

IRRS Follow-up Mission to JAPAN 2020

SARIS Summary Report
(Safety Requirements for Transport of Radioactive Material)

November 2019

Ministry of Internal Affairs and Communication
Ministry of Health, Labour and Welfare
Nuclear Regulation Authority

Japan

Contents

1	Framework for safety regulation of transport of radioactive materials in Japan	3
2	Authorization	4
2.1	Authorization in land transport of nuclear fuel materials etc.	4
2.1.1	Conclusions	4
2.1.2	Generic issues	5
2.1.3	Authorization requirements for transport	5
2.1.4	Improvement of the competence of the staff of Nuclear Regulation Authority related to transport of nuclear fuel materials etc.	6
2.1.5	Action Plan	6
2.2	Authorization in land transport of nuclear source materials	6
2.2.1	Conclusions	6
2.2.2	Generic issues	6
2.3	Authorization in land transport of radioisotopes etc.	7
2.3.1	Conclusions	7
2.3.2	Generic issues	7
2.3.3	Authorization requirements for transport	7
2.3.4	Improvement of the competence of the staff of Nuclear Regulation Authority related to transport of radioisotopes etc.	8
2.4	Authorization in land transport of radiopharmaceuticals	8
2.4.1	Conclusions	8
2.4.2	Generic issues	8
2.5	Authorization in land transport by post etc.	8
2.5.1	Conclusions	8
2.5.2	Generic issues	8
3	Review and assessment	9
3.1	Review and assessment in land transport of nuclear fuel materials etc.	9
3.1.1	Conclusions	9
3.1.2	Generic issues	9
3.2	Review and assessment in land transport of radioisotopes etc.	10
3.2.1	Conclusions	10
3.2.2	Generic issues	10
3.3	Review and assessment in land transport of radiopharmaceuticals	11
3.3.1	Conclusions	11
3.3.2	Generic issues	12
3.4	Review and assessment in land transport by post etc.	12
3.4.1	Conclusions	12
3.4.2	Generic issues	12
4	Inspection	12
4.1	Inspection in land transport of nuclear fuel materials etc.	12
4.1.1	Conclusions	12
4.1.2	Generic issues	12
4.2	Inspection in land transport of nuclear source materials	13
4.2.1	Conclusions	13
4.2.2	Generic issues	13
4.3	Inspection in land transport of radioisotopes etc.	13
4.3.1	Conclusions	13
4.3.2	Generic issues	13
4.4	Inspection in land transport of radiopharmaceuticals	14
4.4.1	Conclusions	14
4.4.2	Generic issues	14
4.5	Inspection in land transport by post etc.	14
4.5.1	Conclusions	14
4.5.2	Generic issues	14
5	Enforcement	14

5.1	Enforcement in land transport of nuclear source materials and nuclear fuel materials etc.	14
5.1.1	Conclusions	14
5.1.2	Generic issues	15
5.2	Enforcement in land transport of radioisotopes etc.	15
5.2.1	Conclusions	15
5.2.2	Generic issues	15
5.3	Enforcement in land transport of radiopharmaceuticals	16
5.3.1	Conclusions	16
5.3.2	Generic issues	16
5.4	Enforcement in transport by post etc.	16
5.4.1	Conclusions	16
5.4.2	Generic issues	17
6	Regulations and guides	17
6.1	Regulations and guides in land transport of nuclear source materials and nuclear fuel materials etc.....	17
6.1.1	Conclusions	17
6.1.2	Generic issues	17
6.1.3	Action plan	19
6.2	Regulations and guides in land transport of radioisotopes etc.	20
6.2.1	Conclusions	20
6.2.2	Generic issues	20
6.3	Regulations and guides in land transport of radiopharmaceuticals.....	20
6.3.1	Conclusions	20
6.3.2	Generic issues	20
6.4	Regulations and guides in transport by post etc.....	21
6.4.1	Conclusions	21
6.4.2	Generic issues	21
7	Emergency response	21
7.1	Emergency response in land transport of radioactive materials	21
7.1.1	Conclusions	21
7.1.2	Generic issues	21
7.1.3	Action Plan.....	22
8	Radiation protection	24
8.1	Radiation protection in land transport of nuclear source materials and nuclear fuel materials etc.....	24
8.1.1	Conclusions	24
8.1.2	Generic issues	24
8.2	Radiation protection in land transport of radioisotopes etc.	24
8.2.1	Conclusions	24
8.2.2	Generic issues	24
8.3	Radiation protection in land transport of radiopharmaceuticals.....	25
8.3.1	Conclusions	25
8.3.2	Generic issues	25
8.4	Radiation protection in transport by post etc.....	25
8.4.1	Conclusions	25
8.4.2	Generic issues	25

1 Framework for safety regulation of transport of radioactive materials in Japan

There are several responsible authorities for the regulation for safe transport of radioactive materials in Japan, according to the type of materials to be transported (nuclear fuel material, nuclear source materials, radioisotopes and radiopharmaceuticals) and mode of transport (land, sea, air and post), they are appropriately developed according to the requirements for authorization on safety regulations specified in IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) without overlapping and thus basically comply with IAEA safety standards on transport, except for the issues described later.

The responsibilities of the related ministries are as follows. (see Figure 1.)

Regarding the safety regulations related to land transportation of nuclear fuel materials, based on the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (hereinafter referred to as “the Reactor Regulation Act”), Nuclear Regulation Authority (NRA) is responsible for the regulations on packages. Additionally, Ministry of Land Infrastructure, Transport and Tourism (MLIT) is responsible for the safety regulations on the transport methods.

Based on the Reactor Regulation Act, NRA is responsible for packages and transport method related to the safety regulations of land transportation of nuclear source materials.

Regarding the safety regulations related to land transport of radioisotopes, based on the Act on the Regulations on Radioisotopes etc. (hereinafter referred to as “the RI Act”), NRA is responsible for the regulations of packages. Additionally, MLIT is responsible for the regulations on the transport methods.

Ministry of Health Labour and Welfare (MHLW) is responsible for the safety regulations for radiopharmaceuticals, both for packages and transport methods, based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as “the Pharmaceuticals and Medical Devices Act”).

Ministry of Internal Affairs and Communication (MIC) is responsible for the safety regulations for transport of radioactive materials by post etc., based on the Postal Act and the Act on Correspondence Delivery by Private Business Operators (hereinafter referred to as “the Postal Act etc”).

Furthermore, MLIT is responsible for the safety regulations for sea transport and air transport of radioactive materials both for packages and transport methods, based on the Ship Safety Act and the Civil Aeronautics Act, respectively. Additionally, the National Police Agency and the Japan Coast Guard are responsible for the date and route of transportation to secure safety.

For the purpose of liaison and coordination among related regulatory authorities responsible for safety regulations for transport of radioactive materials, “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” are regularly held (2 to 4 times a year), where the opinions are exchanged regarding information exchange and issues related to establishment and amendment of IAEA regulations for the safe transport of radioactive material, the matters related to domestic laws and regulations based on the said regulations and the matters related to safety measures for transport.

Please note that the scope of the review related to transport of radioactive materials in the IRRS follow-up mission, will include only following part of land transportation among all the transport modes: the part related to regulations on land transport of nuclear fuel materials and nuclear source materials and radioisotopes that NRA is responsible for (regarding nuclear fuel materials and radioisotopes, limited to the regulations related to packages), the part related the regulations on land transport of radiopharmaceuticals that MHLW is responsible for, and the part related to the regulations on transport of radioactive materials by post etc. that MIC is responsible for, and the part that requires liaison with the relevant bodies such as emergency response (interface related part only).

Mode of Transport Radioactive Materials	Land Transport		Sea Transport (packages/transport method)	Air Transport (packages/transport method)
	Packages	Transport Method		
Nuclear Fuel Materials etc.	Reactor Regulation Act • NRA Ordinance on Off-Site Transportation of Nuclear Fuel materials, etc. (NRA)	Reactor Regulation Act • MLIT Ordinance on Vehicle Transport of Nuclear Fuel Materials, etc. (MLIT)	Ship Safety Act (MLIT)	Civil Aeronautics Act (MLIT)
Radioisotopes	RI Act • NRA Ordinance for Enforcement of the Act on the regulation of Radioisotopes, etc. (NRA)	RI Act • MLIT Ordinance on Vehicle Transport of Radioisotopes (MLIT)		
Radiopharmaceuticals	Pharmaceuticals and Medical Devices Act (MHLW)			

- ✓ Land transport of nuclear source materials are regulated by the Reactor Regulation Act. (NRA)
- ✓ Transport by post etc. is regulated by the Postal Act in addition to the above-mentioned Act. (MIC)

- The National Police Agency and the Japan Coast Guard: the date and route of transportation to secure safety.
- Fire and Disaster Management Agency: response to fire/accidents etc.

Figure 1. Framework for Safety Regulation of Transport of Radioactive Materials in Japan

2 Authorization

2.1 Authorization in land transport of nuclear fuel materials etc.

2.1.1 Conclusions

Based on the self-assessment (SARIS) for the requirements for authorization of land transport of nuclear fuel materials or the materials contaminated by nuclear fuel materials (hereinafter referred to as “nuclear fuel materials etc.”), it finds that the Reactor Regulation Act provide the legal framework for authorizations appropriately. The requirements, formats and contents of applications for approval, and criteria for the review are well developed, tailored for each authorization stage, based on a graded approach according to radiation risk. 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:

- Maintaining consistency and compliance in the management of authorization related to transport of radioactive materials is important. Therefore, NRA should consider to improve the competence of the staff in cooperation with the staff of other regulatory authorities concerned through job training.

To address these challenges, NRA will implement improvement measures based on the Action Plan as shown in 2.1.5.

2.1.2 Generic issues

For transport of nuclear fuel materials, pursuant to Article 59(1) of the Reactor Regulation Act, a nuclear operator (including a person to which shipment has been entrusted from a nuclear operator, etc. The same shall apply hereinafter) shall take the necessary safety measures in compliance with the technical standards specified in the NRA regulations.

Additionally, when necessary for prevention of disasters (in the case of transporting fuel package, fissile package, Type B (U) package or Type B (M) package outside the sites that contain 0.1 kg or more of uranium hexafluoride that requires design approval of package in SSR-6), a nuclear operator shall obtain the confirmation of NRA before shipment in accordance with Article 59(2) of the Reactor Regulation Act. NRA shall require the nuclear operator to submit documents to explain safety of packages upon application for authorization to NRA, pursuant to Article 19 of the NRA Ordinance on Off-Site Transportation of Nuclear Fuel Material etc. (hereinafter referred to as “the Nuclear Off-Site Transportation Ordinance”), NRA has the authority to determine the said authorization of confirmation of the packages related to land transport of nuclear fuel materials etc.

2.1.3 Authorization requirements for transport

A nuclear operator shall be required to obtain package confirmation by NRA before shipment when necessary for prevention of disasters as described in 2.1.2, pursuant to Article 59(2) of the Reactor Regulation Act. The nuclear operator can gradually obtain package design approval and packaging approval prior to package confirmation. In the case where the nuclear operator obtain those approvals, the said nuclear operator shall be able to omit submission of the documents etc. for applications for packaging approval and package confirmation respectively. NRA shall examine compliance with the technical standards specified in the Nuclear Off-Site Transportation Ordinance in each stage of package design approval, packaging approval and package confirmation, based on the applications from nuclear operators according to the type of the nuclear fuel package.

For package design approval, NRA shall examine safety of package design, quality management system of nuclear operators related to design/manufacturing/maintenance/handling of package including the training of the staff, maintenance/handling method of packages. In the case where the design of the package is approved as complying with the technical standard, NRA shall issue “the certificate for package design containing nuclear fuel material”.

For packaging approval, in addition to the examination matters of package design approval, NRA shall examines the specifications of nuclear fuel materials to be contained, manufacturing method of packaging (including the quality management system related to manufacturing method of packaging), that the said packaging complies with the design and manufacturing method and the said package is maintained and manufactured and maintained in compliance with design and manufacturing method. In the case where the packaging is approved as complying with the technical standard, NRA shall issue “the certificate for packaging approval” with individually identified “register number for approved packaging”. Additionally, NRA shall manage the “register number for approved packaging”.

For package confirmation, in addition to the examination matters of packaging approval (possible to be omitted in the case of having obtained package design approval), NRA shall examine the specifications of nuclear fuel materials to be transported and inspection prior to shipment of package. In the case where the package is approved as complying with the technical standard, NRA shall issue “transport confirmation certificate”.

Furthermore, in the case where it is extremely difficult to transport the package in accordance with the transport regulations of the Reactor Regulation Act, NRA shall examines the measures and reasons that are difficult to be taken and take necessary measures pursuant to Article 14 of the Nuclear Off-Site Transportation Ordinance. In the said examination, in the case where NRA recognized that necessary measures are taken to secure safe transport and there is no obstacle to secure safety, it shall issue the certificates related to specific measures (limited to the part related to package).

Additionally, as a part of amendment and establishment of relevant regulations/guides associated with enforcement of new inspection system (scheduled to enact in April of 2020), NRA will requires the nuclear operators that will conduct land transport of nuclear fuel materials etc. to develop the method and the organization related to the implementation of quality management related to transport of nuclear fuel materials and preserve the records.

2.1.4 Improvement of the competence of the staff of Nuclear Regulation Authority related to transport of nuclear fuel materials etc.

For improvement of the competence of the staff of regulatory body related to transport of nuclear fuel materials etc., as well as the staff of related to commercial nuclear reactor facilities, in addition to the ability evaluation as a part of personnel evaluation for the staff, Nuclear Regulation Authority establishes the basic policy for human resource development and specifies the qualifications to the positions that require highly professional expertise and experience. Then it evaluates the competence of individual staff by conducting oral examination corresponding to each qualification for appointment to the staff engaged in the duties as safety examiners and assigned appropriate qualification for appointment. Subsequently, it has been improved continuously by implementing various kinds of training programs including OJT.

As mentioned above, there are several responsible authorities for the authorization of transport of radioactive materials, maintaining consistency and compliance in the management of authorization related to transport of radioactive materials is important. Therefore, NRA will implement improvement measures based on the Action Plan as shown in 2.1.5 in cooperation with the relevant regulatory authorities, considering adoption of the latest Edition of IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition) into domestic regulations.

2.1.5 Action Plan

No.	1
Basis	(B1) IAEA safety standard states “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.) 【GSR Part1 (Rev.1) R11, para 2.35.】.
Recommendation	(R1) Maintaining consistency and compliance in the management of authorization related to transport of radioactive materials is important. Therefore, NRA should consider to improve the competence of the staff in cooperation with the staff of relevant regulatory authorities by utilizing the training programs.
Action Plan	(A1) Maintaining consistency and compliance in the management of authorization related to transport of radioactive materials is important. Therefore, NRA will consider to improve the competence of the staff in cooperation with the staff of relevant regulatory authorities by providing the training programs.

2.2 Authorization in land transport of nuclear source materials

2.2.1 Conclusions

Based on the self-assessment (SARIS) for the requirements for authorization of land transport of nuclear source materials, it finds that the Reactor Regulation Act provide the legal framework for authorizations appropriately based on a graded approach according to radiation risk. Therefore, in principle, it identified that the requirements such as the standards for authorization are in accordance with relevant IAEA safety requirements.

2.2.2 Generic issues

For transport of nuclear source materials, in compliance with the Reactor Regulation Act, a licensed user of nuclear source materials shall conduct shipment in compliance with the technical standards based on Graded approach according to radiation risk specified by the regulatory authority (the NRA Ordinance on Use of Nuclear Source Materials, Article 2(xii)).

2.3 Authorization in land transport of radioisotopes etc.

2.3.1 Conclusions

Based on the self-assessment (SARIS) for the requirements for authorization of land transport of radioisotopes or the materials contaminated by radioisotopes (hereinafter referred to as “radioisotopes etc.”), it finds that the RI 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, based on a graded approach according to radiation risk. 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:

- It is important that NRA has consistency and compliance in the management of authorization related to transport of radioactive materials. Therefore, it is necessary to improve the competence of the staff in cooperation with the staff of other regulatory authorities concerned through training.

To address these challenges, NRA will implement improvement measures based on the Action Plan as shown in 2.1.5.

2.3.2 Generic issues

For transport of radioisotopes etc., pursuant to Article 18(1) of the RI Act, permission or notification users etc. shall take the necessary safety measures to prevent radiation hazards in compliance with the technical standards specified in the NRA regulations.

Additionally, pursuant to Article 18(2) of the RI Act, when necessary for prevention of radiation hazards (in the case of transporting Type B (U) package or Type B (M) package outside the sites that requires design approval of package in SSR-6), permission or notification users shall obtain the confirmation of NRA before shipment by the administration. NRA shall require the applicants to submit documents to explain safety of packages upon application for authorization to NRA, pursuant to the NRA Ordinance for Enforcement of the Act on Regulation of Radioisotopes, etc. (hereinafter referred to as “the RI Ordinance”). In the case of confirmation of the package related to land transport of radioisotopes etc., the certification for transport confirmation related to package shall be issued. Before transport confirmation, the applicants can obtain packaging approval and can also obtain the package design approval. In addition, in the framework, special arrangement regarding transport of radioisotopes etc., can also be approved.

2.3.3 Authorization requirements for transport

Permission or notification users etc. are required to obtain confirmation by the administration (package confirmation) for Type B (U) package or Type B (M) package that the RI Act specifies as specially necessary to prevent radiation hazards before transport, based on Article 18(2) of the RI Act.

Prior to package confirmation, regarding compliance with the technical standard of packaging used for transport, permission or notification users etc. can obtain approval from NRA (packaging approval) can gradually obtain package design approval and packaging approval prior to package confirmation, based on Article 18(3) of the RI Act. When it conducts packaging approval, NRA shall issue “the certificate for packaging” by assigning a series of individually identified “register number for approved packaging”. Additionally, NRA shall manage the “register number for approved packaging”.

Furthermore, prior to packaging approval, regarding the design of packaging partly contained in packaging approval, based on Article 18-17(4) of the RI Ordinance, the permission or notification users etc. can obtain the approval (package design approval) from NRA in advance, regarding compliance with the technical standard.

Moreover, based on Article 18-12 of the RI Ordinance, pursuant to the technical standard for various radioactive package, the permission or notification users can transport the packaging in the case where it is extremely difficult to transport the package in accordance with the technical standards specified in Article 18-3 of the NRA Ordinance for Enforcement of the Act on regulation of Radioisotopes, etc. and

in the case where NRA recognizes that necessary measures are taken to secure safe transport and there is no obstacle to secure safety even if the said users transport the packaging not pursuant to the regulations of radioactive package.

2.3.4 Improvement of the competence of the staff of Nuclear Regulation Authority related to transport of radioisotopes etc.

For improvement of the competence of the staff of regulatory body related to transport of radioisotopes etc., in addition to the ability evaluation as a part of personnel evaluation for the staff, NRA establishes the basic policy for human resource development and specifies the qualifications to the positions that require highly professional expertise and experience. Then it evaluates the competence of individual staff by conducting oral examination corresponding to each qualification for appointment to the staff engaged in the duties as safety examiners and assigned appropriate qualification for appointment. Subsequently, it has been improved continuously by implementing various kinds of training programs including OJT.

There are several responsible authorities for the authorization of transport of radioisotopes etc., maintaining consistency and compliance in the management of authorization related to transport of radioactive materials. Therefore, as well as for transport of nuclear fuel materials etc., NRA will implement improvement measures based on the Action Plan as shown in 2.1.5 in cooperation with the relevant regulatory authorities.

2.4 Authorization in land transport of radiopharmaceuticals

2.4.1 Conclusions

Regarding authorization on transport of radiopharmaceuticals, pursuant to Ministerial Ordinance/Notification based on the provisions of Pharmaceuticals and Medical Devices Act, similarly as the RI Act, MHLW performs necessary regulations appropriately by specifying rules/standard to incorporate IAEA safety standards.

2.4.2 Generic issues

Including the cases to handle radiopharmaceuticals, under the Pharmaceuticals and Medical Devices Act, manufacturers of pharmaceuticals, marketing authorization holders, wholesale distributors and pharmacy proprietors are respectively required to obtain prescribed License. Where and to the extent land transport of radiopharmaceuticals is performed pursuant to the Ministerial Ordinance/Notification based on the provisions of Pharmaceuticals and Medical Devices Act, neither approval nor certificate is required related to the said transport. However, in the case where it is extremely difficult to transport pursuant to the said rule/standard, specific measures can be taken to provide approval for land transport that does not comply with the said rule/standard assuming that there is no obstacle for safety.

2.5 Authorization in land transport by post etc.

2.5.1 Conclusions

Regarding transport by post etc., pursuant to the Ministerial Ordinance/Notification based on the Postal Act etc., MIC performs necessary regulations appropriately by specifying rules/standards regarding handling of radioactive materials etc., in compliance with IAEA safety standard. Additionally, under the Postal Act etc., handling of nuclear fuel materials that require authorizations etc. specified in IAEA safety standard is prohibited. It is specified that the transport of radioactive materials is acceptable only if radiation of the said radioactive materials does not exceed 1/10 of Type L package and satisfies specific conditions.

2.5.2 Generic issues

At present, under the Postal Act etc., while only Japan Post Co., Ltd. can provide post services, there

is a license system for correspondence delivery. Under the Postal Act etc., handling of radioactive materials etc. by post etc. is in principle prohibited. However, the transport of radioactive materials is acceptable only if radiation of the said radioactive materials does not exceed 1/10 of Type L package and satisfies specific conditions. In such case, neither approval nor certificate is required related to the transport of the said radioactive materials.

3 Review and assessment

3.1 Review and assessment in land transport of nuclear fuel materials etc.

3.1.1 Conclusions

Based on the self-assessment (SARIS) for review and assessment related to transport of nuclear fuel materials etc., it finds that the relevant laws and regulations provide the legal framework requiring licensees to conduct safety assessment, and NRA conducts its review and assessment on the licensees' applications before authorization. This legal framework (law, regulation, instruction) is well developed with consideration of a graded approach according to radiation risk. Therefore, it identifies that the framework and measures for review and assessment are in principle systematically in accordance with the relevant IAEA safety requirements, except in the following circumstance as described in **6. Regulations and guides**.

3.1.2 Generic issues

Article 59(2) of the Reactor Regulation Act requires the submission of applications and necessary appendixes that explain the safety and other measures for transport for nuclear fuel materials etc. subject to the conformation by NRA that the conditions for regulatory requirements and authorizations are satisfied.

NRA develops and publishes its ordinances, standards and guides, similar to the examinations for commercial reactor facilities. 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 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.

Information to be provided upon applications

《Package design approval》

- Explanatory documents on safety of nuclear fuel package
- (i) Explanation for nuclear fuel packages and safety analysis of nuclear fuel packages
- (ii) Basic policy for quality management related to design, manufacturing, handling and maintenance etc. of nuclear fuel packages in general
- (iii) Maintenance of packaging and handling method of nuclear fuel packages

《Packaging Approval》

- Explanatory documents on nuclear fuel materials etc. to be transported
- Explanatory documents on safety of package of nuclear fuel materials (possible to be omitted in the case of having obtained package design approval)
- Explanatory documents on manufacturing method of packaging (including explanation on inspection method of packaging, explanation on quality management of manufacturing)
- Explanatory documents that prove that packaging is manufactured according to the method for design and manufacturing (including the results of packaging inspection, the results of quality auditing related to manufacturing of packaging)
- Explanatory documents that proves that packaging is maintained in compliance with the design and the method for manufacturing (maintenance records of packaging after completion of packaging until the application of packaging approval)

《Package confirmation》

- Explanatory documents on nuclear fuel materials etc. to be transported
- Explanatory documents on safety of nuclear fuel package (possible to be omitted in the case of having obtained packaging approval)
- Explanatory documents on manufacturing method of packaging (including explanation related to the method of inspection of packaging and explanation related to quality management related to manufacturing, possible to be omitted in the case of having obtained packaging approval)
- Explanatory documents that proves that packaging is manufactured in compliance with the design and the method for manufacturing (including the results of packaging inspection, the results of quality audits related to manufacturing of packaging, possible to be omitted in the case of having obtained packaging approval)
- Explanatory documents that proves that packaging is maintained in compliance with the design and the method for manufacturing (maintenance records of packaging after completion of packaging until the application of package confirmation; however, possible to be partly omitted in the case of having obtained packaging approval)
- Explanatory documents on the inspection of nuclear materials prior to shipment

Additionally, a certificate is issued for package design approval and packaging approval, which has a period of five years in principle. It may also be renewed when confirmed that there is no modification in design and the packaging is properly maintained and controlled.

3.2 Review and assessment in land transport of radioisotopes etc.

3.2.1 Conclusions

Based on the self-assessment (SARIS) for review and assessment related to transport of radioisotopes etc. specified in IAEA safety standard, it finds that the RI Act provide the legal framework requiring licensees to conduct safety assessment for each authorization stage of regulated facilities and activities, and under which NRA conducts its review and assessment on the users' applications before authorization. This legal framework (law, regulation, instruction) is well developed with consideration of a graded approach according to radiation risk etc. Therefore, it identifies that the framework and measures for review and assessment are in principle systematically in accordance with the relevant IAEA safety requirements, except in the following circumstance as described in **6. Regulations and guides**.

3.2.2 Generic issues

For transport of radioisotopes etc., pursuant to Article 18(1) of the RI Act, permission or notification users etc. shall take the necessary safety measures to prevent radiation hazards in compliance with the technical standards.

Pursuant to Article 18(2) of the RI Act, in the case where it is identified that the measures for the transport of Type B (U) package or Type B (M) package that requires design approval of package required by the administration in order to prevent radiation hazards complies with the technical standard by the applications of packaging confirmation by permission or notification users, by the confirmation of the application and its appendix regarding the following matters or the confirmation of actual delivery place of packaging, NRA shall issue “a certificate for packaging confirmation”.

- ① Explanatory documents regarding radioisotopes etc. to be transported
- ② Explanatory documents regarding the structure, materials and manufacturing method of packaging that packages the said radioisotopes and safety of radioisotopes etc. in the case where the said radioisotopes are packaged in the said packaging
- ③ Explanatory documents that prove that the packaging is manufactured according to the design of the packaging
- ④ Explanatory documents that prove that packaging is maintained in compliance with the design

of the packaging

- ⑤ Explanatory documents on the inspection of package containing the radioactive materials prior to shipment

Prior to the above-mentioned packaging confirmation, based on Article 18(3) of the RI Act, permission or notification users etc. can obtain packaging approval regarding compliance with the technical standard of the packaging used for transport. In the case where the compliance of the packaging with technical standard is approved by permission or notification users' submission of the applications and appendix explanatory documents for the packaging approval application by the users based on the RI Act, NRA shall issue "a certificate for packaging confirmation".

- ① Explanatory documents regarding radioisotopes etc. scheduled to be transported by packaging
- ② Explanatory documents regarding packaging design and radioisotopes etc. in the case where radioisotopes etc. are packaged in the said packaging
- ③ Explanatory documents that prove that the packaging is manufactured according to the design of the packaging
- ④ Explanatory documents that prove that packaging is maintained in compliance with the design of ②

In addition, based on Article 18-17 of the RI Act, regarding compliance with the technical standard regarding the package design as a part of packaging approval, packaging design approval can be obtained in advance. NRA shall issue "the certificate for package design containing nuclear fuel material" upon conducting package design approval.

Upon examination of packaging approval conducted prior to package confirmation, NRA independently evaluates and verifies safety analysis documents and their relevant examination data and technical data for technical standard specified by the RI Act and the RI Ordinance etc. On the occasion, NRA may require the ground of analysis and additional analysis. Furthermore, it is identified that the packaging is manufactured according to the design based on the results of inspections such as material inspections and welding inspections etc.

Additionally, NRA requires the users etc., in compliance with "Examination Guideline for Quality Management related to Manufacturing of Packaging of Nuclear Fuel Materials" to establish and implement quality management system related to packaging.

NRA shall require the users etc. to take necessary measures to prevent radiation hazards pursuant to technical standard based on the RI Act, regarding transport of radioisotopes etc.

For the valid period related to packaging approval, the period of usage in the application of packaging approval shall be described. While there is no legal standard, the said period shall be described in the certificate of packaging approval with consideration of service life of the packaging itself. In addition, upon renewal of the period of package approval, the renewal of the period for use can be approved by proving that the said packaging is maintained in compliance with the design of packaging.

Also, regarding the application for renewal of package design approval, the valid period can be renewed as specified in Article 25 of Notification that specifies the details etc. related to the technical standard regarding transport outside the Sites of Radioisotopes etc. that specifies the details etc. related to the technical standard pursuant to the RI Act regarding transport outside the Sites of Radioisotopes etc. as well, by proving that there is no modification in design.

Regarding transport of radioisotopes etc., the users etc. shall be required to take necessary measures to prevent radiation hazards in accordance with the technical standard based on the RI Act. In the case of transport of Type B (U) package and Type B (M) package, the users etc. shall obtain packaging confirmation by the administration on each occasion. In such cases, NRA confirms the valid period described on the certificate of packaging approval as well.

3.3 Review and assessment in land transport of radiopharmaceuticals

3.3.1 Conclusions

Regarding review and assessment on land transport of radiopharmaceuticals, pursuant to Ministerial Ordinance/Notification based on the provision of the Pharmaceuticals and Medical Devices Act,

similarly as the RI Act, MHLW performs necessary regulations appropriately by specifying rules/standards to incorporate IAEA safety standard. As long as land transport of radiopharmaceuticals is performed according to the said rules/standard, review and assessment in advance related to the said transport shall not be required.

3.3.2 Generic issues

Regarding review and assessment on land transport of radiopharmaceuticals, pursuant to the Ministerial Ordinance/Notification based on the provision of the Pharmaceuticals and Medical Devices Act, MHLW performs necessary regulations appropriately by specifying rules/standard to incorporate IAEA safety standard. As long as land transport of radiopharmaceuticals is performed according to the said rules/standards, review and assessment in advance related to the said transport shall not be required.

3.4 Review and assessment in land transport by post etc.

3.4.1 Conclusions

Under the Postal Act etc., handling of nuclear fuel materials that require authorizations etc. specified in IAEA safety standard is prohibited, which is identified as compliance with IAEA safety standard.

3.4.2 Generic issues

At present, under the Postal Act etc., while only Japan Post Co., Ltd. can provide post services, there is a license system for correspondence delivery. Under the Postal Act etc., handling of radioactive materials etc. by post etc. is in principle prohibited. However, the transport of radioactive materials is acceptable (limited to the case where radiation of the said radioactive materials does not exceed 1/10 of Type L package and satisfies specific conditions) pursuant to Ministerial Ordinance/Notification based on the Postal Act. In such case, neither approval nor certificate is required related to the transport of the said radioactive materials.

4 Inspection

4.1 Inspection in land transport of nuclear fuel materials etc.

4.1.1 Conclusions

Based on the self-assessment (SARIS) for the inspection related to transport of nuclear fuel materials etc., similarly to the inspection system for commercial reactor facilities, it finds that the Reactor Regulation Act provide the legal framework for the inspection related to transport of nuclear fuel materials etc. appropriately. The framework to confirm the licensees' appropriate response to the regulatory requirements related to transport of nuclear fuel materials etc. is well developed by on-site inspection in confirmation system of transport related to package. Therefore, it identified that the framework is in principle in accordance with relevant IAEA safety requirements.

4.1.2 Generic issues

In the inspection for transport of nuclear fuel materials etc., pursuant to the Reactor Regulation Act, based on graded approach according to radiation risk, application for package confirmation of Type B package, NRA shall confirm propriety of the inspection contents by attending the pre-shipment inspection conducted by the nuclear operators, if necessary. Additionally, in the inspection based on application for packaging approval or package design approval, as the prior procedure of package confirmation, regarding the compliance of the contents of the said application with the technical standard, NRA normally confirm by the documents submitted. However, based on graded approach, the staff of NRA may directly confirm the compliance with the technical standard by entering into the sites of the nuclear operators etc. or the manufacturers that manufacture the packaging.

Further, due to enforcement of amended Reactor Regulation Act (scheduled to enact in April of 2020), various inspections that had been conducted by NRA will be integrated to Nuclear Regulation Inspection, allowing NRA to monitor/evaluate the implementation status of the measures to be taken by the licensees pursuant to law by setting the inspection samples according to the risk without limit to the timing and objects. Pursuant to Article 68(2) and Article 61-2-2 of amended Act, NRA will have authority to enter and confirm the sites such as the plants of the licensees, manufacturers and the persons concerned that conduct transport of nuclear fuel materials etc. as the nuclear regulation inspections as required for enforcement of the amended Act. Thus, necessary ordinance/guides shall be developed by the said enforcement (scheduled to enact in April of 2020).

4.2 Inspection in land transport of nuclear source materials

4.2.1 Conclusions

Based on the self-assessment (SARIS) for the inspection related to transport of nuclear source materials, it finds that the Reactor Regulation Act provides the legal framework to confirm that the permission users of nuclear source materials appropriately respond to regulatory requirements related to transport of nuclear source materials by on-site inspections for the permission users of nuclear source materials. Therefore, it identified that the framework is in principle in accordance with relevant IAEA safety requirements.

4.2.2 Generic issues

Article 57-7(6) of the Reactor Regulation Act specifies that the type, volume, handling method of the nuclear source materials transported, and the measures at the occurrence of accidents and other matters to be noticed should be maintained as records regarding the said transport in the case where the permission users of nuclear source materials conduct transport of nuclear source materials. Pursuant to Article 68 of the Reactor Regulation Act, NRA has the authority to conduct on-site inspections for the permission users of nuclear source materials and confirm the records related to transport. Additionally, NRA will conduct follow-ups for incompliance found in on-site inspections.

4.3 Inspection in land transport of radioisotopes etc.

4.3.1 Conclusions

Based on the self-assessment (SARIS) for the inspection related to transport of radioisotopes etc., it finds that the RI Act provides the legal framework to confirm that the permission users of radioisotopes etc. appropriately respond to regulatory requirements related to transport of radioisotopes etc. by on-site inspections for the permission users of radioisotopes etc. Therefore, it identified that the framework is in principle in accordance with relevant IAEA safety requirements.

4.3.2 Generic issues

It is specified that the measures required for transport of radioisotopes etc. should be taken to prevent radiation hazards pursuant to Article 18 of the RI Act. Among these, in the case of transport of Type B (U) package and Type B (M) package outside the Sites etc., it is required to obtain packaging confirmation by the administration. In package confirmation, NRA confirms the matters regarding radioisotopes etc. that the packaging is maintained in compliance with the packaging design and the matters related to the inspection prior to shipping of radioactive package, in addition to the contents approved in the packaging approval.

NRA has the authority to conduct on-site inspections for the permission users of pursuant to Article 43-2(1) of the RI Act, and to enter the office of the users etc. or the Sites to the extent necessary for enforcement of the RI Act and inspect the account books etc. In the case where the users etc. transport all types of radioisotopes etc., the said users shall describe the date, methods and the shippers or the names of shippers or receivers or titles regarding transport to the account books and are required to keep them for five years.

Additionally, pursuant to Article 42 of the RI Act, NRA can collect report for the users etc. In the case where NRA requires the users etc. to report the status of transport of all the transport of radioisotopes etc. conducted outside the Sites, the users etc. shall be required to report the said status within the period.

4.4 Inspection in land transport of radiopharmaceuticals

4.4.1 Conclusions

Regarding land transport of radiopharmaceuticals, pursuant to the Pharmaceuticals and Medical Devices Act, similarly as the RI Act, MHLW conducts confirmations and inspections required as a regulatory authority in order to incorporate IAEA safety standard.

4.4.2 Generic issues

Regarding land transport of radiopharmaceuticals, MHLW specifies the rules/standards in order to incorporate IAEA safety standard pursuant to the Ministerial Ordinance/Notification based on the provisions of the Pharmaceuticals and Medical Devices Act and conducts regular confirmation upon the renewal of the said permission for the Licensees including whether land transport of radiopharmaceuticals is performed in compliance with the said rules/standards. Furthermore, pursuant to the Pharmaceuticals and Medical Devices Act, MHLW can conduct Inspection by entering into the site to handle radiopharmaceuticals for operation when it deems necessary as the regulatory authority.

4.5 Inspection in land transport by post etc.

4.5.1 Conclusions

Regarding transport by post etc., pursuant to Act on Japan Post Co., Ltd. etc., to the extent necessary for enforcement of the act, the regulatory authority can require the report and can conduct on-site inspections. The framework to be well developed to confirm appropriate response. Therefore, it identified that the framework is in principle in accordance with relevant IAEA safety requirements.

4.5.2 Generic issues

The regulatory authority can require the report and can conduct on-site inspections, for Japan Post Co., Ltd. that provides post services pursuant to Article 16(1) of Act on Japan Post Co., Ltd. etc., and for the corresponding delivery operators, pursuant to Article 37(2) of Act on Correspondence Delivery by Private Business Operators, respectively. The regulatory authority can require the report and can conduct on-site inspections, including appropriate transport of radioactive materials etc., to the extent necessary for enforcement of each act.

5 Enforcement

5.1 Enforcement in land transport of nuclear source materials and nuclear fuel materials etc.

5.1.1 Conclusions

Based on the self-assessment (SARIS) for enforcement in land transport of nuclear source materials and nuclear fuel materials etc., it finds that the Reactor Regulation Act clearly provides the requirements for the enforcement actions for land transport of nuclear source materials and nuclear fuel materials etc. and the conditions for such enforcement actions and allow NRA to decide on these enforcement actions for noncompliance and emergency measures. Therefore, it concludes that the framework and measures for enforcement are in principle in accordance with relevant IAEA safety requirements.

5.1.2 Generic issues

In Article 62-3 of the Reactor Regulation Act, in the case of land transport of nuclear source materials and nuclear fuel materials etc., it is specified that the users of nuclear source materials and nuclear operators shall: ① in the case of steal or loss of nuclear fuel materials, ② in the case of abnormal leakage of nuclear fuel materials etc. ③ in the case of injury of persons or being likely to be so, report the above-mentioned status and the measures, as an event of accidents/malfunction, to NRA.

Upon transport of nuclear fuel materials etc., in the case where incompliance occurs that might affect transport, such information shall be promptly shared between the interested parties according to liaison system of “Interagency Coordination Meeting for the Safe Transport of Radioactive Material”.

In the case where NRA identifies that the measures taken by the nuclear operators etc. do not comply with the technical standard, it can order suspend the shipment and other safety and security and measures regarding nuclear fuel materials etc., pursuant to Article 59(4) of the Reactor Regulation Act. Regarding nuclear source materials, pursuant to Article 57-7(5) of the Reactor Regulation Act, it is specified that NRA can order to take corrective measures to comply with the standard.

Additionally, in the case where it is deemed that there is an imminence peril of disasters due to nuclear fuel materials etc., and there is urgent need to prevent disasters, Article 64(3) of the Reactor Regulation Act specifies that NRA can order the nuclear operators etc. to take the measures required to prevent disasters, such as changing the location of nuclear fuel materials etc.

In the case of violation of the provisions of Article 59(2) of the Reactor Regulation Act and Orders pursuant to Article 59(4), pursuant to Article 43-3-20 etc. of the Reactor Regulation Act, NRA can order the nuclear operators etc. to rescind the permission or suspend the operation within one year.

In the case of receiving the above-mentioned report or taking the measure, according the events or the necessity, by utilizing the authority to collect report pursuant to Article 67 of the same Act, NRA can require the said nuclear operators to establish/implement the measures to investigate the cause and prevent reoccurrence and conduct on-site inspection to confirm the implementation status etc., pursuant to Article 68 of the same Act.

- Report to Competent Ministers, etc. (Article 62-3 of the Reactor Regulation Act)
- Suspension of shipment of nuclear fuel materials etc. and order for other necessary measures (Article 59(4) of the Reactor Regulation Act)
- Order for Emergency measures (Article 64(3) of the Reactor Regulation Act)
- Rescission of operation license or suspension of operation (Article 43-3-20 etc. of the Reactor Regulation Act)
- Collection of reports (Article 67 of the Reactor Regulation Act)
- On-site inspections, etc. (Article 68 of the Reactor Regulation Act)

5.2 Enforcement in land transport of radioisotopes etc.

5.2.1 Conclusions

Based on the self-assessment (SARIS) for enforcement of transport of radioisotopes etc., it finds that the RI Act clearly provides the requirements for the enforcement actions for land transport of radioisotopes etc. and the conditions for such enforcement actions and allow NRA to decide on these enforcement actions. Therefore, it concludes that the framework and measures for enforcement are in principle in accordance with relevant IAEA safety requirements.

5.2.2 Generic issues

The RI Act requires the users etc. to prevent radiation hazards in the case of transport of radioisotopes etc. outside the Sites etc. In the case where NRA identifies that the measures taken by the users etc. do not comply with the technical standard, it can order the users etc. to take the measures required for the measures to prevent radiation hazards, such as suspension of transport etc., pursuant to Article 18(4), of the RI Act.

Additionally, in the case where NRA identifies urgent needs to prevent radiation hazards caused by radioisotopes etc., NRA can order the users etc. to take the measures required for the measures to prevent radiation hazards, such as changing the location of radioisotopes etc. and removal of contamination pursuant to Article 33 (3) of the RI Act.

Furthermore, in the case of violation of the provisions of Article 18(2) of the RI Act and the measures pursuant to Article 18(4), Article 26 of the RI Act specifies that NRA can order the users etc. to rescind the permission of radioisotopes etc. or suspend the use of radioisotopes etc.

Besides, upon transport of radioisotopes etc. outside the Sites etc., in the case where the accidents that are likely to cause radiation hazards or the ones where radiation hazards occur (hereinafter referred to as “the accidents that are likely to cause radiation hazards etc.”), Article 31-2 of the RI Act specifies that NRA requires the users etc. to report such accidents to NRA.

Upon transport of radioisotopes etc., in the case where incompliance occurs that might affect transport, such information shall be promptly shared between the interested parties according to liaison system to the relevant bodies established in the framework of “Interagency Coordination Meeting for the Safe Transport of Radioactive Material”.

In addition, Article 42 of the RI Act specifies that NRA can enforce the users to collect reports and requires the users to report all the situations of transport of radioisotopes etc. outside the Sites etc. when required to report by specifying the period, within the specified period.

Regarding coping with the accidents that are likely to cause radiation hazards etc., pursuant to Article 43-2 of the RI Act, NRA can enter the office of the users etc. or the plants or the operation site for on-site inspections regarding account books, documents and other matters related to their properties as required. NRA has the framework for the accidents that are likely to cause radiation hazards etc.

- Reporting of Accidents to NRA (Article 31-2 of the RI Act)
- Suspension of transport of radioisotopes etc. and other measures necessary to prevent radiation hazards (Article 18 of the RI Act)
- Order for Emergency measures (Article 33(3) of the RI Act)
- Rescission of operation license or suspension of operation (Article 26 of the RI Act)
- Collection of Reports (Article 42 of the RI Act)
- On-site inspections (Article 43-2 of the RI Act)

5.3 Enforcement in land transport of radiopharmaceuticals

5.3.1 Conclusions

Regarding land transport of radiopharmaceuticals, pursuant to the Pharmaceuticals and Medical Devices Act, similarly as the RI Act, MHLW conducts enforcement required as a regulatory authority in order to incorporate IAEA safety standard.

5.3.2 Generic issues

Regarding land transport of radiopharmaceuticals, MHLW specifies the rules/standards in order to incorporate IAEA safety standard pursuant to the Ministerial Ordinance/Notification on the Pharmaceuticals and Medical Devices Act. In the case where the Licensees that handle radiopharmaceuticals do not comply with the said rules/standards, MHLW can order necessary measures for improvement and the dispositions of suspension of all or part of the operation pursuant to Pharmaceutical Affairs Law as a regulatory authority. Furthermore, in the case of violation of the said dispositions, MHLW also can rescind the said License.

5.4 Enforcement in transport by post etc.

5.4.1 Conclusions

Regarding transport by post etc., Regulations of Act on Japan Post Co., Ltd. etc. specifies that the regulatory authority can require reports and conduct on-site inspections or enforce the orders required for supervision (order for operation improvement for correspondence delivery operators) to the extent

required for enforcement of laws and conduct necessary regulations appropriately. Thus, it is identified that enforcement in transport by post etc. is in compliance with IAEA safety standard.

5.4.2 Generic issues

The regulatory authority can require the report and can conduct on-site inspections, for Japan Post Co., Ltd. that provides post services pursuant to Article 16(1) of Act on Japan Post Co., Ltd. etc., and for the corresponding delivery operators, pursuant to Article 37(2) of the Act on Correspondence Delivery by Private Business Operators, respectively. The regulatory authority can require the report or conduct on-site inspections or orders required for supervision (order for operation improvement for correspondence delivery operators) including appropriate transport of radioactive materials etc., to the extent necessary for enforcement of the act.

6 Regulations and guides

6.1 Regulations and guides in land transport of nuclear source materials and nuclear fuel materials etc.

6.1.1 Conclusions

Based on the self-assessment (SARIS) for regulations and guides in land transport of nuclear source materials and nuclear fuel materials etc., it finds that the Reactor Regulation Act requires the regulation according to the types of transport of nuclear source materials and nuclear fuel materials etc. and specify and publish as the ordinances/instructions of NRA. Therefore, it concludes that the framework and measures for the regulations and guides are in principle in accordance with relevant IAEA safety requirements, except for the following issues:

- Some provisions of the application procedures of approval related to transport of nuclear fuel materials etc. specified by the notification on Technical Details for Off-Site transportation of Nuclear Fuel Materials, etc. (hereinafter referred to as “Nuclear Off-Site Transportation Notice”) by NRA and guides by Nuclear and Industrial Safety Agency (NISA) is not hierarchized. Therefore, NRA should modify the provisions in order to specify them appropriately.
- NRA should consider rationalization of examination for package design approval related to transport, in case of examining the dual purpose cask which has obtained type designation for transport/storage (Specific Dual Purpose Cask) that is used for storage of spent fuel within the nuclear power plant site, by utilizing the submitted documents from the manufacturer upon application and examinations for type designation of the dual purpose cask.

To address these challenges, NRA will implement improvement measures, based on the Acton Plan as shown in 6.1.3.

6.1.2 Generic issues

Regarding land transport of nuclear fuel materials etc., Article 59(1) of the Reactor Regulation Act specified that the nuclear operators shall take the necessary safety measures in compliance with the technical standards in the case of transport of nuclear fuel materials etc. outside the site. Regarding nuclear source materials, Article 57-7(4) of the Reactor Regulation Act specified that the licensed users of nuclear source materials shall transport in compliance with the technical standards in the case of transport of nuclear source materials outside the site.

Additionally, among these, it is specified that confirmation by NRA is required, in the case of transport of nuclear fuel package that especially requires to prevent disasters caused by nuclear fuel materials etc., based on graded approach according to radiation risk etc.

The Cabinet Order for Enforcement of the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (hereinafter referred to as “Reactor Regulation Enforcement Cabinet Order”) specifies the scope in the case where confirmation by NRA is required, the Nuclear Off-site

Transportation Ordinance specifies the technical standard required for each package, the Nuclear Off-Site Transportation Notice specifies the details of each examination conditions implemented for each package, respectively, which constitutes the legal framework related to transport regulation of nuclear fuel materials etc. Additionally, by establishing the guide documents that describe the interpretation of these legal requirements and operation policy, the legal requirements are complemented by notifying/publishing these to the nuclear operators.

As it is important for the regulatory standard related to transport of nuclear source materials and nuclear fuel materials etc. to be consistent with the international standards, NRA participates in all the committees related to IAEA safe transport standard (TRANSSC), collects information and analyzes the response including the differences between domestic international standards and international standards, and reflects latest knowledge of IAEA safe transport standard into the regulation standard of Japan. Furthermore, upon adoption of IAEA safe transport standard into domestic regulation standard etc., for the purpose of consistency of transport of radioactive materials in general, as undermentioned, NRA has the framework to conduct necessary liaison arrangement in “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” in which all the relevant regulatory authorities participate.

Additionally, regarding adoption of the latest IAEA safe transport regulations (SSR-6), NRA considers adoption of the said regulations together with the technical standard related to hazardous materials transportation (ICAO-TI) based on ICAO convention and the technical standard related to hazardous materials transportation based on SOLAS convention (IMDG Code), in cooperation with the relevant regulatory authorities.

The Reactor Regulation Act specifies the necessary standard and procedures for NRA to implement regulation as the ordinances/directives of NRA. NRA implements the procedures of public comments pursuant to Administrative Procedure Act, before deciding the ordinances/instructions. NRA makes this information, such as the basic approach for safety and criteria in formulating regulations/ guides or important modifications of regulatory framework, available to the public and licensees via the NRA web site, as well as for commercial reactor facilities. Therefore, ordinances and guides decided by NRA are also available for the stakeholders and to the public.

The regulations/guides related to nuclear source materials and nuclear fuel materials etc. are as follows:

- Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Act No. 166 of 1957)
- Cabinet Order for the Definition of Nuclear Source Material, Nuclear Fuel Material, and Nuclear Reactors and Radiation (Cabinet Order No. 325 of 1957)
- Cabinet Order for Enforcement of the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Cabinet Order No. 324 of 1957)
- NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc. (Ministerial ordinance issued by the Prime Minister’s Office No. 57 of 1978)
- NRA Ordinance on Use of Nuclear Materials (Ministerial ordinance issued by the Prime Minister’s Office No. 46 of 1968)
- Notification on Technical Details for Off-Site Transportation of Nuclear Fuel Materials etc. (Notice issued by Science and Technology Agency No. 5 of 1990)
- Notification to Establish Dose Limits in accordance with the provisions of NRA Ordinance on Activity of Refining Nuclear Source or Nuclear Fuel Materials, etc. (Notice issued by NRA No. 8 of 2015)
- “Operational Guide for Confirmation of Nuclear Fuel Packages for Off-Site Transportation” (Decision by Secretary-General, Nuclear Regulation Agency, No. 1402263 of Gen Kan Hai Hatsu of 2014)
- “Administrative Procedure Guide for Confirmation, etc. of Nuclear fuel Packages for Off-Site Transportation” (Notification Gen In issued by NISA, No. 7 of March 7 of 2011)
- “Procedure Guide for Describing the Explanatory Documents Appended to Application Documents for Approval of Vehicle Transport, Application Documents for Approval of Packaging and Application Documents for Approval of Nuclear Fuel Package Design” (Notification Gen In issued by NISA, No. 8 of March 7 of 2011)
- “Guidelines for Quality Management of Manufacturing Method of the Packaging” (Notification Gen In issued by NISA, No. 1 of June 10 of 2008)

Additionally, amendment of the NRA Commercial Reactors Ordinance enacted in April 2 of 2019 to add the cask used both for transport/storage of spent fuel within the nuclear power plant site (within site) as the specific equipment of type designation system. Due to this amendment, it is available to obtain approval of the compliance with the technical standard for storage and a part of the compliance with the technical standard for transport in advance, through the application for type designation of the cask used both for transport/storage by the manufacturer of the cask. Thus, NRA considers rationalization of the examination for the application of package design approval related to transport for the said cask used both for transport/storage.

6.1.3 Action plan

No.	2
Basis	(B2) The IAEA Safety Standard stipulates that “the regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based” 【GSR Part1 (Rev.1) R32】, “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” 【GS G 1.5 3.11】 , “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 Part1 (Rev.1) 4.34.】
Recommendation	(R2) Some provisions of the application procedures of approval related to transport of nuclear fuel materials etc. specified by the Nuclear Off-Site Transportation Notice by NRA and guides by Nuclear and Industrial Safety Agency (NISA) is not hierarchized. Therefore, NRA should modify the provisions in order to specify them appropriately.
Action Plan	(A2) Regarding some provisions of the application procedures of approval related to transport of nuclear fuel materials etc. that are not hierarchized, NRA will specify these provisions on required procedures by partly amending the Nuclear Off-Site Transportation Notice.

No.	3
Basis	(B3) The IAEA Safety Standard stipulates that “the licensing process should be established in a systemic way to facilitate efficient progression of regulatory activities.” 【SSG-12 2.6】
Recommendation	(R3) NRA should consider rationalization of examination for package design approval related to transport, in case of examining the dual purpose cask which has obtained type designation for transport/storage (Specific Dual Purpose Cask) that is used for storage of spent fuel within the nuclear power plant site, by utilizing the submitted documents from the manufacturer upon application and examinations for type designation of the dual purpose cask.
Action Plan	(A3) Regarding the Specific Dual Purpose Cask obtained type designation, NRA will rationalize the examinations in the case of obtaining the package design approval related to transport.

6.2 Regulations and guides in land transport of radioisotopes etc.

6.2.1 Conclusions

Based on the self-assessment (SARIS) for regulations and guides related to transport of radioisotopes etc., pursuant to the RI Act, it finds that NRA announces the regulatory requirements according to the type of transport of radioisotopes etc. by complementing by the notices etc. Therefore, it is identified that is regulations and guides related to transport of radioisotopes etc. is in compliance with IAEA safety standard.

6.2.2 Generic issues

Regarding land transport of radioisotopes etc., the RI Act specifies that the users etc. shall take the necessary safety measures to prevent radiation hazards in compliance with the technical standards in the case of transport of radioisotopes etc. outside the Sites etc. Specifically, Regulations on enforcement of the said Act specifies the scope and technical standard required for the standard and each packaging in the case where NRA requires confirmation related to transport. Additionally, the standard for each packaging is specified in the Notification on Technical Details for Off-Site transportation of Radioisotopes etc. Therefore, NRA has the legal framework related to regulations for transportation of radioisotopes etc.

Furthermore, NRA specifies the notification documents that describe the procedures for these legal requirements as the internal regulations of the administration and the legal requirements are complemented by indicating these to the users etc.

In the case where IAEA safe transport regulations etc. are amended, such amendments shall be incorporated into domestic laws and regulations as required. The information of the said amendments shall be shared in “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” by the relevant ministries and agencies.

Moreover, after gaining approval in the open meetings of NRA, according to the contents of amendment, then sending to the procedures of public comments pursuant to Administrative Procedure Law and receiving the decision by NRA based on the opinions obtained, the procedures for amendment of the laws and regulations shall be proceeded. The amended domestic laws and regulations shall be released on the NRA website, as well as on the official gazette.

6.3 Regulations and guides in land transport of radiopharmaceuticals

6.3.1 Conclusions

Regarding land transport of radiopharmaceuticals, pursuant to Ministerial Ordinance/Notifications based on the provisions of the Pharmaceuticals and Medical Devices Act, similarly as the RI Act, MHLW conducts regulations/guides required by specifying regulations/standards in order to incorporate IAEA safety standards.

6.3.2 Generic issues

Regarding land transport of radiopharmaceuticals, MHLW specifies the rules/standards in order to incorporate IAEA safe standard pursuant to Ministerial Ordinance/Notification based on the provision of the Pharmaceuticals and Medical Devices Act, similarly as the RI Act. In the case of amendment of IAEA safety standards etc., as well as the RI Act, necessary amendment regarding the said the Ministerial Ordinance/Notification shall be considered. Additionally, in the case of amendment of the said the Ministerial Ordinance/Notification, such amendment shall be notified to the relevant operators/bodies etc.

6.4 Regulations and guides in transport by post etc.

6.4.1 Conclusions

Regarding transport by post etc., MIC specifies the rules/standards by the Postal Act etc. or the regulations/notifications based on the said Act. These are specified in compliance with Convention of Universal Postal Union (UPU) etc. that incorporates IAEA safe standard. Therefore, it is identified that transport by post etc. is in compliance with IAEA safe standard.

6.4.2 Generic issues

MIC specifies the rules/standards by the Postal Act etc. or the regulations/notifications based on the said Act, which are specified in compliance with convention of Universal Postal Union (UPU) etc. that incorporates IAEA safety standards. Additionally, regarding transport by the correspondence delivery, MIC specifies the rules/standards by Act on Correspondence Delivery by Private Business Operators and the regulations/notifications based on the said Act, as well as the Postal Act etc., which have the same contents with the ones of the Postal Act etc.

7 Emergency response

7.1 Emergency response in land transport of radioactive materials

7.1.1 Conclusions

Based on the self-assessment (SARIS) for emergency response for land transport of radioactive materials, it found that the regulatory framework is well established in advance to regulate emergency response including collaboration with the relevant bodies. Therefore, it is identified that the framework and measures for emergency response is in accordance with relevant IAEA safety requirements, except in the following matters:

- In the existing system in land transport of nuclear fuel materials, despite the results of risk assessment quoted in “Emergency Preparedness for Nuclear facilities etc.” determined by Nuclear Safety Commission in 2003, the said assessment has not been updated. NRA should consider accidents that can be reasonably assumed based on actual present situations of the transport and review the NRA Guide for Emergency Preparedness and Response etc.
- The existing system of land transport of radioactive materials is developed in advance for the measures to be taken by the relevant organizations and sharing of roles based on the framework of the existing laws and regulations etc. However, it is needed for NRA to clarify the procedures for the initial response including collaboration with the relevant organizations for more appropriate response based on the framework of the existing laws and regulations etc.

To address these challenges, NRA will implement improvement measures, based on the Action Plan as shown in 7.1.3.

7.1.2 Generic issues

Regarding emergency response in land transport of radioactive materials, based on the competent authorities’ laws and regulations related to land transport of radioactive materials including NRA, in the case where the accidents of transport of radioactive materials occur or are likely to occur, the nuclear operators are required to report to the competent authorities and take necessary measures etc. Additionally, based on the document about “Measures Regarding Safety Measures Against Accidents of Transport of Radioactive Materials” prepared by “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” that composes of the departments and divisions in charge of the

competent authorities related to safe transport of radioactive materials and the framework of Act on Special Measures Concerning Nuclear Emergency Preparedness, the following matters are organized in advance by specifying the sharing of roles of the relevant organizations;

- ① Notification/liaison system
- ② Organizational system that consists of the relevant organizations
- ③ Collecting/summarizing/sharing of information
- ④ Dispatch of the staff and experts to the site
- ⑤ Response on the site (lifesaving, fire extinguishing, contamination prevention, restricted entry etc.)
- ⑥ Public relation
- ⑦ Measures for restoration from nuclear emergency (termination of restrictions, evaluation of dose exposure, health consultation, measures against reputational damage etc.)

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

[Measures Regarding Safety Measures Against Accidents of Transport of Radioactive Materials (Interagency Coordination Meeting for the Safe Transport of Radioactive Material), Act on Special Measures Concerning Nuclear Emergency Preparedness, Basic Plan for Emergency Preparedness, NRA Guide for Emergency Preparedness and Response, Manual for Nuclear Emergency Preparedness and Response (transport version)]

7.1.3 Action Plan

No.	4
Basis	(B4) IAEA standard specifies that “the competent authority should periodically access the risk of an accident involving the transport of radioactive materials and its potential consequences. Emergency planning by the competent authority and other responsible authorities, usually organizations with responsibility for public health and safety, should be based on these and other relevant assessments.” 【TS-G-1.5 4.99】
Recommendation	(R4) In the existing system in land transport of nuclear fuel materials, despite the results of risk assessment quoted in “Emergency Preparedness for Nuclear facilities etc.” determined by Nuclear Safety Commission in 2003, the said assessment has not been updated. NRA should consider accidents that can be reasonably assumed based on actual present situations of the transport and review the NRA Guide for Emergency Preparedness and Response etc.
Action Plan	(A4) The accidents that can be reasonably assumed based on the actual situations of transport should be assessed as the risk of the accidents related to transport of nuclear fuel materials and their potential effects. Based on the results of such assessment, NRA should consider enhancement of descriptions of necessary protective measures in the NRA Guide for Nuclear Emergency Preparedness and Response. Additionally, NRA assesses and reviews the NRA Guide for Nuclear Emergency Preparedness and Response etc., as needed.

No.	5
Basis	(B5) IAEA safety standard specifies that “in the event of accidents or incidents during transport of radioactive materials, emergency provisions, as established by relevant national and/or international organizations, shall be observed to protect persons, property and the environment. Appropriate guidelines for such provisions are contained in TS-G-1.2 (ST-3)” 【SSR-6 304】, “detailed recommendations on emergency planning and preparedness are provided in TS- G-1.2” 【TS-G-1.5 4.100】, and “When a transport

	<p>accident involving radioactive material occurs, several governmental organizations, the consignor, the carrier and their personnel may have responsibilities to act to mitigate its consequences. In most transport accident situations this response consists of life saving, medical aid, fire suppression and control, and the normal police work associated with any accident. In addition, consideration should be given to calling in specialized organizations trained to deal with radioactive material to assess the accident and implement the protective measures used to contain, control or eliminate any radiological hazard. The degree of involvement of the various organizations may vary during the progress of the operation.” 【TS-G-1.2 (ST-3) 3.1】</p>
<p>Recommendation</p>	<p>(R5) The existing system of land transport of radioactive materials is developed in advance for the measures to be taken by the relevant organizations and sharing of roles based on the framework of the existing laws and regulations etc. However, it is needed for NRA to clarify the procedures for the initial response including collaboration with the relevant organizations for more appropriate response based on the framework of the existing laws and regulations etc.</p>
<p>Action Plan</p>	<p>(A5) NRA will develop the manual to clarify the procedures for the initial response including collaboration with the relevant organizations.</p>

8 Radiation protection

8.1 Radiation protection in land transport of nuclear source materials and nuclear fuel materials etc.

8.1.1 Conclusions

Based on the self-assessment (SARIS) for land transport of nuclear fuel materials etc., it finds that the requirements such as standards are based on graded approach according to radiation risk under the Reactor Regulation Act. Therefore, it concludes that the framework for land transport of nuclear fuel materials etc. is in principle in accordance with relevant IAEA safety requirements.

8.1.2 Generic issues

The licensed users of nuclear source materials and nuclear operators etc. are required to control the occupational exposure not to exceed the limits, pursuant to the Reactor Regulation Act, by measuring exposure dose of occupationally exposed persons that create packaging within the controlled area and record/keep the exposure dose of the occupationally exposed persons. The exposure limits of occupationally exposed persons shall be specified as 50 mSv per year and 100 mSv in five years, pursuant to Article 5 of the Notification to Establish Dose Limits in Accordance with the provisions of NRA Ordinance on Activities of Refining Nuclear Source or Nuclear Fuel Materials, etc. (“Nuclear Dose Limit Notice”) In the case where the exposure dose exceeds the said limits, the licensed users of nuclear source materials and nuclear operators etc. shall report to NRA, based on Article 62-3 of the Reactor Regulation Act. And the licensed users of nuclear source materials and nuclear operators etc. shall record/keep the exposure dose of the occupationally exposed persons, and NRA shall confirm the said records upon on-site inspections.

Additionally, regarding land transport of nuclear source materials, based on the actual situation of transport at present according to graded approach, NRA does not require to establish radiation protection plan due to low radiation risk.

8.2 Radiation protection in land transport of radioisotopes etc.

8.2.1 Conclusions

Based on the self-assessment (SARIS) for land transport of radioisotopes etc., it finds that the requirements such as standards are based on graded approach according to radiation risk under the RI Act. Therefore, it concludes that the framework for land transport of radioisotopes etc. is in principle in accordance with relevant IAEA safety requirement.

8.2.2 Generic issues

The licensed users of radioisotopes etc. are required to control the occupational exposure not to exceed the limits, pursuant to the RI Act, by measuring exposure dose of occupationally exposed persons that create packaging within the controlled area and record/keep the exposure dose of the occupationally exposed persons. The exposure limits of occupationally exposed persons shall be specified as 50 mSv per year and 100 mSv in five years, pursuant to Article 5 of the Notification that Specify Standards for amount of Radioisotopes based on the provisions of the RI Ordinance etc. In the case where the exposure dose exceeds the said limits, the licensed users of radioisotopes and notification users etc. shall report to NRA, based on Article 31-2 of the RI Act. And the licensed users of radioisotopes etc. shall record/keep the exposure dose of the occupationally exposed persons, and NRA shall confirm the said records upon on-site inspections.

8.3 Radiation protection in land transport of radiopharmaceuticals

8.3.1 Conclusions

Regarding radiation protection in land transport of radiopharmaceuticals, pursuant to Ministerial Ordinance/Notification based on the provisions of the Pharmaceuticals and Medical Devices Act, similarly as the RI Act, MHLW performs necessary regulations appropriately by specifying rules/standard to incorporate IAEA safe standard.

8.3.2 Generic issues

In order to appropriately prevent radiation hazards upon transport of radiopharmaceuticals, pursuant to Ministerial Ordinance/Notification on the Pharmaceuticals and Medical Devices Act, MHLW requires consigner and consignees to specify radiation protection programme that includes the matters regarding radiation dose measurement method and dose assessment and the matters etc. regarding separation and radiation protection from package. Additionally, each licensee is required to appoint the manager who is responsible for supervision on the prevention of radiation hazards.

8.4 Radiation protection in transport by post etc.

8.4.1 Conclusions

Regarding transport by post etc., MIC can require reports regarding whether appropriate training is conducted pursuant to the regulations of Act on Japan Post Co., Ltd. etc. In addition, MIC requires the correspondence delivery operators to conduct education/training pursuant to the ministerial ordinance. Therefore, it is concluded that radiation protection in transport by post etc. is in accordance with relevant IAEA safety requirements.

8.4.2 Generic issues

It is specified that MIC can require the regulatory authorities to report whether training for appropriate transport of radiation materials etc. is conducted or not, for the Japan Post Co., Ltd., pursuant to Article 16 of Act on Japan Post Holdings Co., Ltd. etc. and for the correspondence delivery operators, pursuant to the Article 37 of regulations related to Act on Correspondence Delivery by Private Business Operators. As the conditions of the approval of Article 31(2)(iv) of the correspondence management rules of enforcement regulations of Act on Correspondence Delivery Operator, implementation of education and training for the correspondence delivery operators is required.

List of SARIS Documentary Evidence

		Documentary Evidence	Applicable Provisions
Concerning the Reactor Regulation Act	1	the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Act No. 166 of 1957)	Article 43-3-20~22, Article 57-7, Article 59, Article 62-3, Article 64, Article 67, Article 68
	2	the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Act No. 166 of 1957) 【amended】	Amended Article 61-2-2, Amended Article 68(2)
	3	the Cabinet Order for the Definition of Nuclear Source Material, Nuclear Fuel Material, Nuclear Reactors and Radiation (the Cabinet Order No. 325 of 1957)	Article 1, Article 2
	4	the Cabinet Order for Enforcement of the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Cabinet Order No. 324 of 1957)	Article 2, Article 3, Article 47, Article 48, Article 49
	5	the NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc. (Ministerial ordinance issued by the Prime Minister's Office No. 57 of 1978)	Full text
	6	the NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc. (Ministerial ordinance issued by the Prime Minister's Office No. 57 of 1978) 【 Amendment proposal in public comment】	Amended proposal Article 17-2, Amended proposal Article 19, Amended proposal Article 20, Amended proposal Article 21, Amended proposal Article 22
	7	the NRA Ordinance Concerning the Installation and Operation of Commercial Power Reactors (Ordinance for Ministry of International Trade and Industry No. 11 of 1978)	Article 67, Article 79
	8	the NRA Ordinance on Use of Nuclear Source Materials (Ministerial ordinance issued by the Prime Minister's Office No. 46 of 1968)	Article 2(v) and (xii), Article 3, Article 5
	9	the Notification on Technical Details for Off-Site Transportation of Nuclear Fuel Materials, etc. (Notice issued by Science and Technology Agency No. 5 of 1990)	Full text
	10	the Notification to Establish Dose Limits in Accordance with the Provisions of NRA Ordinance etc. on Activity of Refining Nuclear Source or Nuclear Fuel Materials (Notice issued by NRA No. 8 of 2015)	Article 5
	11	Operational Guide for Confirmation of Nuclear Fuel packages for Off-Site Transportation (Decision by Secretary-General, Secretariat of NRA, No. 1402263 of Gen Kan Hai Hatsu of 2014)	Full text
	12	Administrative Procedure Guide for Confirmation, Etc. of Nuclear Fuel Packages for Off-Site Transportation (METI NISA) (Notification Gen In NISA-316a-11-1, No. 7 of March 7 of 2011)	Full text

IRRS Follow-up Mission to JAPAN 2020

	Documentary Evidence	Applicable Provisions	
	13	Procedure Guide for Describing the Explanatory Documents Appended to Application Documents for Approval of Vehicle Transport, Application Documents for Approval of Packaging and Application Documents for Approval of Nuclear Fuel Package Design (METI NISA) (Notification Gen In NISA-316a-11-2, No. 8 of March 7 of 2011)	Full text
	14	Guidelines for Quality Management of Manufacturing Method of the Packaging (METI NISA) (Notification Gen In NISA-316a-08-2, No. 1 of June 10 of 2008)	Full text
Concerning the RI Act	1	the Act on the Regulation of Radioisotopes, etc. (Act No. 167 of 1957)	Article 18, Article 20, Article 22, Article 23, Article 26, Article 31-2, Article 33, Article 42, Article 43-2
	2	the NRA Ordinance for Enforcement of the Act on Regulation of Radioisotopes, etc. (Ministerial ordinance issued by the Prime Minister's Office No. 56 of 1960)	Article 1, Article 18-3, Article 18-4, Article 18-5, Article 18-6, Article 18-7, Article 18-12, Article 18-15, Article 18-16, Article 18-17, Article 18-18, Article 18-19, Article 18-20, Article 20, Article 21-2, Article 22, Article 24, Article 39
	3	the Notification on Technical Details for Off-Site Transportation of Radioisotopes, etc. (Notice issued by Science and Technology Agency No. 7 of 1990)	Full text
	4	the Notification on the Details of Standards Concerning the Carriage of Radioactive Material by Ships (Notice of Ministry of Transport of 1977)	Attached Table 1 - Table 6
	5	the Notification to Specify Standards for Amount of Radioisotopes (Notice issued by Science and Technology Agency No. 5 of 2000)	Article 5
	6	Regulatory Guide for Reviewing Quality Control of the Manufacture of Nuclear Fuel Material Transport Containers (Notice issued by Ministry of Education, MEXT, Director of Nuclear Safety Division, Science and technology Policy Bureau, 18, Gen An, No. 139, January 11, 2007)	Full Text

IRRS Follow-up Mission to JAPAN 2020

		Documentary Evidence	Applicable Provisions
Concerning the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices	1	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of August 10, 1960)	Article 4(1) and (4), Article 9 (1), Article 12(1) and (2), Article 13(1) and (3), Article 18(1) and (2), Article 23-2(1) and (2), Article 23-2-15(1) and (2), Article 24(1) and (2), Article 25(iii), Article 36-2(1), Article 69(1) and (2), Article 72-4(1), Article 75(1), Article 75-2(1)
	2	Regulation on Manufacture and Handling of Radiopharmaceuticals (February 1, 1961) (Order of the Ministry of Health and Welfare No. 4)	Article 1, Article 2(6) and (7), Article 6, Article 12, Article 15, Attached Table 1
	3	Standards for Transport of Radioactive Materials (November 24, 2005) (Public Notice of the Ministry of Health, Labour and Welfare No. 491)	Full text
	4	Standards for Activities of Radioactive Materials (December 26, 2000) (Public Notice of the Ministry of Health and Welfare No. 399)	Article 9
Concerning the Postal Act etc.	1	the Postal Act (Act of No. 165 of 1947)	Article 12
	2	the Public Notice on Designation of Explosive, Inflammable or Other Dangerous Substances under Article 12, Item (i) of the Postal Act (Public Notice of the Ministry of Communications No. 384 of 1947)	9
	3	the Act on Correspondence Delivery by Private Business Operators (Act No. 99 of 2002)	Article 37(2), Article 48
	4	the Public Notice on Designation of Explosive, Inflammable or Other Dangerous Substances under Article 48, Paragraph (1), Item (i) of the Act on Correspondence Delivery by Private Business Operators (Public Notice of the Ministry of Internal Affairs and Communications No. 203 of 2003)	Full text
	5	the Act on Japan Post Co., Ltd. (Act No. 100 of 2005)	Article 16(1)
	6	Regulation for Enforcement of the Act on Correspondence Delivery by Private Business Operators (Order of the Ministry of Internal Affairs and Communications No. 27 of 2003)	Article 31(2)(iv)
	7	Universal Postal Convention (Convention No. 16 of 2017)	Article 19
	8	Convention Regulations	19-006

IRRS Follow-up Mission to JAPAN 2020

		Documentary Evidence	Applicable Provisions
Concerning Act on Special Measures Concerning Nuclear Emergency Preparedness	1	the Act on Special Measures Concerning Nuclear Emergency Preparedness (Act No. 156 of 1999)	Article 1, Article 2, Article 3, Article 4, Article 4-2, Article 5, Article 6, Article 10, Article 15, Article 25, Article 26, Article 27, Article 31, Article 32
	2	the Cabinet Order for Enforcement of the Nuclear Emergency Act (Cabinet Order No. 195 of 2000)	Article 4, Article 5, Article 6, Article 9
	3	Order on events, etc. pertaining to transport outside the nuclear site, which nuclear emergency preparedness manager should notify, based on Act on Special Measures Concerning Nuclear Emergency Preparedness (Ministerial Order No. 2 by MEXT, METI, MLIT)	Article 1, Article 2, Article 3, Article 4
	4	the NRA Guide for Emergency Preparedness and Response (July 3, 2019 NRA)	Preamble, 3 (6)
	5	the Manual for Nuclear Emergency Preparedness and Response (transport version)	Full text
	6	Basic Plan for Emergency Preparedness (May of 2019, Central Disaster Prevention Council)	The 12th volume Chapter 1, section 6, the 12th volume Chapter 2, section 10
	7	Emergency Preparedness for Nuclear Facilities etc. (partly amended on October of 2008, Nuclear Safety Commission) "Virtual Accident Evaluation Concerning Transport of Nuclear Fuel Materials etc."	Full text
	8	Order regarding notification procedures, etc. for events involved in transport outside the nuclear site that nuclear emergency preparedness manager should notify based on the Act on Special Measures Concerning Nuclear Emergency Preparedness (Ministerial Order by MEXT, METI, MLIT No. 3 of 2012)	Article 1, Article 2, Article 3