopes based on a graded approach.
Response Status (A23)	This Action Plan is implemented as a part of response to Recommendation 12.
Documentary Evidence	
Results of Self-Assessment	Closed

11 Additional areas

11.1 Occupational radiation protection

11.1.1 Conclusions

Based on the self-assessment (SARIS) for occupational radiation protection, it found that the regulatory framework for occupational radiation protection is well developed by the NRA and Ministry of Health, Labour, and Welfare and so, it basically complies with IAEA safety standards.

The related ordinances were revised in August 2015 to allow an increase of dose limits (e.g. from 100 mSv to 250 mSv in effective dose) provided that radiation workers undergo the necessary training, that they are committed to undertaking emergency work even after being briefed on the dangers of exposure, and the high possibility that radioactive material could be released beyond the site border. Preparations are under way for its enactment in April 2016.

Therefore, it concludes that the framework and measures for occupational radiation protection are, in principle, in accordance with the relevant IAEA safety requirements, while new systems of radiation protection for emergency workers are being prepared (See Action Plan No.21 in [Section 10.6](#)), with the following exception.

The NRA also [conducted](#) the action to respond to new criteria for lens of eyes applicable to occupational exposure as introduced in the IAEA safety standard. (See Action Plan No.18 and No.19 in [Section 9.9](#)).

11.2 Control of discharges and material for clearance; Environmental monitoring for public radiation protection

11.2.1 Conclusions

Based on the self-assessment (SARIS) for control of discharge, materials for clearance, and environmental monitoring, it [found](#) that the appropriate regulatory frameworks are in place under the Reactor Regulation Act and [the RI Act](#) for control of discharge and clearance. Local governments and other agencies conduct environmental monitoring with the support of the government.

Therefore, it [concluded](#) that the framework and measures for control of discharge, clearance and environmental monitoring are, in principle, in accordance with the relevant IAEA safety requirements. [However, in the initial mission, the recommendation \(R2\) on the measures related to technical services was provided including the contents. The NRA addressed this challenge after considering response to it as shown in Section 1.9.](#)

11.3 Remediation safety requirements for regulatory authorities

11.3.1 Conclusions

Based on the self-assessment (SARIS) for remediation safety requirements over the situation that is regulated by the NRA, it [found](#) that the completion of decommissioning (site release) may be applicable to the remediation if some areas are contaminated. The regulatory criteria for confirming the completion of decommissioning have not been established [so far](#), and this issue [was](#) addressed in accordance with the Action Plan (No. 13) in [Section 9.9](#). [However](#), there is no facility that intends to conduct site release in the near future.

11.4 Safety requirements for management of radioactive waste

11.4.1 Conclusions

Based on the self-assessment (SARIS) for management of radioactive waste, it finds that the appropriate regulatory framework [is](#) in place under the Reactor Regulation Act and the [RI Act](#) for management of radioactive waste, commensurate with risk involved in the waste based on a graded approach. The predisposal facilities for radioactive waste within nuclear facilities and RI facilities are regulated under

those same conditions for nuclear facilities and RI facilities.

Therefore, it **concluded** that the framework and measures for management of radioactive waste are in principle in accordance with the relevant IAEA safety requirements with the identified exceptions in **Section 5.6** Authorization of waste management facilities.

11.5 Code of conduct on the safety and security of radioactive source³³

11.5.1 Conclusions

Based on the self-assessment (SARIS) for safety of radioactive sources, it found that the appropriate regulatory frameworks are in place under the **RI Act** for radioisotopes and radiation generating apparatuses. The NRA develops and implements the registration system to identify and track the location of radioactive sources for those under Categories 1 and 2, and a part of those under Category 3.

Therefore, it **concluded** that the framework and measures for safety of radioactive sources are, in principle, in accordance with safety provisions under the Code of Conduct on the Safety and Security of Radioactive Sources.

The following instance was identified as the challenge in the self-assessment.

- A system to foster a safety culture among authorized operators authorized under the **RI Act** should be considered.

To address this challenge, the NRA implemented the measures for improvement **based on** the Action Plans in **Section 11.5.2**

11.5.2 Action Plan

Basis	(B30) The Code of Conduct on the Safety and Security of Radioactive Sources states that “it shall be ensured that the regulatory body promotes the establishment of a safety culture and of a security culture among all individuals and in all bodies involved in the management of radioactive sources.” [CoC ³⁴ 2004 para 22. (d)] However, currently, authorized operators under the RI Act are not explicitly required to take measures fostering a safety culture.
Recommendation	(R29) A system to foster a safety culture should be considered for the authorized operators under the RI Act , based on a graded approach.
Action Plan	(A24) The NRA will consider taking specific measures for fostering safety culture in authorized operators under the RI Act , such as inclusion of “fostering a radiation safety culture in their Radiation Hazards Prevention Program or other means, with consideration of a graded approach based on the level of risk associated with the handling of radioisotopes.”
Response Status (A24)	The NRA made clear in the RI Act as the responsibilities of the licensees that, by taking state-of-the-art knowledge related to safety into consideration, RI licensees have the responsibility to take necessary measures for prevention of radiation hazards and protection of specified radioisotopes such as improvement of work, enhancement of education/training, etc., for the purpose of enhancing safety culture for all the licensees. Additionally, the NRA amended the RI Ordinance to require the specified permission users and permission waste management operators to describe the implementation system and the record of activities required for operation improvement activities among the quality assurance activities in their Radiation Hazards Prevention Program and it has been enforced since April 2018.

³³“Radioactive source” in this section means sealed radiation source of radioisotope according to the definition of IAEA Code of Conduct.

³⁴ CoC : Code of Conduct on the Safety and Security of Radioactive Sources

IRRS Follow-up Mission to JAPAN 2020

Documentary Evidence	<ul style="list-style-type: none">• Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act (The RI Act Article 38-4)• RI Ordinance Article 21
Results of Self-Assessment	Closed

12 Interface with nuclear security

12.1 Conclusions

Based on the self-assessment (SARIS) for interface with nuclear security, it finds that the NRA is now responsible for **nuclear safety** (Safety), **nuclear security** (Security), and safeguards (Safeguards) in an integrated manner, after the restructuring of government organizations incorporating lessons learned from the Fukushima Dai-ichi accident, which allows the NRA to prevent harmful interactions among regulatory activities for safety, security and safeguards.

Therefore, it **concluded** that the framework and measures for interface with security are, in principle, in accordance with the relevant IAEA safety requirement.

However, in the initial mission, the suggestion on studies for comprehensive assessment/monitoring of nuclear safety and security was provided. The NRA addressed this issue after considering response to it.

12.2 Legal basis and regulatory oversight activities

Based on the NRA Establishment Act, the NRA is responsible for **nuclear safety** (Safety), **nuclear security** (Security), and safeguards (Safeguards) and also for the coordination among the competent authorities for security matters on radioactive materials.

In the initial mission, the IRRS team observed that the improvement of the safety and security interface is one of the priority goals of actual NRA midterm 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 formalized. A concrete approach and project planning to put an effective safety and security interface into place has not been established yet. The NRA responded to the suggestion as follows.

Suggestion 13	Contents of Proposal
	The NRA should consider expediting improvements in the arrangements to assess, oversee, and enforce nuclear safety and security in an integrated manner.
	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.”
	Response Status
	The NRA formalized coordination and cooperation between the divisions responsible for safety and security. For example, when the application for permission is submitted from licensees, the division in charge of safety review refers to the division in charge of nuclear security and confirms whether there are any adverse effects from each perspective; the NRA started such operation in July 2018. The shared information is confirmed, and if there are any concerns about adverse effects, etc., an interview with the licensee will be organized, as required, to eliminate mutual adverse effects as much as possible.
	Also, from the aspect of inspections, it is assumed that the inspectors engaged in safety may also observe the actual situations related to nuclear security during the inspections. Therefore, in the case where the inspectors notice any matter related to nuclear security, the inspectors call the division in charge of nuclear security directly and notify the contents of the matter. In a case where there is any concern about adverse effects, etc., the NRA organizes an interview with the licensee, as required, and makes efforts to eliminate mutual adverse effects as much as possible.
	These procedures are similarly conducted for the communication from the division in charge of nuclear security to the one in charge of safety, not only for the communication from the division in charge of safety, but the one in charge of nuclear security. Similar efforts are being implemented

Suggestion 13	<p>not only between safety and security but also between safety and safeguards, and between security and safeguards. The NRA documented these operation methods and published it in April 2019.</p> <p>Moreover, in order to ensure that only qualified staff members including those related to safety have appropriate access to the documents related to confidential information on physical protection of nuclear material, the NRA formulated “Official Directives on Confirming the Trustworthiness of Staff in the NRA” in April 2018 to develop a new system for confirming the eligibility of persons who see confidential information on physical protection of nuclear material, etc. Confirmation of eligibility of staff members has been carried out sequentially.</p> <p>Additionally, the NRA conducted interviews for 27 licensees that are supposed to formulate the Physical Protection Program based on the Reactor Regulation Act among all licensees, and required the licensees to eliminate mutual adverse effects as much as possible and take appropriate measures, as well as to satisfy the standards for Safety, Security, and Safeguards respectively.</p> <p>As an additional effort, the NRA works on collecting interference cases for the purpose of examining the necessity of regulatory requirements, etc.</p>
Documentary Evidence	
<ul style="list-style-type: none"> • Practical work to coordinate the departments responsible for nuclear safety, nuclear security and safeguards 	
Results of Self-Assessment	
Closed	

12.3 Interface among authorities

The NRA supervises [planning/implementation](#) of safety, security, and safeguards, and manages the interface among these various regulatory activities to prevent any harmful interactions. The NRA is also responsible for coordination among competent authorities on security matters of radioactive materials.

The NRA developed the Code of Conduct on Nuclear Security Culture in January 2015 and the Policy Statement on Nuclear Safety Culture in May 2015, which stipulated the harmonization of regulatory activities for nuclear safety and nuclear security. The NRA management system incorporates these codes and statement into its basic policy. The NRA’s midterm goals (April 2015 through March 2020) under its management systems stipulate the efficient coordination for enhancing both safety and security.

The NRA is also responsible for safeguards, and, if there is a need, coordinates the interfaces among safety, security, and safeguards.

A List of Self Assessment Report Documentary Evidences

	Documentary Evidence	Applicable Article	File Name
Recommendation 1	1 The NRA Establishment Act	Article 4, Paragraph 2	[R1-1]The NRA Establishment Act.pdf
	2 The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority	the full text	[R1-2]The Policy on Ensuring the Operational Transparency.pdf
	3 Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	Act on Technical Standards for Prevention of Radiation Hazards Act, Article 5, para. 2	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
Recommendation 2	1 The Commercial Reactors Ordinance	Article 67, Article 79	[R2-1] The Commercial Reactors Ordinance.pdf
	2 The RI Act	Article 20	[R2-2] The RI Act Article 20.pdf
	3 The RI Ordinance	Article 20	[R2-3] The RI Ordinance Article 20.pdf
	4 Ordinary Radiation Monitoring (supplementary reference materials for Nuclear Emergency Response Guideline) (April 4, 2018 Nuclear Regulation Authority, Radiation Monitoring Division)	the full text	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
Recommendation 3	1 The RI Cabinet Order	Article 30 (Entry into force: September, 2019)	[R3-1] The RI Cabinet Order Article 30.pdf
Recommendation 4	1 Framework for management of the NRA	the full text	[R4-1,6-1] Framework for management of the NRA.pdf
	2 NRA Management Rules	the full text	[R4-2,6-2] NRA Management Rules.pdf
	3 Improvement of the NRA Management System	the full text	[R4-3,S4-1,5-1] Improvement of the NRA Management System.pdf
	4 Annual Priority Plan for FY2019	the full text	[R4-4] Annual Priority Plan for FY2019.pdf
Recommendation 5	1 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)	the full text	[R5-1] List of Items for EducationTraining.pdf
	2 Official Directives Related to Appointment of Positions that Require Highly Specialized Expertise and Experience (Chariman of the NRA, July 2 of 2019).	the full text	[R5-2] Official Directives Related to Appointment of Positions.pdf
	3 Basic Policy of Human Resource Development for NRA Officials (NRA, June 25 of 2014)	the full text	[R5-3,S10-1,A1-1] Basic Policy for Human Resource Development for NRA Officials.pdf
	4 Basic Policy for Safety Research in NRA (NRA, July 6 of 2016)	the full text	[R5-4] Basic Policy for Safety Research in NRA.pdf
	5 Joint Research Implementation Rules (Nuclear Regulatory Agency, April 21 of 2017)	the full text	[R5-5] Joint Research Implementation Rules.pdf
Recommendation 6	1 Framework for management of the NRA	the full text	[R4-1,6-1] Framework for management of the NRA.pdf
	2 NRA Management Rules	the full text	[R4-2,6-2] NRA Management Rules.pdf
Recommendation 7	1 The RI Act	Article 12-2, Article 12-8, Article 41-5, Article 43-3	[R7-1] The RI Act Article 12-2, 12-8, 41-5,43-3.pdf
	2 The RI Ordinance	Article 14-16	[R7-2] The RI Ordinance Article 14-16.pdf
	3 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.	the full text	[R7-3,11-5,S1-3] Perspective of Examination Standards for Operational Rules of.pdf
Recommendation 8	1 Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors Article 12-5-2, Article 22-7-3, Article 43-3, Article 43-3-33, Article 43-26-4, Article 50-4-3, Article 51-24-3, Article 57-4	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
	2 The Commercial Reactors Ordinance	Article 115-2 to 4	[R8-2] The Commercial Reactors Ordinance.pdf
	3 Operation guide related to preparation of decommissioning measures implementation policy (November 22 of 2017, NRA)	the full text	[R8-3, A7-1] Operation guide related to preparation of decommissioning.pdf
	4 The RI Act	Article 27, Article 28	[R8-4] The RI Act Article 27,28.pdf
	5 The RI Ordinance	Article 26	[R8-5] The RI Ordinance Article 26.pdf
Recommendation 9	1 List of relevant regulations/guides etc	the full text	[R9-1] List of relevant regulationsguides etc.pdf
	2 Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	The Reactor Regulation Act 61-2-2	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
	3 Enforcement Guide (for trial operation)	the full text	[R9-3,10-1] Enforcement Guide (for trial operation).pdf
Recommendation 10	1 Enforcement Guide (for trial operation)	the full text	[R9-3,10-1] Enforcement Guide (for trial operation).pdf

		Documentary Evidence	Applicable Article	File Name
Recommendation 11	1	The Latest Findings Reflection Process	the full text	[R11-1,S8-1] The Latest Findings Reflection Process.pdf
	2	List of 76 Latest Findings	the full text	[R11-2] List of 76 Latest Findings.pdf
	3	List of Correspondence Relations between Reviewd Regulatory Requirements and Guides	the full text	[R11-3] List of Correspondence Relations between Reviewd Regulatory.pdf
	4	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)	the full text	[R11-4, S7-2] Operational Guide for the Periodic Safety Assessment .pdf
	5	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.	the full text	[R7-3,11-5,S1-3] Perspective of Examination Standards for Operational Rules of.pdf
	6	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.	the full text	[R11-6] Interpretation on Reporting of the Accidents etc. to NRA.pdf
	7	Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program	the full text	[R11-7,12-3] Guide for the Particulars to be Mentioned in a Radiation Hazards .pdf
	8	On-site Inspection Guide for Registered Certification Organization, etc.	the full text	[R11-8,S1-4] On-site Inspection Guide for Registered Certification Organization.pdf
Recommendation 12	1	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	Act Concerning Prevention from Radiation Hazards due to Radioisotopes, etc. Article (The RI Act) Article 31-2, Article 38-4	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
	2	The RI Ordinance	Article 21	[R12-2] The RI Ordinance Article 21.pdf
	3	Guide for the Particulars to be Mentioned in a Radiation Hazards Prevention Program	the full text	[R11-7,12-3] Guide for the Particulars to be Mentioned in a Radiation Hazards .pdf
Recommendation 13	1	NRA EPR Guide (October 1 of 2018 NRA)	Table 2 8. and 9.	[R13-1] NRA EPR Guide 2.8,9.pdf
	2	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)	Article 7, Paragraph 1, Item 1, (ix) and (x) Article 14, para1 (ix) and (x)	[R13-2] Regulations relating to the events etc. to be reported by Nuclear Emergency Preparedness.pdf
	3	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)	Article 2, Paragraph 1, Item 17	[R13-3] Order Concerning Nuclear Operator's EPR Plan and Others that should be .pdf
	4	Explanations of Criteria for Determining the Emergency Categories in NRA EPR Guide (July 5 of 2017 NRA)	8. and 9.	[R13-4] Explanations of Criteria for Determining the Emergency Categories in NRA EPR Guide.pdf
	5	Viewpoints in reviewing the nuclear operator's EPR plan (September of 2017 NRA)	Ordinance for Nuclear Operator Emergency Action Plan etc. related to Article 2, para.1, item 17	[R13-5] Viewpoints in reviewing the nuclear operator's EPR plan .pdf
Suggestion 1	1	The RI Act	Article 12-2, Article 39, Article 41, Article 41-5, Article 41-11, Article 41-14, Article 43-3	[S1-1]The RI Act article 12-2, 39, 41, 41-5,41-11,41-14,43-3.pdf
	2	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))	the full text	[S1-2] The procedures for Conducting on-site inspections based on the Act on the Prevention.pdf
	3	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.	the full text	[R7-3,11-5,S1-3] Perspective of Examination Standards for Operational Rules of.pdf
	4	On-site Inspection Guide for Registered Certification Organization, etc.	the full text	[R11-8,S1-4] On-site Inspection Guide for Registered Certification Organization.pdf
Suggestion 2	1	Track record of adoption of new graduates and experienced workers	the full text	[S2-1] Track record of adoption of new graduates and experienced workers.pdf
Suggestion 3	1	The Policy on Ensuring the Operational Transparency of the Nuclear Regulatory Authority	the full text	[S3-1] The Policy on Ensuring the Operational Transparency of the Nuclear Regulator.pdf

		Documentary Evidence	Applicable Article	File Name
Suggestion 4	1	Improvement of the NRA Management System	the full text	[R4-3,S4-1,5-1] Improvement of the NRA Management System.pdf
	2	Statements on Nuclear Safety Culture	the full text	[S4-2] Statements on Nuclear Safety Culture.pdf
Suggestion 5	1	Improvement of NRA Management System	the full text	[R4-3,S4-1,5-1] Improvement of the NRA Management System.pdf
Suggestion 7	1	The Commercial Reactors Ordinance	Article 113	[S7-1] The Commercial Reactors Ordinance Article 113.pdf
	2	Operational Guide for the Periodic Safety Assessment of Continuous Improvement of Commercial Nuclear Reactors (established by NRA, amended on March 29 of 2017)	the full text	[R11-4, S7-2] Operational Guide for the Periodic Safety Assessment .pdf
Suggestion 8	1	The Latest Findings Reflection Process	the full text	[R11-1,S8-1] The Latest Findings Reflection Process.pdf
	2	The Technical Information Committee	the full text	[S8-2] The Technical Information Committee.pdf
Suggestion 10	1	Basic Policy for Human Resource Development for NRA Officials (NRA, June 25 of 2014)	the full text	[R5-3,S10-1,A1-1] Basic Policy for Human Resource Development for NRA Officials.pdf
Suggestion 11	1	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)	the full text	[S11-1] Nuclear Regulation Authority Initial Response Manual~NRA's response to large.pdf
Suggestion 12	1	Categorization of Emergency Worker	the full text	[S12-1] Categorization of Emergency Worker.pdf
	2	Ordinance on Prevention of Ionizing Radiation Hazards	Article 7-2_ Exceptional Emergency Dose Limit	[S12-2] Ordinance on Prevention of Ionizing Radiation Hazards Article7-2 .pdf
	3	Radiation Hazard Prevention for Staff ·National Personnel Authority's Rules 10-5	Article 4-2 and 3_ Dose Limit	[S12-3] Radiation Hazard Prevention for Staff ·National Personnel Authority's Rules 10-5 .pdf
	4	The Notification to Establish Dose Limits in Accordance with the Provisions of NRA Ordinance on Activity of Refining Nuclear Source or Nuclear Fuel Materials	Article 7_Dose Limit in Emergency Work	[S12-4] The Notification to Establish Dose Limits in Accordance with the Provisions of NRA Ordinance.pdf
Suggestion 13	1	Practical work to coordinate the departments responsible for nuclear safety, nuclear security and safeguards	the full text	[S13-1] Practical work to coordinate the departments responsible for nuclear safety.pdf
A1	1	Basic Policy of Human Resource Development for NRA Officials (Materials of Committee as of June 25 of 2014)	the full text	[R5-3,S10-1,A1-1] Basic Policy for Human Resource Development for NRA Officials.pdf
A2	1	NRA Organization Chart	the full text	[A2-1,3-3] NRA Organization Chart.pdf
	2	Image of Education and Training Courses (FY2018 Annual Report Figure 4-2)	the full text	[A2-2,3-2] Image of Education and Training Courses (FY2018 Annual Report Figure 4-2).pdf
A3	1	Procedures related to Development of Staff.(September 3, 2014, the NRA Secretariat / the NRA Human Resource Development Center)	the full text	[A3-1] Procedures related to Development of Staff.pdf
	2	Image for Education/Training Curriculum (FY2018 Annual Report Figure 4-2)	the full text	[A2-2,3-2] Image of Education and Training Courses (FY2018 Annual Report Figure 4-2).pdf
	3	NRA Organization Chart	the full text	[A2-1,3-3] NRA Organization Chart.pdf
A6	1	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors Article 13, Article 14, Article 23, Article 24, Article 43-3-5, Article 43-3-6, Article 43-4, Article 43-5, Article 51-2, Article 51-3	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
A7	1	Operation guide related to preparation of decommissioning measures implementation policy (November 22 of 2017, NRA)	the full text	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
	2	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	The Reactor Regulation Act Article 12-5-2, Article 22-7-3, Article 43-3, Article 43-3-33, Article 43-26-4, Article 50-4-3, Article 51-24-3, Article 57-4	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
A8	1	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	The Reactor Regulation Act Article 16-2, Article 27, Article 43-3-9, Article 43-8, Article 45, Article 51-7	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
A11	1	The Guideline for a Safety Improvement Evaluation of Uranium Fabrication Facilities (March 6 of 2019)	the full text	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
A16	1	The interpretation of the regulations regarding the location, structure, and equipment standards of Category 2 waste disposal facilities	Article 13	[A11-1] The Guideline for a Safety Improvement Evaluation of Uranium Fabrication Facilities.pdf
A17	1	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	Act Concerning Prevention from Radiation Hazards due to Radioisotopes, etc. (the RI Act, etc.) Article 33-2	[A16-1] The interpretation of the regulations regarding the location, structure, and.pdf
A19	1	Principles of radiation protection measures of the crystalline lens of the eye (advice)	the full text	[R1-3,8-1,9-2,12-1,A6-1,7-2,8-1,17-1,24-1] Comparison table of prior and amended .pdf
A24	1	Comparison table of prior and amended article provisions for Act to partly amend the Reactor Regulation Act	The RI Act Article 38-4	[A19-1] Principles of radiation protection measures of the crystalline lens of the eye.pdf
	2	The RI Ordinance	Article 21	[A24-2] The RI Ordinance Article21.pdf