

SELF-ASSESSMENT OF THE NATIONAL REGULATORY INFRASTRUCTURE FOR SAFETY

Japan

Generated By

SARIS

**the IAEA Self Assessment of Regulatory Infrastructure
for Safety**

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IAEA SAFETY STANDARDS (the basis of the SARIS self-assessment questionnaires)

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of these standards to peaceful nuclear activities.

The regulatory related publications by means of which the IAEA establishes safety standards and measures are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (that is, of relevance in two or more of the four areas), and the categories within it are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**:

Safety Fundamentals (blue lettering) present basic objectives, concepts and principles of safety and protection in the development and application of nuclear energy for peaceful purposes.

Safety Requirements (red lettering) establish the requirements that must be met to ensure safety. These requirements, which are expressed as 'shall' statements, are governed by the objectives and principles presented in the Safety Fundamentals.

Safety Guides (green lettering) recommend actions, conditions or procedures for meeting safety requirements. Recommendations in Safety Guides are expressed as 'should' statements, with the implication that it is necessary to take the measures recommended or equivalent alternative measures to comply with the requirements.

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA.

Information on the IAEA's safety standards programme (including editions in languages other than English) is available at the IAEA Internet site:

www-ns.iaea.org/standards/

Or on request to the Safety and Security Coordination Section, IAEA, P.O. Box 100, A-1400 Vienna, Austria.

OTHER RELEVANT SAFETY RELATED PUBLICATIONS

Under the terms of Articles III and VIII.C of its Statute, the IAEA makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety and protection in nuclear activities are issued in other series, in particular the **IAEA Safety Reports Series**, as informational publications. Safety Reports may describe good practices and give practical examples and detailed methods that can be used to meet safety requirements. They do not establish requirements or make recommendations.

Other IAEA series that include safety related publications are the **Technical Reports Series**, the **Radiological Assessment Reports Series**, the **INSAG Series**, the **TECDOC Series**, the **Provisional Safety Standards Series**, the **Training Course Series**, the **IAEA Services Series**, the **Computer Manual Series**, and **Practical Radiation Safety Manuals** and **Practical Radiation Technical Manuals**. The IAEA also issues reports on radiological accidents and other special publications.

SELF-ASSESSMENT OF THE NATIONAL REGULATORY INFRASTRUCTURE FOR SAFETY

BACKGROUND

The International Atomic Energy Agency (IAEA) is responsible for the development of standards for the safety and protection of health, environment and property against ionizing radiation and for assisting their application in States through appropriate mechanisms such as peer review, appraisal and training. The IAEA applies the standards to its own operations and wherever it is supporting Member States. In addition, at the request of third parties, the IAEA applies the standards to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning nuclear energy.

IAEA standards and guidance are based on the presumption that a national infrastructure is in place to enable a government to discharge its responsibilities for radiation protection, safety and the security of radioactive sources.

A national infrastructure for nuclear and radiation safety includes all persons, organizations, qualified experts, systems, documents, facilities and equipment, and technical services that are, in whole or in part, dedicated to nuclear and radiation safety.

The IAEA offers a range of reviews, appraisals and advisory services to help States' verify that standards and international undertakings are adequately applied at the national level and to evaluate the effectiveness and sustainability of State regulatory infrastructure. In particular, the IAEA offers the *Integrated Regulatory Review Service* (IRRS) covering all aspects of nuclear, radiation, transport and waste safety and emergency planning. The IRRS is a comprehensive and modular service addressing all components of a national regulatory infrastructure for safety. It comprises an *internal* self-assessment phase, followed by an *external* expert team review.

To facilitate States' regular and routine self-assessment of national regulatory infrastructure for nuclear and radiation safety, the Agency has developed the IAEA Self-Assessment Methodology and its associated software, the Self-Assessment of Regulatory Infrastructure for Safety (SARIS). The SARIS is a stand-alone system; however, it is fully compatible with the IRRS Guidelines and may also be used in preparation for IRRS.

This Report contains factual answers to the SARIS questions (themselves derived from the IAEA standards and international undertakings). In addition, it incorporates appended documentary evidence to support the answers given and an analysis of the responses, both by SARIS Module and collectively for all Modules addressed in this self-assessment cycle. Within this report there is also an electronically generated 'Priority Assignment' (PA) value for each Module and for the whole self-assessment, providing an indication of where the most immediate needs for improvement may lie.

The SARIS and this report are structured in such a way to facilitate action planning for the continuous improvement of regulatory infrastructure in accordance with identified priorities and realistically achievable objectives.

The Report is freely editable, but once agreed as a complete and accurate record, it can be archived in unchangeable form, thus serving as an important record of the status of the regulatory infrastructure at a particular point in time.

THE SELF-ASSESSMENT REPORT FOR JAPAN

Self-Assessment Project Manager (SAPM):

| | |
|-----------------------------------------|-----------------------------------------------------------------|
| Self-Assessment Project Manager (SAPM): | |
| | |
| Job Title: | Senior Coordinator |
| Department: | Regulatory Reform Office, Secretary-General's Secretariat |
| Organisation: | Nuclear Regulation Authority |
| | |
| Date of Completion of this Report | 01, Nov, 2019 |

REPORT FOR THE JAPAN

Introduction

This electronically-generated SARIS Report documents findings against each completed SARIS Module, together with an overview and the basis for any findings. It also provides a Priority Assignment (PA) value for each completed Module and for the national regulatory infrastructure as a whole. Both the electronically-generated report and the PA values are for guidance only. In the analysis phase of a self-assessment cycle (performed in accordance with the IAEA methodology) it is expected that the content of the SARIS Report will be modified manually to reflect extensive internal discussion and consensus on the findings, conclusions and recommendations for improvement.

The SARIS Report and the PA values contained within it are not an alternative to a properly conducted peer review or appraisal. The IAEA self-assessment methodology and the SARIS provide a comprehensive process of self-assessment and indicate priority areas for improvement. It is recommended that the outcomes of any such *internal* assessment are occasionally verified by an *external* review process (such as the IRRS).

The SARIS report and PA values may be used to objectively inform discussions with IAEA and other organisations with regard to advice, guidance, support and assistance as appropriate, in all areas addressed during a self-assessment.

FINDINGS

This section presents your responses to the questionnaire, which is arranged in a number of core and thematic SARIS Modules. An electronically-generated conclusion and PA value is provided for each completed SARIS Module.

ANALYSIS

When the question-answering (response phase) for each SARIS Module is completed, the analysis phase begins for that Module. The SARIS is structured to enable the SARIS questionnaire responses to be reviewed and analyzed. The Analysis Team's output for each Module and for the overall scope of the self-assessment, are presented in terms of the regulatory infrastructure's identified strengths, weaknesses, opportunities and threats, culminating in the Analysis Team's overall conclusions and recommendations, as incorporated in this SARIS Report.

Contents

| | |
|-------------------------------------------------------------------------------------------------|----|
| BACKGROUND | 3 |
| Introduction..... | 5 |
| OUTCOMES OF THE SELF-ASSESSMENT FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS | 7 |
| Module: Safety Requirements for Transport of Radioactive Material | 7 |
| ACTION PLANS FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS | 73 |
| ELECTRONICALLY GENERATED CONCLUSION FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS | 76 |
| Module: Safety Requirements for Transport of Radioactive Material | 76 |
| PRIORITIES ASSIGNMENT (PA) VALUES FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS | 77 |

OUTCOMES OF THE SELF-ASSESSMENT FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS

Module: Safety Requirements for Transport of Radioactive Material

Findings

Question 11.1

In the context of paragraph 802 of SSR-6, does the Competent Authority for transport issue the necessary approval or validation certificates as appropriate?

Answer

Yes

Finding

The competent authority for transport issues the necessary approval or validation certificates as appropriate

Response

○Plural Competent Authorities have responsibility for the safety regulations for the transport of radioactive materials in Japan, depending on the type of material to be transported (nuclear source materials, nuclear fuel materials, radioisotopes and radiopharmaceuticals) and mode of transport (land transport, sea transport, air transport or postal transport). The matters described in paragraph 802 of the IAEA Safety Standards on Regulations for the Safe Transport of Radioactive Material (SSR-6) are divided between the Competent Authorities and all transport modes are considered without duplication in a framework. Based on the graded approach, among those matters, validation certificates are issued only to those which are necessary to prevent disaster or radiation hazard.

○In divided duties of Competent Authorities for transportation, NRA issues certificates for package of land transportation of nuclear fuel materials and radioisotopes, and Ministry of Land, Infrastructure and Transport and Tourism (MLIT) issues certificates of sea and air transportation of radioactive materials (including nuclear source materials, nuclear fuel

materials, radioisotopes and radiopharmaceuticals). MLIT is responsible for the issue of certificate for transportation methods in all transportation modes, except land transportation of radiopharmaceuticals and nuclear source materials *.

* : MHLW is responsible for the package and transport method of radiopharmaceuticals on land, and NRA is responsible for the package and transport method of nuclear source materials on land.

○The scope of evaluation related to the transportation of radioactive materials in this IRRS follow-up mission covers only land transportation among all transport modes. Furthermore, among land transportation, the matters related to the regulations of land transportation of nuclear fuel materials, nuclear source materials, and radioisotopes regulated by NRA (for nuclear fuel materials and radioisotopes, limited to regulations pertaining to package), matters related to the regulations of land transport of radiopharmaceuticals regulated by MHLW, matters related to the regulation of the transportation of radioactive materials by mail etc. regulated by MIC, and matters requiring cooperation with related organizations, such as emergency response (matters related to interfaces) are covered. Therefore, only responses within evaluation scope are described in this document.

[Nuclear Regulation Authority(NRA)]

○Based on the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Act No.166 of 1957) (hereinafter referred to “the Reactor Regulation Act”) and the Act on Regulation of Radioisotopes, etc. (Act No.167 of 1957) (hereinafter referred to “the RI Act”), NRA is responsible for confirming the standard conformity of package for land transportation of nuclear fuel materials and radioisotopes. In addition, NRA is responsible for the regulations of package and transportation method related to land transportation of nuclear source materials based on the Reactor Regulation Act, however, issue of approval certificates is not required according to the graded approach of SSR-6, so NRA does not issue certificates.

《Nuclear fuel materials》

○Regarding the land transportation of nuclear fuel materials, when nuclear operators (including those entrusted to transport by nuclear operators, etc. The same shall apply hereinafter) transport nuclear fuel material or materials contaminated with nuclear fuel materials (hereinafter referred to as “nuclear fuel material, etc.”) outside the sites, package confirmation by NRA is required prior to transportation under the Reactor Regulation Act, if there is a particular need to prevent disasters caused by the nuclear fuel materials (in case of transporting of nuclear fuel package containing 0.1kg or more of uranium hexafluoride, Type B (U) package or Type B (M) package, fissile package outside the sites). NRA confirms the package and issues “package certificate” when it finds that the package conforms to the technical standards as described below.

Regarding package confirmation, it is possible to obtain the package design approval and the packaging approval of nuclear fuel package step by step based on the Reactor Regulation Act. For this reason, NRA examines whether the design of the nuclear fuel package conforms to the technical standards stipulated in the NRA regulations, based on the application from the nuclear operator. If the conformity is recognized, “Nuclear fuel material package design approval” is issued (corresponding to 802 (a) (iv) (v) (vi)). Furthermore, NRA issues “packaging approval” for packaging consist of package, if the packaging is manufactured in accordance with the design and manufacturing methods that have been approved for the design of nuclear fuel packages, and if NRA approves that the packaging conform to technical standards. 【Article 59(2) and (3) of the Reactor Regulation Act, Article 48 of the Reactor Regulation Enforcement Cabinet Order, Articles 18 to 22 of the NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc. (Cabinet Order No.57 of 1978) (hereinafter referred to as “the Nuclear Off-Site Transportation Ordinance”, Article 41(1) and (2) of the Notice on Technical Details for Off-Site Transportation of Nuclear Fuel Materials, etc. (Notice of Science and Technology Agency No.5 of 1990) (hereinafter referred to as “the Nuclear Off-Site Transportation Notice”)】

○Regarding the land transportation of nuclear fuel materials, if it is extremely difficult to transportation in accordance with the regulations of the Reactor Regulation Act, NRA issues an approval for special arrangements (limited to the matters related to the package) if NRA approves that the necessary measures are taken to ensure safe transportation and that there is no safety problem even if transportation is not carried out in accordance with these provisions, after reviewing the measures that are extremely difficult to take in accordance with the provisions and the reasons based on applications from nuclear operators. (equivalent to 802 (b)) 【Article 14 of the Nuclear Off-Site Transportation Ordinance, Article 34 of the Nuclear Off-Site Transportation Notice】

○Regarding the land transportation of nuclear fuel materials, when nuclear fuel package with the original certificate issued by the competent authority of the country of origin of design and shipment, since the Reactor Regulation Act does not have the provision to validate the certificate issued by foreign authorities, nuclear operators are required to apply the confirmation regarding transportation under the Reactor Regulation Act, then after the review of the application, “transportation certificate” relating to the package is issued when conformity with the technical standards is confirmed, as with domestic transport procedures.

《Nuclear source materials》

○Regarding the land transportation of nuclear source materials , based on the Reactor Regulation Act, users of nuclear source materials are required to transport in accordance with technical standards established by the competent authorities based on the graded approach according to radiation risks. 【Article 57-7(4) of the Reactor Regulation Act, Article

2(xii) of the NRA Ordinance on Use of Nuclear Source Materials (Cabinet Order No.46 of 1968) (hereinafter referred to as “the Nuclear Source Materials Use Ordinance”)]

《Radioisotopes》

○Regarding the land transportation of radioisotope, under the RI Act, users etc. (including those entrusted with transportation by users, etc.) are required to take necessary measures against package to prevent radiation hazards according to technical standards when they transport radioisotopes outside the plant. 【Article 18 (1) of the RI Act】

○Regarding the Type B (U) and Type B (M) packages that are specifically required by NRA to prevent radiation hazards, the measures taken by the users etc. for the package must be confirmed by the competent authority before shipment (package confirmation) whether it conforms to the technical standards stipulated in the NRA Ordinance for Enforcement of the Act on Regulation of Radioisotopes, etc.(hereinafter referred to as “the RI Ordinance”).

【Article 18 (2) of the RI Act】

○Prior to the package confirmation, the user, etc. can obtain approval (packaging approval) from NRA in advance for conformity to the technical standards of the packagings used for transportation. 【Article 18 (3) of the RI Act】

Prior to packaging approval, regarding the design of packagings included in a part of packaging approval, approval by NRA (package design approval) for compliance with technical standards can be obtained in advance. 【Article 18(2) of the RI Act, Article 18-17(4) of the RI Ordinance, Article 25 of the Notification on Technical Details for Off-Site Transportation of Radioisotopes, etc. (hereinafter referred to as the RI Off-Site Transportation Notice)】

○Regarding the land transportation of radioisotopes, etc., when a radioactive package with the original certificate issued by the competent authority in the country where the design or transportation occurred is transported on land, NRA must conduct package confirmation in the same manner as the procedures for domestic transportation, without the validation of original certificate specified in paragraph 840 of IAEA SSR-6.

[Ministry of Health, Labour and Welfare (MHLW)]

《Radiopharmaceuticals》

○The competent authority for the land transport of radiopharmaceuticals is MHLW. Regarding the land transport of radiopharmaceuticals, MHLW sets regulations and standards to incorporate IAEA safety standards such as SSR-6, as with the RI Act, based on the provisions of the “Act on Securing Quality, Efficacy and Safety of Products Including

Pharmaceuticals and Medical Devices” (Act No.145 of 1960) (hereinafter referred to as the “Pharmaceuticals and Medical Devices Act”).

Regarding the transport of radiopharmaceuticals, nothing falls under Type B (U) package, Type B (M) package, or special form radioactive materials, etc. and land transport of radiopharmaceuticals is usually carried out in accordance with the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005). In such a case, the package is not required to be approved or certificated. In Article 2(6) and (7) of the “Regulations on Manufacture and Handling of Radiopharmaceuticals” (MHLW Ordinance No.4 of 1966) (including the case of applying to Article 15), it is stipulated that the shipment is specifically approved by the regulatory authority of medicine on the condition that there is no safety hindrance, when it is extremely difficult to transport radiopharmaceuticals on land in accordance with the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005). However, no case has required such approval to date. 【Article 2(6) and (7) of the Regulations on Manufacture and Handling of Radiopharmaceuticals (including the case of applying to Article 15)】

[Ministry of Internal Affairs and Communications (MIC)]

《Postal mail》

○Based on the Postal Act (Act No.165 of 1947) and the Act on Correspondence Delivery by Private Business Operators(Act No.99 of 2002) (hereinafter referred to as “the Postal Act etc.”), MIC is responsible for regulations related to transportation of radioactive materials by mail etc. Currently, under the Postal Act, postal services are only provided by Japan Post Co., Ltd., and the letter service is licensed. Under the Postal Act, etc., in principle, handling of radioactive materials by mail is prohibited. However, transportation is possible as long as it is carried out in accordance with regulations/standards established by regulations/notifications established by ordinances/notifications based on the Postal Act etc., (radioactive substances with a radioactivity amount not exceeding 1/10 of Type L package are submitted in conformity with certain conditions). Approvals or certificates for the transportation of the radioactive materials are not required.

○The application status of each item in paragraph 802 of SSR-6 is as follows.

802(a)(i) Approval of designs for Special form radioactive material

[NRA]

《Nuclear fuel materials》

• If the special form nuclear fuel materials etc. exceed the limit of the radioactivity stipulated by the same regulations (A1 value), or they fall under packages containing 0.1 kg

or more of uranium hexafluoride or fissile package stipulated in the Notice, when the package is transported, the package design for special form nuclear fuel materials, etc. is examined for conformity with technical standards according to the classification of nuclear fuel package stipulated in the Nuclear Off-Site Transportation Ordinance, in line with graded approach according to radiation risk. If the conformity is recognized, the “Nuclear Fuel Package Design Approval Certificate” is issued. 【Article3(1)(i) , Article 4 and appended form 1 of the Nuclear Off-Site Transportation Notice 】

《Radioisotopes》

• *“Special form radioisotopes etc.” mean solid radioactive isotopes, etc. that are not easily dissipated, or capsules that seal radioactive isotopes, etc. and meet the standards stipulated in the RI Off-Site Transportation Notice. 【Article 18(1) of the RI Act, Article 18-3 of the RI Ordinance, Article 2 of the RI Off-Site Transportation Notice 】*

《Nuclear source materials》

• N/A

[MHLW]

《Radiopharmaceuticals》

• N/A

[MIC]

《Postal mail etc.》

• *Under the Postal Act, Universal Postal Convention and Convention Regulations (hereinafter referred to as “Universal Postal Convention etc.”), and the Act on Correspondence Delivery by Private Business Operators, these kinds of radioactive materials cannot be handled by mail or letter service, approval certificates are not issued.*

802(a)(ii) Approval for design of Low dispersible radioactive materials

• *Since NRA, MHLW, and MIC are not responsible for package design approval for low dispersible radioactive materials, it is not covered in the evaluation this time.*

802(a)(iii) Approval for design of fissile material excepted under para. 417 (f)

[NRA]

《Nuclear fuel materials》

• The requirement of nuclear fuel packages that are not fissile packages is stipulated in the Nuclear Off-Site Transportation Notice. The design of fissile materials excepted under para. 417 (f) is excluded from nuclear fissile packages if it is designated (approved) by NRA.

【Article 11 of the Nuclear Off-Site Transportation Ordinance, Article 23(vi) of the Nuclear Off-Site Transportation Notice】

《Nuclear source materials》、《Radioisotopes》

• N/A

[MHLW]

《Radiopharmaceuticals》

• N/A

[MIC]

《Postal mail》

• Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, these kinds of radioactive materials cannot be handled by mail or letter service. Therefore, approval certificates are not issued.

802(a)(iv) Approval for design of packages containing 0.1 kg or more uranium hexafluoride

[NRA]

《Nuclear fuel materials》

• Regarding packages containing 0.1 kg or more of uranium hexafluoride, NRA examine whether the design complies with the technical standards for nuclear fuel packages related to uranium hexafluoride specified in the Nuclear Off-Site Transportation Ordinance, in response to applications from nuclear operators. If the conformity is recognized, a “Nuclear

Fuel Package Design Approval” is issued. 【Article 59(2) of the Reactor Regulation Act, Article 48 of the Reactor Regulation Enforcement Cabinet Order, Article 12 and 21(2) of the Nuclear Off-Site Transportation Ordinance, Article 41(1) and (2) of the Nuclear Off-Site Transportation Notice】

《Nuclear source materials》、《Radioisotopes》

• N/A

[MHLW]

《Radiopharmaceuticals》

• N/A

[MIC]

《Postal mail》

• Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, these kinds of radioactive materials cannot be handled by mail or letter service. Therefore, approval certificates are not issued.

802(a)(v) Approval for Packages containing fissile material

[NRA]

《Nuclear fuel materials》

• Regarding Design approval for fissile package, NRA examines whether the design complies with the technical standards for nuclear fuel packages related to fissile package specified in the Nuclear Off-Site Transportation Ordinance, in response to applications from nuclear operators, etc. If the conformity is recognized, a “Nuclear Fuel Package Design Approval” is issued. 【Article 59(2) of the Reactor Regulation Act, Article 48 of the Cabinet Order for Enforcement of the Act on the Regulation of Nuclear Source Material and Nuclear Fuel Materials and Reactors(hereinafter referred to as “the Reactor Regulation Enforcement Cabinet Order”), Article 11 and 21(2) of the Nuclear Off-Site Transportation Ordinance, Article 41(1) and (2) of the Nuclear Off-Site Transportation Notice】

《Nuclear fuel materials》, 《Radioisotopes》

- N/A

[MHLW]

《Radiopharmaceuticals》

- N/A

[MIC]

《Postal mail》

• *Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, these kinds of radioactive materials cannot be handled by mail or letter service. Therefore, approval certificates are not issued.*

802(a)(vi) Approval for design of Type B(U) packages and Type B(M) packages

[NRA]

《Nuclear fuel materials》

• *Regarding Design approval for Type B(U) packages and Type B(M) packages, NRA examines whether the design complies with the technical standards for Type B(U) packages and Type B(M) packages specified in the Nuclear Off-Site Transportation Ordinance, in response to applications from nuclear operators. If the conformity is recognized, a “Nuclear Fuel Package Design Approval” is issued. 【Article 59(2) of the Reactor Regulation Act, Article 48 of the Reactor Regulation Enforcement Cabinet Order, Article 6, 7, and 21(2) of the Nuclear Off-Site Transportation Ordinance, Article 41(1) and (2) of the Nuclear Off-Site Transportation Notice】*

《Radioisotopes》

• *Regarding Design approval for Type B(U) packages and Type B(M) packages, NRA examine whether the design complies with the technical standards for Type B(U) packages and Type B(M) packages specified in the RI Ordinance, in response to applications from nuclear operators, etc. If the conformity is recognized, a “Radioactive Package Design Approval” is issued. “Radioactive Package Design Approval” is generally issued in the method in accordance with paragraph 838 of IAEA SSR-6, however, for the identification*

number of the “Radioactive Package Design Approval”, an identification number specific to the RI Act (RI Design No. 0001 to 0003) is assigned instead of the general format defined in paragraph 832. 【Article 18(1) of the RI Act, Article 18-6, 18-7, 18-17(4) of the RI Ordinance, Article 25 of the RI Off-Site Transportation Notice】

《Nuclear source materials》 ,

- N/A

[MHLW]

《Radiopharmaceuticals》

- N/A

[MIC]

《Postal mail》

- *Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, these kinds of radioactive materials cannot be handled by mail or letter service. Therefore, approval certificates are not issued.*

802(a)(vii) Approval for design of Type C packages

- *NRA, MHLW, and MIC are not responsible for design approval of Type C packages, therefore, it is not covered in the evaluation this time.*

802(b) Approval for Special arrangements

[NRA]

《Nuclear fuel materials》

- *Regarding the approval for special arrangements, if it is extremely difficult to transport the package in accordance with the transport regulations of the Reactor Regulation Act, NRA shall, in response to the application by nuclear operators, examine the measures and reasons that is difficult to be taken. In case where NRA recognized the necessary measures are taken to ensure safe transportation and there should be no safety problems even if transportation is carried out not under these provisions. In this case, it is stipulated that the*

maximum value of the 1 centimeter dose equivalent rate of the package must not exceed 10 mSv per hour on the surface. When the approval is given, NRA issue an “Approval for the Special arrangements” (limited to the part related to the package). 【Article 14 of the Nuclear Off-Site Transportation Ordinance, Article 34 of the Nuclear Off-Site Transportation Notice】

《Nuclear source materials》

- *The approval procedure of the Special arrangements for land transport of nuclear source materials is not stipulated.*

《Radioisotopes》

- *When it is extremely difficult to transport in accordance with the technical standards for each radioactive package specified in Article 18-3 of the RI Ordinance, users can transport radioisotopes if they receive approval from NRA in the effect that necessary measures to secure safe transportation are taken and there is no safety problem even if they are transported not under provisions for each radioactive package. In this case, it is stipulated that the maximum value of the 1 centimeter dose equivalent rate of the package must not exceed 10 mSv per hour on the surface. 【Article 18(1) of the RI Act, Article 18-12 of the RI Ordinance, Article 21 of the RI Off-Site Transportation Notice】*

[MHLW]

《Radiopharmaceuticals》

- *Regarding land transport of radiopharmaceuticals, Article 2(6) and (7) of the "Regulations on Manufacture and Handling of Radiopharmaceuticals" (MHLW Ordinance No.4 of 1961) (including the case of applying to Article 15), stipulate that the shipment is specifically approved by the regulatory authority of medicine on the condition that there is no safety hindrance, when it is extremely difficult to transport radiopharmaceuticals on land in accordance with the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005). However, no case has required such approval to date. 【Article 2(6) and (7) of the Regulations on Manufacture and Handling of Radiopharmaceuticals (including the case of applying to Article 15)】*

[MIC]

《Postal mail》

• Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, these kinds of radioactive materials cannot be handled by mail or letter service. Therefore, approval certificates are not issued.

802(c) Approval for certain shipments

• Since NRA, MHLW, and MIC are not responsible for approval for certain shipments, it is not covered in the evaluation this time.

802(d) Approval for radiation protection program for special use of vessels

• Regarding approval for radiation protection program for special use of vessels, since NRA, MHLW, and MIC are not responsible for approval for certain transport, therefore, it is not covered in the evaluation this time.

802(e) Approval for calculation of radionuclide values that are not listed in Table 2

[NRA]

《Nuclear fuel materials》

• Regarding land transportation of nuclear fuel materials, radionuclide values are not listed in SSR-6 Table 2, based on the adoption of SSR-6 Table 3 and the provisions of TS-G-1.1, the calculation method is stipulated with detailed conditions in the Nuclear Off-Site Transportation Notice. In addition, if the package requires confirmation by NRA for transportation, in response to the application by nuclear operators, NRA evaluates the adequacy of the value in the examination process whether the design of the package confirms with the technical standards according to the classification of nuclear fuel package specified in the Nuclear Off-Site Transportation Ordinance.

If the conformity is approved, NRA issues “Nuclear Fuel Package Design Approval”. 【Article 59(1) of the Reactor Regulation Act, Article 3 of the Nuclear Off-Site Transportation Ordinance, A1 value and A2 value: Article 4 and Appended Table 1–6 of the Nuclear Off-Site Transportation Notice】

《Nuclear source materials》

• Not applicable since there are no radionuclides that are not listed in SSR-6 Table 2 for nuclear source materials.

《Radioisotopes》

• Regarding radionuclide values not listed in SSR-6 Table 2, based on the incorporation of SSR-6 Table 3 and the provisions of TS-G-1.1, the calculation method is stipulated with detailed conditions, etc. in the RI Off-Site Transportation Notice etc. 【Article 18(1) of the RI Act, Article 18-3 of the RI Ordinance, A1 value and A2 value: Article 2 and Appended Table 1–6 of the RI Off-Site Transportation Notice, Activity concentration limit for exempt material and Activity limit for an exempt consignment: Appended Table 1–6 of the Notification on the Details of Standards Concerning the Carriage of Radioactive Material by Ships 】

[MHLW]

《Radiopharmaceuticals》

• Radiopharmaceuticals are only those listed in Appended Table 1 in the "Regulations on Manufacture and Handling of Radiopharmaceuticals " (MHLW Ordinance No.4 of 1961) and they don't contain radionuclides not listed in SSR-6 Table 2. Regarding radionuclide activity not listed in SSR-6 Table 2, in the case where licensees that manufacture or handle radiopharmaceuticals transport radioactive materials or substances contaminated with radioactive materials (hereinafter referred to as "radioactive materials") on land, based on the incorporation of SSR-6 Table 3 and the provisions of TS-G-1.1, the calculation method is stipulated with detailed conditions in the "Standards for Transport of Radioactive Materials" (MHLW Notice No.491 of 2005) under the provision of Article 2(6) and (7) of the Regulations on Manufacture and Handling of Radiopharmaceuticals (MHLW Ordinance No. 4 of 1961) (including the case of applying to Article 15). Land transportation of radioactive materials, etc. is usually conducted in accordance with the "Standards for Transport of Radioactive Materials" (MHLW Notice No.491 of 2005) and the transport is not required to obtain approval. 【Article 2(6) and (7) and Appended Table 1 of the Regulations on Manufacture and Handling of Radiopharmaceuticals (including the case of applying to Article 15), A2 value: Article 2 and Appended Table 1–6 of the Standards for Transport of Radioactive Materials, Activity concentration limit for exempt material and Activity limit for an exempt consignment: Appended Table 1 of the Standards for Transport of Radioactive Materials 】

[MIC]

《Postal mail》

• Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, these kinds of radioactive materials cannot be handled by mail or letter service. Therefore, approval certificates are not issued.

802(f) Approval for calculation of alternative activity limits for an exempt consignment of instrument or articles

[NRA]

«Nuclear fuel materials» , «Nuclear source materials»

• The Reactor Regulation Act does not prescribe regulatory exemption values themselves, nor approval procedures for calculation of alternative activity limits for exempt consignment of instrument or articles. However the applicable instrument or articles are not assumed and particular problem has not occurred.

«Radioisotopes»

• The RI Act does not prescribe approval procedures for calculation of alternative radioactivity limits for regulatory exempt consignment of instrument or articles fall under paragraph 403 (b) of IAEA SSR-6, and there are no special considerations for radioactivity limits.

[MHLW]

«Radiopharmaceuticals»

• N/A

[MIC]

«Postal mail»

• Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, radioactive materials to be approved for calculation value cannot be handled by mail or letter service, therefore, approval certificates are not issued.

Attachments

A01_ the Reactor Regulation Act

A02_ the Reactor Regulation Act (amended)

A03_ the Cabinet Order for Definition

A04_ the Reactor Regulation Enforcement Cabinet Order
A05_ the Nuclear Off-Site Transportation Ordinance
A07_ the Commercial Reactors Ordinance
A08_ the NRA Ordinance on Use of Nuclear Source Materials
A09_ the Nuclear Off-Site Transportation Notice
B01_ the RI Act
B02_ the RI Ordinance
B03_ the RI Off-Site Transportation Notice
B04_ the Notification on Carriage Standards by Ships
C01_ Pharmaceuticals and Medical Devices Act
C02_ Regulation on Manufacture and Handling of Radiopharmaceuticals
C03_ Standards for Transport of Radioactive Materials
C04_ Standards for Activities of Radioactive Materials
D01_ the Postal Act
D02_ the Notice on Designation of Dangerous Goods under the Postal Act
D03_ the Act on Correspondence Delivery by Private Business Operators
D04_ the Notice on Designation of Dangerous Goods under the Correspondence Delivery Act
D06_ Regulation for Enforcement of the Act on Correspondence Delivery by Private Business Operators
D07_ Universal Postal Convention
D08_ Convention Regulations

Question 11.2

Does the competent authority for transport register serial numbers of transport packaging manufactured to an approved design?

Answer

Yes

Finding

The competent authority for transport registers serial numbers of

transport packaging manufactured to an approved design

Response

[NRA]

○Under the Reactor Regulation Act and RI Act, NRA adequately register and manage transport packagings used for packages that require confirmation (approval) for land transportation of nuclear fuel materials and radioisotopes. In the land transportation of nuclear source materials, there is no package that requires confirmation (approval), so the transport packaging is not registered.

《Nuclear fuel materials》

○Regarding the transport packaging for nuclear fuel materials and transport packaging used for packages that require confirmation (approval) (packages containing 0.1 kg or more of uranium hexafluoride, Type B (U) packages or Type B (M) packages, fissile packages), it is possible to obtain approval (packaging approval) by NRA in advance that packagings that have obtained package design approval are manufactured and maintained as designed and conform to technical standards. In the procedures, NRA issues a “packaging approval” assigned with a series of “approved packaging registration numbers” that can be individually identified for transport packagings that have received packaging approval. NRA manages “approved packaging registration numbers”. 【Article 59(3) of the Reactor Regulation Act, Articles 18, 21, and 22 of the Nuclear Fuel Materials Off-Site Transportation Ordinance】

《Nuclear source materials》

N/A

《Radioisotopes》

○Regarding land transport of radioisotopes, etc., users can obtain packaging approval from the NRA in advance for all Type B (U) packages and Type B (M) packages in advance. A series of “approved packaging registration numbers” that are individually identifiable are issued to transport packagings that have been approved for compliance with technical standards. “Approved packaging registration numbers” are managed appropriately at NRA.

【Article 18(3) of the RI Act, Article 18-7 to 18-20 of the RI Ordinance】

[MHLW]

《Radiopharmaceuticals》

○Regarding the land transport of Radiopharmaceuticals, nothing falls under Type B (U) packages, Type B (M) packages, and special form radioactive materials, etc. In addition, for the land transport of radiopharmaceuticals, transport packagings comply with the package standards stipulated in the “Standards for Transport of Radioactive Materials” (MHLW Notice No. 491 of 2005) are usually used. In such cases, it is not necessary to obtain approval and registration for the packaging. 【Standards for Transport of Radioactive Materials】

[MIC]

《Postal mail》

○Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business, radioactive materials whose amount of radioactivity does not exceed 1/10 of Type L package only can be handled. In addition, it is not required in SSR-6, therefore, transport packagings are not registered.

Attachments

A01_the Reactor Regulation Act

A05_ the Nuclear Off-Site Transportation Ordinance

B01_ the RI Act

B02_ the RI Ordinance

C03_ Standards for Transport of Radioactive Materials

Question 11.3

Does the competent authority for transport perform review and assessment of relevant information for determining whether the applicant for authorization or the authorized party complies with applicable regulatory requirements?

Answer

Yes

Finding

The competent authority for transport performs review and assessment of relevant information for determining whether the applicant for authorization or the authorized party complies with applicable regulatory requirements.

Response

[NRA]

○Under the Reactor Regulation Act and RI Act, NRA is responsible for confirmation of standard conformity of packages among regulations relating to land transportation of nuclear fuel materials and radioisotopes. NRA requires applicants to submit application describing matters to explain safety and necessary attached documents for each license of activities regulated by the Reactor Regulation Act and RI Act to ensure that the activity meets the regulatory requirements and the conditions necessary for the permission and authorization. In this connection, since the review and evaluation related to land transportation of nuclear source materials are not required even in SSR-6, NRA does not

conduct review and evaluation. In addition, NRA publishes the matters to be confirmed in reviews in Acts and ordinances, examination standards, and notification to determine that application meets the criteria, so applicants could recognize the information to be submitted at the time of application in advance.

《Nuclear fuel materials》

○When nuclear operators, transport nuclear fuel materials or materials contaminated with nuclear fuel materials on land outside the sites, they are required to take necessary measures for safety in accordance with the technical standards stipulated in the Ordinance of the NRA, etc. based on the Reactor Regulation Act. 【Article 59(1) of the Reactor Regulation Act】

○Regarding packages that are particularly necessary for disaster prevention (Type B (U) packages and Type B (M) packages, fissile packages, nuclear fuel packages containing 0.1 kg or more of uranium hexafluoride), NRA confirms them with the following documents attached to the application form or on-site inspection by NRA staff before transportation, in response to the package confirmation application by nuclear operators under the Reactor Regulation Act. When it is confirmed that the measures for transportation conform to the technical standards, NRA issues “package confirmation”.

(1) Explanatory documents on nuclear fuel materials to be transported

(2) Explanatory documents on structure and material (packaging design) of the packaging to store nuclear fuel materials (transport packaging), and safety of the nuclear fuel packages when the nuclear fuel material is stored in the transport packaging

(3) Explanatory documents on how to manufacture the transport packaging

(4) Explanatory documents indicating that the transport packaging is manufactured according to the design and manufacturing method

(5) Explanatory documents indicating that the transport packaging is maintained in conformity with the design and manufacturing method

(6) Explanatory documents on inspection before shipment of nuclear fuel packages

【Article 59(2) of the Reactor Act, Article 48 of the Reactor Regulation Enforcement Cabinet Order, Article 18, 19, 20 of the Nuclear Off-Site Transportation Ordinance, “Operational Guidelines for Confirmation of Transport of Nuclear Fuel Packages Outside Plants” (No. 1402263 of Gen Kan Hai Hatsu, Feb. 26, 2014, Decision by Secretary-General of the Secretariat of NRA)(hereafter referred to as “the Nuclear Off-Site Transportation Operation Guide”)】

○In addition, prior to the application for confirmation of package, NRA can approve the design of the transport packaging, the safety of package containing nuclear fuel materials,

manufacturing method of transport packaging, and that the transport packaging is manufactured and maintained according to the design and manufacturing method stepwise. Based on the nuclear fuel package design approval application and packaging approval application from nuclear operators, NRA reviews compliance with technical standards and when the conformity is confirmed, it issues “Nuclear Fuel Package Design Approval” and “Packaging Approval”. 【Article 59(3) of the Reactor Regulation Act, Article 21 and 22 of the Nuclear Off-Site Transportation Ordinance, Article 41(1) and (2) of the Nuclear Off-Site Transportation Notice 】

○NRA evaluates the safety analysis document prepared by the applicant as well as the test data and technical data for nuclear fuel package design approval. At that time, the evidence of analysis or additional analysis may be requested, if necessary. For these reviews, NRA has a internal mechanism that can seek opinions from a specialized perspective in each field. When reviewing packaging approval, NRA confirms that the transport packaging is manufactured according to the design approved in the nuclear fuel package design approval based on various inspection results such as material inspection and welding inspection by nuclear operators. 【“Procedure 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” (June 1, 2011, NISA No. 8 dated March 7, 2011, Nuclear and Industrial Safety Agency Notice) “3. Explanatory documents on how to manufacture transport packaging” Chapter B】

○In addition, NRA requires nuclear operators to describe explanations on the quality management system related to the design, manufacturing, maintenance and handling of transport packagings in the nuclear fuel package design approval application according to the Nuclear Off-Site Transportation Notice and “Procedure 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” (Nuclear and Industrial Safety Agency Notice) upon design approval. When approving packagings, NRA requires nuclear operators and designer, manufacturer, and parts supplier to provide explanations on quality management systems related to transport packaging manufacturing in accordance with the guidelines based on “Procedure 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” (Nuclear and Industrial Safety Agency Notice) and “Guidelines for Quality Management of Manufacturing Method of the Packaging”. Based on the application, NEA reviews establishment and proper functioning of overall quality management system for the design, manufacturing, maintenance and handling of transport packagings in the review through document confirmation and on-site inspection. 【Article 41 and Form 1 Note 1 of the Nuclear Off-Site Transportation Notice, “Procedure 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” (June 1, 2011, NISA No. 8 dated March 7, 2011, Nuclear and Industrial Safety Agency Notice) “2. Explanatory documents on the design of the transport packaging and the safety of the nuclear fuel package when containing nuclear fuel material, etc.” Chapter C, and “3. Explanatory documents on how to manufacture transport packaging” Chapter D, “Guidelines for Quality Management of Manufacturing Method of the Packaging” (June 20, 2008, NISA No. 1 dated June 10, 2008, Nuclear and Industrial Safety Agency Notice)】

《Radioisotopes》

○Regarding the shipment of radioisotopes, etc., users are required to take necessary measures to prevent radiation hazard according to technical standards. 【Article 18(1) of the RI Act】

○Among the above, regarding the B (U) type package and B (M) type package that are specifically required by the administrative authorities for the prevention of radiation damage, NRA, in response to the package confirmation application by users according to the RI Act, issues “certificate of shipment” if the measures related to transportation comply with the technical standards by confirming with the documents attached to the application form or confirming the actual package at the shipping location.

(1)Explanatory documents on radioisotopes shipped

(2)Explanatory documents on structure and material of the packaging to store radioisotopes, and safety of the radioisotopes when the radioisotopes are stored in the transport packaging

(3)Explanatory documents that the packaging is manufactured according to the package design

(4)Explanatory documents indicating that the transport packaging is maintained in conformity with the design and manufacturing method

(5)Explanatory documents on inspection before shipment of radioactive packages

【Article 18(2) of the RI Act, Article 18-15, 18-16 of the RI Ordinance】

○Prior to the confirmation of the above-mentioned package, users can obtain the packaging approval for conformity to the technical standards of the packaging used for transportation in advance. In response to an application for packaging approval by users under the RI Act, NRA issues “packaging approval” when users submit the attached Explanatory documents for the following items and NRA approves that packaging for shipment meet technical standards.

(1)Explanatory documents on radioisotopes that are scheduled to be transported in packagings

(2)Explanatory documents on the design of the packaging and the safety of radioactive packages when the radio isotopes are stored in the packaging

(3)Explanatory documents that the packaging is manufactured according to the packaging design

(4)Explanatory documents indicating that the transport packaging is maintained in conformity with the design of (2)

When transport is conducted using approved packaging, (2) and (3) can be omitted among Explanatory documents submitted for application for package confirmation. 【Article 18(3) of the RI Act, Article 18-17 of the RI Ordinance 】

○In addition, design approval can be obtained in advance for compliance with technical standards for packaging design included as part of packaging approval. NRA issues “radioactive package design approval” when design approval is given. 【Article 18-17 of the RI Ordinance, Article 25 of the RI Off-Site Transportation Notice 】

○For the review of packaging approval prior to package confirmation, safety analysis documents prepared by users, and test data and technical data related to them are independently evaluated and verified for the technical standards stipulated in the RI Act and RI Ordinance, etc. At that time, the basis of the analysis or additional analysis may be required. In addition, NRA confirms that it is manufactured according to the design based on various inspection results such as material inspection and welding inspection by users.

【Article 18(3) of the RI Act, Article 18(6) of the RI Ordinance, (Type B(M) package), Article 18-7 of the RI Ordinance (Type B(U) package), Article 11 of the RI Off-Site Transportation Notice (Type B(M) package), Article 16 of RI Off-Site Transportation Notice (Type B(U) package) 】

○In addition, NRA requires users to establish and implement a quality management system for transport packagings in accordance with the “Quality Control Review Guidelines for the Manufacturing of Nuclear Fuel Material Transport Packagings”. 【“Quality Control Review Guidelines for the Manufacturing of Nuclear Fuel Material Transport Packagings” (18 SNS Notice No. 139 of January 11, 2007) 2. Appendix 2 】

[MHLW]

《Radiopharmaceuticals》

○Regarding the land transport of radiopharmaceuticals, nothing falls under Type B(U) package and Type B(M) package or special-form radioactive materials. In addition, land transport of radiopharmaceuticals is usually carried out in accordance with the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005) and approval or certification is not required for the land transport. In order to manufacture radiopharmaceuticals, manufacturing license under Article 13(1) of the “Pharmaceuticals

and Medical Devices Act” is required and in order to distribute radiopharmaceuticals, Marketing license under Article 12(1) of the “Pharmaceuticals and Medical Devices Act” or wholesale distribution license under Article 25(iii) of the Act is required. In addition, a pharmacy proprietor licensed under the provisions of Article 4(1) may also be a consignee of a radiopharmaceutical. The regulatory authority of medicine regularly confirms compliance with laws related to land transport of radiopharmaceuticals when renewing the licenses of each licensees. Other than that, MLHW conducts on-site inspection under Article 69(1) of the “Pharmaceuticals and Medical Devices Act” as necessary. 【Article 4(1), Article 12(1), Article 13(1), Article 25(iii), and Article 69(1) of the Pharmaceuticals and Medical Devices Act】

[MIC]

《Postal mail》

○Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, radioactive materials whose amount of radioactivity does not exceed 1/10 of Type L package only can be handled. In addition, it is not required in SSR-6, therefore, review or evaluation is not carried out.

Attachments

A01_ the Reactor Regulation Act

A04_ the Reactor Regulation Enforcement Cabinet Order

A05_ the Nuclear Off-Site Transportation Ordinance

A10_ the Nuclear Dose Limit Notice

A11_ the Nuclear Off-Site Transportation Operation Guide

A13_ the Nuclear Off-Site Transportaion Describing Procedure Guide

A14_ the Manufacturing Quality Management Guide

B01_ the RI Act

B02_ the RI Ordinance

B03_ the RI Off-Site Transportation Notice

B06_ Quality Control Review Guidelines

C01_ Pharmaceuticals and Medical Devices Act

Subsidiary Question 11.3.1

Does the competent authority for transport continue to review and assess as necessary, relevant information associated with the transport approvals during the validity period of the transport approvals?

Subsidiary Response

[NRA]

«Nuclear fuel materials»

○NRA stipulates that the validity period of the nuclear fuel package design approval certificate and the packaging approval certificate is 5 years under the Reactor Regulation Act, in principle. When nuclear operators intend to transport nuclear fuel materials that require confirmation regarding transportation outside the sites during the period of validity, NRA confirms that the packagings used are properly maintained and managed so that they meet the technical standards, and that inspections before shipping are properly conducted in the process of review based on the application for confirmation of package transportation. NRA also conducts review and evaluation during the valid period of nuclear fuel package design approval and packaging approval. 【Article 19 of the Nuclear Off-Site Transportation Ordinance】

○Packages that have obtained a nuclear fuel package design approval certificate and a packaging approval certificate can update the validity period by showing that there is no change in its design. In addition, the Nuclear Off-Site Transportation Notice stipulates that nuclear fuel package design approval must be obtained if change the design of an approved nuclear fuel package is intended, regardless of the period of validity of the package.

【Article 23 of the Nuclear Off-Site Transportation Ordinance, Article 41(1) (3) (4)and(5) of the Nuclear Off-Site Transportation Notice】

○The technical standards and evaluation standards that NRA use as a bases of the confirmation on transportation of nuclear fuel materials are, basically, made in the form that incorporating SSR-6 into the Reactor Regulation Act, related ordinances and notices. Along with the revision of SSR-6, if these Acts, ordinances or notices are revised, unless otherwise required, immediate retrospective application to nuclear fuel shipments within the validity period is not required. However, when nuclear operators renew the validity period of the latest design approval for nuclear fuel packages, they need to check for

compliance with the latest technical standards and see if any changes need to be made to the design.

《Nuclear source materials》

N/A

《Radioisotopes》

○NRA stipulates that users take necessary measures for the prevention of radiation damage in accordance with technical standards based on the RI Acts and regulations regarding the transport of radioisotopes.

The effective period for packaging approvals that are included in the measures is described in the packaging approval application form. Although legal standards do not exist, it is described in the packaging approval form in consideration of the useful life of the packaging itself.

In addition, for the renewal of packaging approval, update of use period can be obtained by showing that the packaging is maintained to conform to the design of the packaging. 【Article 18-19 of the RI Ordinance】

In addition, regarding the application for renewal of design approval, the Off-Site Transportation Notice stipulate that it is also possible to receive a renewal of the validity period by showing that there is no change in the design of the radioactive package.

【Article 25 of the RI Off-Site Transportation Notice】

○Regarding transportation of radioisotopes, users are required to take necessary measures to prevent radiation damage according to technical standards based on RI Acts and regulations. Among the measures, when users try to transport using packagings that have obtained a packaging approval certificate, they are supposed to receive package confirmation of the package by the administrative authorities. At that time, in addition to the matters that have been approved in advance in the packaging approval, instructions for inspection prior to shipping of radioactive packages are required, and at the same time, the validity period of the packaging approval form is also confirmed. 【Article 18(2) of the RI Act, Article 18-15 of the RI Ordinance】

○NRA has the authority to conduct on-site inspections for users. In the on-site inspection, NRA can enter the office or plant or business office and inspect the books of the user to the extent necessary to enforce the RI Act. When users transport all radioisotopes, they are required to enter the date and method of transport, the name of the consignee or shipper or

the name of the shipper, etc., and the name of the shipper in the book, and keep it for 5 years. 【Article 43-2(1) of the RI Act, Article 24 of the RI Ordinance】

○In addition, NRA has the authority to collect information from users based on the RI Act. Users have the obligation to report the status of transportation of radioisotopes carried out outside of the plant within a period, if the report is required. 【Article 31-2 of the RI Act, Article 39(3)(iii) of the RI Ordinance】

[MHLW]

《Radiopharmaceuticals》

○Regarding the land transport of radiopharmaceuticals, nothing falls under Type B(U) package and Type B(M) package or special form radioactive material. In addition, land transport of radiopharmaceuticals is usually conducted in accordance with the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005) and approval or certification is not required for the land transport. In Article 2(7)(ii) of the "Regulations on Manufacture and Handling of Radiopharmaceuticals" (MHLW Ordinance No.4 of 1961) (including the case of applying to Article 15), it is stipulated that the operators prepare and store the record each time radiopharmaceuticals are transported on land. If necessary, the competent authority will inspect the records in accordance with Article 69(1) of the “Pharmaceuticals and Medical Devices Act”, in order to see whether the land transport of radiopharmaceuticals was conducted in accordance with the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005). 【Standards for Transport of Radioactive Materials, Article 2(7)(ii) of Regulations on Manufacture and Handling of Radiopharmaceuticals (including the case of applying to Article 15), Article 69(1) of the Pharmaceuticals and Medical Devices Act】

[MIC]

《Postal mail》

○Under the Postal Act, Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators, radioactive materials whose amount of radioactivity does not exceed 1/10 of Type L package only can be handled. In addition, it is not required in SSR-6, therefore, review or evaluation is not carried out.

Subsidiary Attachments

A05_the Nuclear Off-Site Transportation Ordinance

A09_ the Nuclear Off-Site Transportation Notice

B01_ the RI Act

B02_ the RI Ordinance

B03_ the RI Off-Site Transportation Notice

C01_ Pharmaceuticals and Medical Devices Act

C02_ Regulation on Manufacture and Handling of Radiopharmaceuticals

C03_ Standards for Transport of Radioactive Materials

Question 11.4

Prior to issuance of approval of special arrangement shipments, is it required that the competent authority for transport is satisfied that conformity with some of the provisions of the regulations is impracticable and that the requisite standards of safety established by the regulations have been demonstrated?

Answer

Yes

Finding

Approval of special arrangements takes place only if the regulatory restrictions are met.

Response

[NRA]

○Among the approval procedures for land transport by Special arrangements, NRA has jurisdiction over the approval procedures for Special arrangements relating to the packages of nuclear fuel materials and radioisotopes. On the other hand, the Ministry of Land, Infrastructure, Transport and Tourism has jurisdiction over the approval procedures for

Special arrangement relating to the transportation method of nuclear fuel materials and radioisotopes, and it is not covered in the evaluation this time.

《Nuclear fuel materials》

○If it is extremely difficult to transport in accordance with the Reactor Regulation Act, the NRA examines measures and the reasons that are difficult to take in accordance with the regulations based on applications from nuclear operators, and if the NRA approves that there are no safety hazards even if the measures are taken to ensure safe transportation and transportation is not carried out according to these regulations, it can be transported. In this case, it is stipulated that the maximum value of the 1 centimeter dose equivalent rate of the transported object must not exceed 10 mSv per hour on the surface. 【Article 14 of the Nuclear Off-Site Transportation Ordinance, Article 34 of Nuclear Off-Site Transportation Notice】

《Nuclear source materials》

○There are no special arrangements approval procedures for land transport of nuclear source material.

《Radioisotopes》

○The NRA has decided that users, etc. shall take necessary measures to prevent radiation hazards in accordance with technical standards based on the RI Act and regulations regarding the transport of radioisotopes, etc. 【Article 18 of the RI Act】.

○Among the necessary measures mentioned above, the pre-approval procedure for transport by Special arrangements is included in the approval procedure for transported goods such as radioisotopes, etc. and is under the jurisdiction of the NRA 【Article 18-12 of the RI Ordinance, Article 21 of the RI Off-Site Transportation Notice】.

○When it is extremely difficult to carry in accordance with the provisions for each radioactive package under the RI Act, and when necessary measures are taken to ensure safe transportation, and approval from the NRA is obtained based on an application from the user, etc., that there are no safety problems even if these rules are not followed, it can be transported. In this case, it is stipulated that the maximum value of the 1 centimeter dose equivalent rate of the transported object must not exceed 10 mSv per hour on the surface. The NRA has not yet received any application. 【Article 18-12 of the RI Ordinance, Article 21 of the RI Off-Site Transportation Notice】

[MHLW]

《Radiopharmaceuticals》

○In Article 2(6) and (7) (including the cases of applying to Article 15.) of the “Regulations on Manufacture and Handling of Radiopharmaceuticals” (Ministry of Health and Welfare Ordinance No.4 in 1961), in cases where it is extremely difficult to transport radiopharmaceuticals on land in compliance with the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005), it is stipulated that the regulatory authority of medicine gives special approval for the land transport, provided that there are no safety hindrance. However, no cases has required such approval to date. 【Article 2(6) and (7) (including the cases of applying to Article 15.) of the Regulations on Manufacture and Handling of Radiopharmaceuticals, Standards for Transport of Radioactive Materials】

[MIC]

《Postal mail etc.》

○No special arrangements have been approved since the only radioactive materials that can be handled under the Postal Act, the Universal Postal Convention etc. and the Act on Correspondence Delivery by Private Business Operators are radioactive materials that do not exceed 1/10 of the Type L package.

Attachments

A05_ the Nuclear Off-Site Transportation Ordinance

A09_ the Nuclear Off-Site Transportation Notice

B01_ the RI Act

B02_ the RI Ordinance

B03_ the RI Off-Site Transportation Notice

C02_ Regulation on Manufacture and Handling of Radiopharmaceuticals

C03_ Standards for Transport of Radioactive Materials

Question 11.5

Does the competent authority for transport carry out inspections of facilities and activities related to transport of radioactive materials to verify compliance with regulatory requirements and the conditions specified in any approvals?

Answer

Yes

Finding

The competent authority for transport carries out inspections of facilities and activities related to transport of radioactive materials to verify compliance with regulatory requirements and the conditions specified in any approvals.

Response

[NRA]

《Nuclear fuel materials》

○The NRA has the authority to conduct on-site inspections for nuclear operators, and it has the authority to exercise its authority when a serious nonconformity event related to the transportation of nuclear fuel is detected. **【Article 68(1) of the Reactor Regulation Act】**

○In addition, regarding land transportation of nuclear fuel materials, etc., it is supposed to take necessary measures for safety in accordance with the technical standards based on the Reactor Regulation Act, and, among them, when nuclear operators transport Type B packages or fissile packages containing 0.1 kg or more of uranium hexafluoride outside the site, the application requires confirmation of the packages by the NRA. In the examination based on the application for confirmation of the packages, confirmation is made by the submitted documents that the application conforms to technical standards. Under the concept of graded approach, when an application for confirmation of packages related to Type B packages departure from Japan, NRA staff members witness the pre-shipment inspections conducted by nuclear operators, and confirm the appropriateness of the inspection contents. In addition, in the examination based on the application for packaging approval or nuclear fuel package design approval, which is the procedure before the confirmation of package, conformity to technical standards of the application content is

usually confirmed by the submitted documents. However, based on the idea of a graded approach, NRA staff members may visit nuclear operators or manufacturers that manufacture packagings to check directly, if necessary. 【Article 59(2) of the Reactor Regulation Act, Article 19 of the Nuclear Off-Site Transportation Ordinance, the Nuclear Off-Site Transportation Operation Guide】

○Based on the authority to confirm applications from nuclear operators based on the Reactor Regulation Act, the above confirmation has been carried out as a part of comprehensive confirmation including audits of management systems of the concerned nuclear operators, packaging designers, manufacturers, parts suppliers, etc., attending various tests and on-site confirmation, concerning transportation measures complying with the technical standards stipulated by the Act.

*○On the other hand, in the package confirmation, including access to offices, factories, place of activity by persons other than the applicant, the scope of legal authority was unclear, so the confirmation related to transportation was incorporated into the amendment of the Reactor Regulation Act taking the opportunity to review the inspection system for all nuclear facilities *, so that it could be carried out as part of a systematic inspection,. 【Article 61-2-2 and Article 68(2) of Amended Reactor Regulation Act】*

** : It is not yet implemented at this time and is scheduled to be implemented in April 2020.*

○Making it clear that nuclear operators themselves have an obligation to carry out inspections and have a primary responsibility for ensuring safety, nuclear regulatory inspections structured as a mechanism that allows the NRA to monitor and evaluate the implementation status of measures that should be taken by nuclear operators based on laws and regulations, deciding inspection samples according to risk, without restrictions on time and scope. Among them, legal authority is also granted when an inspector of the NRA enters and confirms a factory or a place of activity of a nuclear operator. Therefore, even when nuclear operators transport nuclear fuel materials outside the sites and place of activity, the framework enables the NRA to monitor and evaluate the safety measures taken by the nuclear operator in accordance with technical standards without restrictions on time and scope.

○The scope of the on-site inspection based on the Reactor Regulation Act has been limited to those who welded nuclear facilities in addition to nuclear operators, however, it has been newly clarified that the design and construction of nuclear facilities, equipment manufacturers and other related parties are included in the scope. Therefore, using this framework, it is legally ensured that on-site inspections can be carried out for packaging designers, manufacturers, parts suppliers, etc. to the extent of implementation of the Reactor Regulation Act. 【Article 68(2) of Revised Reactor Regulation Act】

○Currently, the necessary ordinances and guides are being prepared for the enforcement of the amended Reactor Regulation Act (scheduled for April 2020) incorporating nuclear regulatory inspections.

○The scope of current on-site confirmation conducted by the NRA is limited to what is necessary for the NRA to make an approval based on the application, because it is implemented as part of the examination based on the nuclear fuel package design approval application, packaging approval application and package confirmation application from nuclear operators. On the other hand, the nuclear regulatory inspection * in the new inspection system will establish a legal framework that can inspect even package that does not require the issuance of package design approval. After the amended Reactor Regulation Act comes into force, from the viewpoint of confirming that transport measures implemented by nuclear operators conform to technical standards, it will allow NRA to monitor and evaluate the implementation status of measures that should be taken based on laws and regulations without restrictions on time and scope. 【Article 61-2-2 of Revised Reactor Regulation Act】

* : It is not yet implemented at this time and is scheduled to be implemented in April 2020.

《Nuclear source materials》

○When a user of nuclear source materials transports nuclear source materials, the Reactor Regulation Act stipulates that the type, amount, handling method, measures taken in the event of an accident, and other matters to be noted regarding transportation must be recorded. The NRA has the authority to conduct on-site inspections for users of nuclear source materials based on the Reactor Regulation Act, and on-site inspections can confirm records related to transportation. The NRA also follows up on nonconformity events that were revealed during the on-site inspection. The results of the on-site inspection are provided to the user after the inspection. 【Article 57-7(6) and Article 68 of the Reactor Regulation Act, Article 3 of the Nuclear Source Materials Use Ordinance】

《Radioisotopes》

○Regarding land transport of radioisotopes, etc., it is supposed to take necessary measures to prevent radiation damage according to technical standards based on Article 18 of the RI Act, in particular, when transporting Type B(M) packages and Type B(U) packages outside the sites, etc., it is necessary to receive a package confirmation. In the confirmation of transported objects, in addition to the contents approved in packaging approval, confirmation is made regarding the radioisotopes to be transported, that the packagings are maintained so as to conform to the design of the packagings, and that the inspections are related to the shipment before the shipment of the radioactive packages. 【Article 18(2) of the RI Act】

○NRA has the authority to conduct on-site inspections for users, etc., and in the on-site inspection, NRA can enter the office or factory or place of activity of the user, etc. to the extent necessary for the enforcement of the RI Act, and inspect the account books. When

transporting all radioisotopes, etc., users, etc. are obliged to write in the account books the date of transportation, method, and the name or name of the consignee or consignor, and to keep them for 5 years. 【Article 43-2(1) of the RI Act, Article 24 of the RI Ordinance】

○In addition, NRA has decided to collect reports based on RI Act from users, etc., and when NRA requests a report for a certain period of time regarding the status of transport of all radioisotopes, etc. that takes place outside the sites, etc., an obligation to report within that period is imposed. 【Article 31-2 of the RI Act, Article 39(3) (iii) of the RI Ordinance】

[MHLW]

《Radiopharmaceuticals》

○The regulatory authority of medicine regularly confirms compliance with laws related to land transport of radiopharmaceuticals when renewing the license of each licensed company, furthermore, on-site inspections, etc., as stipulated in Article 69(1) of the “Pharmaceuticals and Medical Devices Act” shall be conducted as necessary. 【Articles 4(4) and 12(2), 13(3), 24(2), and 69(1) of the Pharmaceuticals and Medical Devices Act】

[MIC]

《Postal mail etc.》

○In accordance with Article 16(1) of the Act on Japan Post Co., Ltd. or Article 37(2) of the Act on Correspondence Delivery by Private Business Operators, to the extent necessary for the enforcement of these laws, including proper transport of radioactive materials, it is possible to ask for a report from Japan Post Co., Ltd. or a letter service provider, and to give orders necessary for on-site inspection or supervision. 【Article 16(1) of the Act on Japan Post Co., Ltd., Article 37(2) of the Act on Correspondence Delivery by Private Business Operators】

Attachments

A01_the Reactor Regulation Act

A02_the Reactor Regulation Act (amended)

A08_the NRA Ordinance on Use of Nuclear Source Materials

A11_the Nuclear Off-Site Transportation Operation Guide

B01_ the RI Act

B02_ the RI Ordinance

C01_ Pharmaceuticals and Medical Devices Act

D03_ the Act on Correspondence Delivery by Private Business Operators

D05_ the Act on Japan Post Co., Ltd.

Question 11.6

Does the competent authority for transport make arrangements for assessments of radiation doses to persons due to transport of radioactive material, to ensure the system of protection and safety for transport complies with GSR Part 3?

Answer

Yes

Finding

The competent authority for transport has made arrangements for assessment of radiation doses of persons due to transport of radioactive material.

Response

[NRA]

《Nuclear fuel materials》

○Based on the Reactor Regulation Act, nuclear operators are obliged to measure the exposure dose of radiation workers who manufacturing package in the controlled area, manage the exposure dose not to exceed the exposure limit, and record and store the exposure dose. In accordance with Article 5 of the Notifications that Establish Dose limits in accordance with the Provisions of NRA Ordinance on Activity of Refining Nuclear Source or

Nuclear Fuel Materials, etc. (hereinafter referred to as "the Notifications to Establish Dose Limits"), the maximum radiation exposure for radiation workers is 50 mSv per year and 100 mSv per five years. In the case of exceeding this exposure, nuclear operators shall report to the NRA based on Article 62-3 of the Reactor Regulation Act. In addition, nuclear operators are required to keep records of radiation doses of workers engaged in radiation work, and the NRA confirms the records during on-site inspections. 【Article 43-3-21, Article 43-3-22 and Article 62-3 of the Reactor Regulation Act, Article 79 and Article 67(1) (v) (d) to (g) of the NRA Ordinance concerning the Installation and Operation of Commercial Power Reactors, Article 5 of the Notifications to Establish Dose Limits】

○In addition, the assessment of the radiation dose to the carriers caused by land transportation of nuclear fuel materials falls under the category of transportation methods and it is not covered in the evaluation this time because it is under the jurisdiction of MLIT.

《Nuclear source materials》

○Based on the Reactor Regulation Act, users of nuclear source materials are required to measure the exposure dose of radiation workers who manufacturing package within the controlled area, manage the exposure dose not to exceed the exposure limit, and record and store the exposure dose. In accordance with Article 5 of the Notification, which sets dose limits based on the rules and regulations concerning the refining business of nuclear source materials or nuclear fuel materials, the maximum radiation exposure for radiation workers is 50 mSv per year and 100 mSv per five years. In the case of exposure exceeding this, users of nuclear source materials shall report to the NRA based on Article 62-3 of the Reactor Regulation Act. In addition, users of nuclear source materials are to keep records of radiation doses of workers engaged in radiation work, and the NRA confirms the records during on-site inspections. Regarding land transport of nuclear source materials, there is no requirement to establish a radiation protection plan because of the low radiation risks, based on the current approach to transportation in line with the graded approach to meet radiation risks. 【Article 57-7(4) and (6), and Article 62-3 of the Reactor Regulation Act, Articles 2(v), Articles 3 and 5 of the Nuclear Source Materials Use Ordinance, Article 5 of the Nuclear Dose Limits Notice】

《Radioisotopes》

○Based on the RI Act, users, etc. are obliged to measure the exposure dose of radiation workers who produce transported goods in the controlled area, manage the exposure dose not to exceed exposure dose limit, and record and store the exposure dose. In accordance with Article 5 of the Notification to Specify Standards for Amount of Radioisotopes based on the provisions of the RI Act Enforcement Regulations, etc. (hereinafter referred to as "the Amount of RI Notice"), the maximum radiation exposure for radiation workers is 50 mSv per year and 100 mSv per five years. If there is more exposure than this, the users, etc. shall

report to the NRA in accordance with Article 31-2 of the RI Act. In addition, users, etc. are to keep records of radiation doses of workers engaged in radiation work, and the NRA is to confirm such records during on-site inspections. 【Articles 20 and 31-2 of the RI Act, Article 1(viii), Article 20 of the RI Ordinance, Articles 5 of the Amount of RI Notice 】

○The assessment of the radiation dose to the carriers caused by land transportation of radioisotopes falls under the scope of the transport method and is outside the scope of this evaluation because it is under the jurisdiction of the Ministry of Land, Infrastructure, Transport and Tourism.

[MHLW]

《Radiopharmaceuticals》

○As with the RI Act, rules and standards have been established to incorporate IAEA safety standards for radiological protection in the land transport of radiopharmaceuticals by ministerial ordinance and notification based on the provision of the “Pharmaceuticals and Medical Devices Act”. Specifically, in order to appropriately prevent radiation hazards in the land transport of radiopharmaceuticals, require that licensed companies that manufacture or handle radiopharmaceuticals, in Article 6(iv) (including the cases of applying to Article 15.) of the “Regulations on Manufacture and Handling of Radiopharmaceuticals” (Ministry of Health and Welfare Ordinance No. 4 in 1961), to establish preventive rules in order to prevent the occurrence of hazards due to radiation exposure in relation to the land transport of radiopharmaceuticals, and in Article 12 (including the cases of applying to Article 15.), licensed companies that manufacture or handle radiopharmaceuticals appoint the manager to prevent hazards and require them to supervise for the prevention of hazards caused by radiation exposure. In addition, in Article 26 of the “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005), in order to prevent hazards from radiation exposure, the shipper and consignee are obliged to establish a radiation protection programme that includes matters related to radiation dose measurement methods and dose assessment, as well as matters related to segregation and protection from packages, and Article 9 of the “Standards for Activities of Radioactive Materials” (MHLW Notice No. 399 of 2000) stipulates that the dose limit for persons engaged in the land transport of radioactive materials, etc. is 1 mSv per year. 【Article 6(iv) and Article 12 of the Regulations on Manufacture and Handling of Radiopharmaceuticals (including cases where it is applied mutatis mutandis in Article 15.), Article 26 of the Standards for Transport of Radioactive Materials, Article 9 of the Standards for Activities of Radioactive Materials 】

[MIC]

《Postal mail etc.》

○The regulatory authority may request a report from Japan Post Co., Ltd., which provides the mail, as to whether proper transport of radioactive materials, etc. has been conducted in accordance with Article 16 of the Act on Japan Post Co., Ltd., and in addition, from a letter service provider providing a letter service, may request a report in accordance with the rules of Article 37 of the Act on Correspondence Delivery by Private Business Operators. Furthermore, letter service operators are required to implement education and training for letter service workers, as a condition for approval of the Letter Service Management Regulations of Article 31(2)(iv) of the Enforcement Regulations of the Act on Correspondence Delivery by Private Business Operators. 【Article 31(2)(iv) of the Enforcement Regulations of the Act on Correspondence Delivery by Private Business Operators, Article 37 of the Act on Correspondence Delivery by Private Business Operators】

Attachments

A01_ the Reactor Regulation Act

A07_ the Commercial Reactors Ordinance

A08_ the NRA Ordinance on Use of Nuclear Source Materials

A10_ the Nuclear Dose Limit Notice

B01_ the RI Act

B02_ the RI Ordinance

B05_ the Amount of RI Notice

C02_ Regulation on Manufacture and Handling of Radiopharmaceuticals

C03_ Standards for Transport of Radioactive Materials

C04_ Standards for Activities of Radioactive Materials

D03_ the Act on Correspondence Delivery by Private Business Operators

D06_ Regulation for Enforcement of the Act on Correspondence Delivery by Private Business Operators

Question 11.7

Does the competent authority for transport require appropriate action to be taken on discovery of a non-compliance?

Answer

Yes

Finding

The competent authority for transport ensures that appropriate action is taken in the event of a non-compliance.

Response

[NRA]

«Nuclear fuel materials»

○According to the regulations of the Reactor Regulation Act, nuclear operators must report the situation and measures for accidents to the NRA when transporting nuclear fuel materials outside the site,(1) when the nuclear fuel material is stolen or lost, (2) when the nuclear fuel material leaks abnormally, and (3) when a person's fault occurs or is likely to occur. 【Article 62-3 of the Reactor Regulation Act, Article 25 of the Nuclear Off-Site Transportation Ordinance】

○When non-conformances that affect transportation occur when transporting nuclear fuel packages, the information will be promptly shared among the parties concerned in accordance with the system of communication to the relevant organizations established within the framework of the “Interagency Coordination Meeting for the Safe Transport of Radioactive Material”.

○When it is found that the transportation measures taken by the nuclear operators do not conform to the technical standards stipulated in the Reactor Regulation Act, the NRA may order nuclear operators to stop transportation or take other measures necessary for safety and protection. 【Article 59(4) of the Reactor Regulation Act】

○In addition, when there is an urgent danger of a disaster due to nuclear fuel materials, when it is recognized that there is an urgent need to prevent a disaster, based on the Reactor Regulation Act, the NRA may order nuclear operators to changes in the location of

nuclear fuel materials or take other necessary measures to prevent disasters. 【Article 64(3) of the Reactor Regulation Act】

○Furthermore, in case of violation of regulations and violation of an order, the NRA may order a nuclear operators to revoke license or to stop the business within one year. 【Article 43-3-20, etc. of the Reactor Regulation Act】

○Depending on the event that occurred and its necessity, the NRA that has received the above report or ordered to take action seeks investigation of the cause and formulation/implementation of recurrence prevention measures, etc., from the relevant nuclear operator, etc. with the authority to collect reports based on the Reactor Regulation Act, and the NRA may conduct on-site inspections to confirm the implementation status. 【Articles 67 and 68 of the Reactor Regulation Act】

- Report to the competent minister (Article 62-3 of the Reactor Regulation Act)*
- Order to stop transportation of nuclear fuel materials and other necessary measures (Article 59(4) of the Reactor Regulation Act)*
- Order for measures in case of danger (Article 64(3) of the Reactor Regulation Act)*
- Cancellation of license or suspension of activity (Article 43-3-20, etc. of the Reactor Regulation Act)*
- Collection of reports (Articles 67 of the Reactor Regulation Act)*
- On-site inspection (Articles 68 of the Reactor Regulation Act)*

*○In addition, after the revision of the Reactor Regulation Act, in the new inspection system that is currently considering implementation, when nuclear operators transport nuclear fuel materials outside the sites, the nuclear operators will be able to carry out nuclear regulatory inspections that monitor and evaluate the necessary measures for safety in accordance with technical standards, with no restrictions on time and scope *. When a nonconformity event is confirmed in this inspection, a comprehensive evaluation is performed according to the event, and the result can be notified to the nuclear operator and publicized.*

In addition, packaging designers, manufacturers, and parts suppliers can be requested to investigate the cause and formulate and implement measures to prevent recurrence using the on-site inspection authority that has been strengthened through the revision of the furnace regulations, and it will be possible to conduct on-site inspections to confirm the

implementation status*. **【Article 61-2-2 and Article 68 (2) of Revised Reactor Regulation Act】**

* : It is not yet implemented at this time and is scheduled to be implemented in April 2020.

《Nuclear source materials》

○According to the Reactor Regulation Act, each nuclear material user must report the situation and actions to the NRA as an accident failure event when each nuclear source materials are transported by land, (1) when the nuclear source materials are stolen or unidentified, (2) when the nuclear source materials or material contaminated with the nuclear source materials leak abnormally, and, (3) when radiation dose workers exceed the dose limit stipulated in the notification, or when there is an exposure that may exceed. **【Article 62-3 of the Reactor Regulation Act, Article 5 of the Nuclear Source Materials Use Ordinance, Article 5 of Nuclear Dose Limits Notice】**

○Moreover, in the Reactor Regulation Act, in the same case, when it is found that the transport measures taken by nuclear source materials users do not conform to the technical standards stipulated by the Act, the NRA may order nuclear source materials users to correct what they meet. **【Article 57-7(5) of the Reactor Regulation Act】**

○Depending on the event that occurred and its necessity, the NRA that has received the above report or ordered to take action seeks investigation of the cause and formulation/implementation of recurrence prevention measures, etc., from the relevant nuclear source materials users with the authority to collect reports based on the Reactor Regulation Act, and the NRA may conduct on-site inspections to confirm the implementation status. **【Articles 67 and 68 of the Reactor Regulation Act】**

- Report to the competent minister (Article 62-3 of the Reactor Regulation Act)
- Order for correction (Article 57-7(5) of the Reactor Regulation Act)
- Collection of reports (Article 67 of the Reactor Regulation Act)
- On-site inspection (Article 68 of the Reactor Regulation Act)

《Radioisotopes》

○Under the RI Act, when transporting radioactive isotopes, etc. outside the sites, users are required to take necessary measures to prevent radiation damage in accordance with technical standards stipulated in the RI Act Enforcement Rules, but if the NRA finds that this

standard is not met, it may order the necessary measures to stop transportation and prevent radiation hazards. 【Article 18(4) of the RI Act】

○In addition, if the transportation measures in Article 18(1) of the RI Act do not conform to technical standards, the NRA can order users to revoke permission to use radioisotopes, etc., or stop using radioisotopes within one year. 【Article 26 of the RI Act】

○In addition, in transporting radioisotopes, etc. outside the sites, etc., users are obligated to report to the NRA if there is an accident that may cause radiation damage or an accident that causes radiation damage (hereinafter referred to as “accidents that may cause radiation damage”). 【Article 31-2 of the RI Act】

○In addition, the NRA can collect reports based on the RI Act from users, etc., and when users are required to report on the state of transportation of all radioisotopes, etc. performed outside of the sites, etc., they are obliged to report within that period. 【Article 31-2 of the RI Act, Article 39(3)(iii) of the RI Act Ordinance】

○For handling with accidents that may cause radiation damage, the NRA may enter the office or factory or place of activity of the user, etc. as necessary, and conduct on-site inspections of account books, documents, and other necessary properties. For accidents that may cause radiation damage, the investigation of the cause and prevention of recurrence can be confirmed through on-site inspections as necessary. 【Article 43-2 of the RI Act】

- *Report to the competent minister, etc. (Article 31-2 of the RI Act)*
- *Order to stop transportation of radioisotopes, etc. and other necessary measures (Article 18(4) of the RI Act)*
- *Order for measures in case of danger (Article 33(3) of the RI Act)*
- *Cancellation of business permission, etc. or business suspension (Article 26 of the RI Act)*
- *Collection of reports (Article 42 of the RI Act)*
- *On-site inspection (Article 43-2 of the RI Act)*

[MHLW]

《Radiopharmaceuticals》

○Based on the provisions of Article 72-4(1) of the “Pharmaceuticals and Medical Devices Act”, the regulatory authority of medicine shall order the necessary improvements to

licensed companies that violate the “Regulations on Manufacture and Handling of Radiopharmaceuticals” (Ministry of Health and Welfare Ordinance No.4 in 1961), “Standards for Transport of Radioactive Materials” (MHLW Notice No.491 of 2005), and “Standards for Activities of Radioactive Materials” (MHLW Notice No.399 of 2000). In addition, when there is an act that violates the order, based on the provisions of Article 75(1) of the “Pharmaceuticals and Medical Devices Act”, the license can be revoked, or the suspension of part or all of the business can be ordered by setting a period. 【Article 72-4(1) and Article 75(1) of the Pharmaceuticals and Medical Devices Act】

[MIC]

《Postal mail etc.》

○Reports are required by the regulations of Article 16(1) of the Act on Japan Post Co., Ltd. or Article 37(2) of the Act on Correspondence Delivery by Private Business Operators, and will be handled by orders required for on-site inspection or supervision. 【Article 16(1) of the Act on Japan Post Co., Ltd., Article 37(2) of the Act on Correspondence Delivery by Private Business Operators】

Attachments

A01_ the Reactor Regulation Act

A02_ the Reactor Regulation Act (amended)

A08_ the NRA Ordinance on Use of Nuclear Source Materials

A10_ the Nuclear Dose Limit Notice

B01_ the RI Act

B02_ the RI Ordinance

C01_ Pharmaceuticals and Medical Devices Act

D03_ the Act on Correspondence Delivery by Private Business Operators

D05_ the Act on Japan Post Co., Ltd.

Question 11.8

Has the competent authority for transport established or adopted regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based?

Answer

Yes

Finding

The competent authority for transport has established or adopted regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.

Response

○In Radioactive material transport safety regulations in Japan, as a basic policy, for land transport, make regulatory requirements in compliance with the IAEA Radioactive Material Safe Transport Regulations (SSR-6), and for marine transportation, in accordance with the International Maritime Organization (IMO) International Maritime Dangerous Goods Regulations (IMDG Code), for air transport, in accordance with the International Civil Aviation Organization (ICAO) Technical Guidelines for Safe Transport of Dangerous Goods (ICAO-TI), and for postal mail, make regulatory requests in accordance with the Universal Postal Convention etc., taking into account the regulatory system based on domestic acts and the domestic situation concerning safe transport of radioactive materials, etc., it has been incorporated into laws and regulations, etc., which the competent authorities have jurisdiction over.

[NRA]

《Nuclear fuel materials》, 《Nuclear source materials》

○Regarding land transportation of nuclear fuel materials, etc., the Reactor Regulation Act stipulates that nuclear operators, etc. must take necessary measures for safety in accordance with technical standards when transporting nuclear fuel materials, etc. outside the sites. 【Article 59(1) of the Reactor Regulation Act】

Regarding land transportation of nuclear source materials, the Reactor Regulation Act stipulates that nuclear source materials users must transport them in accordance with technical standards when transporting nuclear source materials outside the Sites. 【Article 57-7(4) of the Reactor Regulation Act, Article 2 of the Nuclear Source Materials Use Ordinance】

○Based on a graded approach to meet radiation risks, etc., it also stipulates that the NRA must be confirmed when transporting nuclear fuel shipments that are particularly necessary for the prevention of disasters caused by nuclear fuel materials, etc. and for the protection of specified nuclear fuel materials. 【Article 59(2) of the Reactor Regulation Act, Article 48 of the Reactor Regulation Enforcement Cabinet Order】

○In addition, the scope that requires confirmation by the Nuclear Regulatory Commission on transportation is stipulated in the Ordinance on Enforcement of the Reactor Regulation Act, the technical standards required for each package are stipulated in the Nuclear Transport Regulations, and the details of each test condition performed on each package are stipulated in the Nuclear Transport Notification, a legal framework for the regulation of transportation of nuclear fuel materials, etc. has been established. 【the Nuclear Off-Site Transportation Ordinance, the Nuclear Off-Site Transportation Notice】

○Furthermore, we have prepared a guide document indicating the interpretation and operational policy of these legal requirements, and supplementing the legal requirements by providing notifications and announcements to nuclear operators.

○The rules and guides related to the transportation of 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 Fuel Material, Nuclear Source Material, 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)*
- "The NRA Ordinance on Off-Site Transportation of Nuclear Fuel Materials, etc." (Ministerial Ordinance No. 57 of 1978)*
- "The NRA Ordinance on Use of Nuclear Source Materials" (Ministerial Ordinance No. 46 of 1968)*
- "The Notification on Technical Details for Off-Site Transportation of Nuclear Fuel Materials, etc." (Notice of Science and Technology Agency No. 5 of 1990)*

- *“The Notifications to Establish Dose limits in accordance with the Provisions of NRA Ordinance on Activity of Refining Nuclear Source or Nuclear Fuel Materials, etc.” (NRA Notification No.8 of 2015)*
- *“Operational Guide for Confirmation of Nuclear Fuel Packages for Off-Site Transportation” (No. 1402263 of Gen Kan Hai Hatsu, Feb. 26, 2014, Decision by Secretary-General of the Secretariat of NRA)*
- *“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)*
- *“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)*
- *“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)*

《Radioisotopes》

○For land transport of radioactive isotopes, etc., when transporting radioisotopes, etc. outside the sites, the RI Act stipulates that users must take necessary measures to prevent radiation damage in accordance with technical standards, in particular, the scope of technical requirements and the technical standards required for each package when confirmation by the NRA on transportation is required are stipulated in the RI Act Enforcement Regulations, in addition, technical standards for each package are stipulated in the outside transportation notice, a legal framework for the regulation of the transport of radioisotopes is established.

Furthermore, a notification document indicating the procedure of these legal requirements is an internal regulation of the administrative authority, and this is complemented by showing this to the notification user.

[MHLW]

《Radiopharmaceuticals》

○In addition to manufacturers of radiopharmaceuticals, marketing license holders, wholesale distributors, and pharmacy proprietors licensed under the “Pharmaceuticals and Medical Devices Act” are assumed to be shippers or consignees for land transport of radiopharmaceuticals. The MHLW has enacted the following ministerial ordinances and notifications based on the provisions of the “Pharmaceuticals and Medical Devices Act” as

matters to be observed when licensed companies under the “Pharmaceuticals and Medical Devices Act” manufacture or handle radiopharmaceuticals.

- *"Regulation on Manufacture and Handling of Radiopharmaceuticals"(Order of the MHLW No. 4, 1961)*
- *"Standards for Transport of Radioactive Materials"(Public notice of MHLW No. 491, 2005)*
- *"Standards for Activities of Radioactive Materials"(Public notice of MHLW No. 399, 2000)*

【Article 9(1), Article 18(1) and(2), Article 36-2 (1) of the Pharmaceuticals and Medical Devices Act】

[MIC]

《Postal mail etc.》

○Since Japan is a member of the Universal Postal Union (UPU), and the Universal Postal Convention etc., incorporates the IAEA regulations for safe transport of radioactive materials, the Postal Act, which is a domestic law, and notifications based on this Act are also stipulated in accordance with the Universal Postal Convention etc. In addition, the Act on Correspondence Delivery by Private Business Operators complies with the notification of the Postal Act.

Attachments

A01_ the Reactor Regulation Act

A04_ the Reactor Regulation Enforcement Cabinet Order

A05_ the Nuclear Off-Site Transportation Ordinance

A08_ the NRA Ordinance on Use of Nuclear Source Materials

A09_ the Nuclear Off-Site Transportation Notice

A11_ the Nuclear Off-Site Transportation Operation Guide

A12_ the Nuclear Off-Site Transportation Administrative Procedure Guide

A13_ the Nuclear Off-Site Transportation Describing Procedure Guide

A14_ the Manufacturing Quality Management Guide

C01_ Pharmaceuticals and Medical Devices Act

Subsidiary Question 11.8.1

How does the competent authority for transport establish or adopt transport regulations and guides?

Subsidiary Response

○When revisions to the IAEA transport regulations, etc. are made, they will be incorporated into domestic laws as necessary. Information on revisions to the IAEA Transport Regulations, etc. will be shared at the Interagency Coordination Meeting for the Safe Transport of Radioactive Material established as a practical coordination site for government agencies related to the transport of radioactive materials in Japan. When revision of domestic acts is required due to revision of IAEA transport regulations, based on discussions at meetings with relevant industries, experts, etc., revisions, etc. will be considered by the competent authorities, and the requests and opinions of interested parties in the relevant industries will be taken into account during this process. In addition, the draft act amendment is submitted to the public opinion solicitation procedure (Public Comment) based on the Administrative Procedure Act, and the amendment procedure is conducted based on the opinions obtained. The revised domestic acts and regulations are communicated to the relevant industry from the regulatory authorities through official gazettes, notifications and workshops on safe transport of radioactive materials for businesses.

[NRA]

《Nuclear source materials》 《Nuclear fuel materials》 《Radioisotopes》

○Regarding the regulations regarding the transport of nuclear source materials, nuclear fuel materials, etc., since consistency with international standards is important, the NRA participates in the IAEA Transport Safety Standards Committee (TRANSSC) every time and collects and analyzes information, including differences between domestic and international standards, and it reflects the latest knowledge.

○The NRA has established a TRANSSC Study Committee consisting of participants including external experts in various fields related to relevant industries and transportation regulations, and is following up on the revision cycle of the IAEA Transport Regulations (SSR-6) in the IAEA Transport Safety Standards Committee (TRANSSC). Based on the domestic transport regulations operation, experience, and lessons learned (including requests and opinions of interested parties.), this Study Committee will compile Japan's proposals for the

IAEA transport rules revision at TRANSSC, and conduct various examinations related to the revised regulations.

○In addition, when the IAEA Transport Regulations are revised, the necessity of revision of domestic acts accompanying the revision and the revision policy, etc. when revision is required will be reviewed and compiled. In this process, the requests and opinions of interested parties in related industries are also considered. This information will be shared at the “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” established as a place for practical coordination by government agencies related to the transport of radioactive materials in Japan. As a result of examination, when revision of domestic acts is required, a revision plan etc. will be examined by the competent authority, the amendments drafted through this procedure are, after obtaining approval at a public NRA meeting, submitted to the public opinion solicitation procedure (Public Comment) based on the Administrative Procedure Act, depending on the amendment contents, and based on the opinions obtained, the NRA decides on the amendment procedure. These amendments will be incorporated into domestic acts, regarding the latest SSR-6, in conjunction with the timing of importation into the technical standards for the transport of dangerous goods (ICAO-TI) based on the ICAO convention required by the convention and the technical standards for the transport of dangerous goods (IMDG Code) based on the SOLAS convention. The revised domestic acts will be published in the official gazette and will be made public on the NRA website.

○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.

[MHLW]

《Radiopharmaceuticals》

○The MHLW has established rules and standards for the land transport of radiopharmaceuticals, in the ministerial ordinances and notifications based on the provisions of the “Pharmaceuticals and Medical Devices Act”, in order to incorporate IAEA safety standards such as SSR-6 as well as the RI Act. When the IAEA safety standards are revised, necessary revisions are considered for the relevant ministerial ordinances / notifications. In addition, when the relevant ministerial ordinances / notifications are revised, they are made known to related businesses and organizations.

Question 11.9

Does the competent authority for transport require that persons engaged in transport receive adequate training?

Answer

Yes

Finding

The competent authority for transport ensures that persons engaged in transport receive adequate training

Response

[NRA]

«Nuclear fuel materials»

○Nuclear operators are required to describe their plans, in the instructions attached to the nuclear fuel package design approval application to be submitted to the NRA under the Reactor Regulation Act, for education and training for personnel engaged in the design, manufacturing, handling and maintenance of nuclear fuel packages. This plan is confirmed to be comprehensive and sufficient in the process of review based on each application.

In addition, nuclear operators, etc. shall clarify the competence required for personnel (including those who have been commissioned to manufacture transport packagings and those who supply packaging parts to packaging manufacturers) engaged in work that affects the quality related to the manufacturing of transport packagings, educate and train them to have the necessary competence, and maintain their records, describing in the instructions attached to the packaging approval application submitted to the NRA under the Reactor Regulation Act. The NRA has confirmed that those involved in transportation are to receive sufficient education and training during the design approval and packaging approval reviews. 【“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” (June 1, 2011, NISA No. 8 dated March 7, 2011, Nuclear and Industrial Safety Agency Notice) “2. Design of transport packaging and safety instructions for nuclear fuel transport when nuclear fuel material is stored in the transport packaging” C- (c) and “3. Instructions on how to manufacture the shipping packaging” Chapter 2- (c) / “Guidelines for Quality Management of Manufacturing method of the Packaging”(2008/06/10 No. 1, NISA Notification)】

○As part of the revision and establishment of related rules and guides associated with the implementation of the new inspection system, at present, the NRA explicitly requires nuclear operators, etc., who intend to transport nuclear fuel materials, etc., to establish quality control methods and record preservation related to the transportation of nuclear fuel materials, etc., and matters concerning education and training for personnel involved in transportation are also considered in the quality control method. (To be implemented in April 2020) 【Article 17-2 of Revised Nuclear Off-Site Transportation Ordinance (in public comment)】

○In addition, if necessary the NRA maintain internal rules regarding the application and interpretation of domestic laws and regulations, and will share necessary information by notifying nuclear operators, etc., and, in cooperation with the Ministry of Land, Infrastructure, Transport and Tourism, it is intended for nuclear operators, etc., to understand the regulations on safe transport of radioactive materials and to improve the safety of radioactive materials, regularly hold transportation classes, in this way, the NRA strives to increase awareness and understanding of the regulations.

《Nuclear source material》

○The NRA, if necessary, share necessary information on the application and interpretation of domestic laws and regulations concerning the use of nuclear material including transportation, by notifying users of nuclear material, etc., and it hold briefing sessions for users of nuclear materials, and endeavor to raise awareness of and understand the contents of regulations.

《Radioisotopes》

○Regarding education and training for persons engaged in transportation (including shippers and consignees), in the case of users, etc., education and training are required by the RI Act and RI Act Enforcement Rules for workers engaged in radiation work or those handling radioisotopes, etc., where the shipper works in the controlled area. 【Article 22 of the RI Act, Article 21-2 of the RI Ordinance】

《Nuclear source materials》 《Nuclear fuel materials》 《Radioisotopes》

○Regarding the capacity building of NRA regulatory agency personnel, the NRA establishes a basic policy for human resource development, and in addition to capacity evaluation as part of personnel evaluation (Appointment Qualification), define the qualifications required for those who are appointed to jobs that require highly specialized knowledge and experience, it grants qualifications to employees engaged as safety examiners and inspectors after evaluating the competence of individual employees through training and oral examinations corresponding to each appointment qualification. Since then, the NRA continues to improve through various training programs including OJT.

In addition, radiation protection is set as a common basic training item for all Appointment Qualifications.

○In the NRA, it is not specialized in transportation, but desktop training and reporting training are conducted as emergency response training resulting from the disaster of nuclear facilities.

[MHLW]

《Radiopharmaceuticals》

○Under Article 27 of the "Standards for Transport of Radioactive Materials" (MHLW Notice No.491 of 2005), it is stipulated that radiopharmaceutical shippers and consignees should ensure that staffs engaged in land transport must be educated and trained to possess the knowledge and skills necessary for their work. 【Article 27 of the Standards for Transport of Radioactive Materials】

○In addition, the MHLW has ensured that the staff in charge has acquired the necessary knowledge by actively participating in workshops and study groups hosted by related organizations and organizations as the competent authority for the land transport of radiopharmaceuticals.

[MIC]

《Postal mail etc.》

○According to the provisions of Article 16(1) of the Act on Japan Post Co., Ltd., it is possible to request a report on whether or not appropriate training has been conducted on the transport of radioactive materials at Japan Post Co., Ltd.

Under the Act on Correspondence Delivery by Private Business Operators, education and training are required as a condition for approval of the Letter Service Management Regulations of Article 31(2)(iv) of the Enforcement Regulations of Act on Correspondence

Delivery by Private Business Operators. In addition, from the point of view of whether or not the management regulations are complied with, it is possible to request a report service provider to report in accordance with Article 37 of the Act on Correspondence Delivery by Private Business Operators. 【Article 16 (1) of the Act on Japan Post Co., Ltd., Article 31 (2) (iv) of the Regulations for Enforcement of the Act on Correspondence Delivery by Private Business Operators , Article 37 of the Act on Correspondence Delivery by Private Business Operators】

Attachments

A06_the Nuclear Off-Site Transportation Ordinance (Amendment proposal in Public Comment)

A13_the Nuclear Off-Site Transportaion Describing Procedure Guide

A14_the Manufacturing Quality Management Guide

B01_the RI Act

B02_the RI Ordinance

C03_Standards for Transport of Radioactive Materials

D03_the Act on Correspondence Delivery by Private Business Operators

D05_the Act on Japan Post Co., Ltd.

D06_Regulation for Enforcement of the Act on Correspondence Delivery by Private Business Operators

Question 11.10

Are adequate emergency arrangements in place for the transport of radioactive material?

Answer

Yes

Finding

Adequate emergency arrangements are in place for the transport of radioactive material.

Response

○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.

【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)】

Attachments

E01_ the Nuclear Emergency Act

E02_ the Nuclear Emergency Enforcement Cabinet Order

E03_ the Nuclear Off-Site Transport Notification Events Order

E04_ the NRA EPR Guide

E05_ the Manual for Nuclear Emergency Preparedness and Response (transport version)

E06_ Basic Plan for Emergency Preparedness

E07_ Emergency Preparedness for Nuclear Facilities etc.

E08_ the Nuclear Off-Site Transport Notification Procedures Order

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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| S1 | <p><i>(The competent authority approval)</i></p> <ul style="list-style-type: none"><i>• Regarding land transport of nuclear fuel materials and radioisotopes, in addition to the approval system of package design that competent authority is required to review and approve that package design as specified by the IAEA Regulations of safe transport of the radioactive material (SSR-6) meets the standards, the packaging approval system has been established in which the competent authority is required to review and approve that a packaging was fabricated as required by the approved design and has been adequately maintained since it started being used. And furthermore, the Package confirmation system has been introduced in which the competent authority is required to confirm before shipment that nuclear fuel material etc. or radioisotope etc. contained in the said package meets the standards. Therefore, these systems contribute to secure the compliance of the package with the standards.</i><i>• 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.</i> |
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(Registration of packaging)

• *Regarding land transport of nuclear fuel material etc. or radioisotope etc., a packaging approval system has been introduced in which the competent authority is required to review and approve that a packaging was fabricated as required by the approved design and has been properly maintained since it started being used in order to secure the registration and management of packaging to ensure the compliance of package with the standards.*

(Review and Evaluation)

• *Regarding land transport of nuclear fuel materials etc. or radioisotopes etc., the Nuclear Regulation Authority has established a system which allows the said organization to request the assistance of research divisions as needed for implementing a review and evaluation on a package design to be confirmed in order to ensure the conformity review and evaluation. Furthermore, a review and evaluation is implemented on whether a packaging was fabricated and has been maintained as required by the design at the time of design approval application in order to ensure the review and evaluation of the compliance of packaging with the relevant standards. In respect to the shipment of a package to be confirmed, a review and evaluation is implemented before the shipment on whether each package is provided as required by the design to ensure the compliance of package with the relevant standards. The package design approval and packaging approval are imparted with the validity terms (normally of 5 years), which provide the system to continuously review and evaluate whether a licensee conforms to latest criteria or reflects latest technical knowledge.*

• *Regarding review and assessment on land transport of radiopharmaceuticals, pursuant to the Ministerial Ordinance/Notification based on the provision of 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.*

(Inspection)

• *Regarding land transport of nuclear fuel material etc. or radioisotope etc., the package confirmation system has been introduced in which nuclear plant operators etc. or those who are involved in the use of nuclear fuel material etc. or radioisotope etc. are required to receive a confirmation for a package before the shipment from the Nuclear Regulation Authority if he/she intends to transport a Type B(U) package, a Type B(M) package, a package containing more than 0.1 kg of uranium hexafluoride or a fissile package. In some of these cases (Type B package), the Nuclear Regulation Authority*

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| | <p><i>conducts an on-site confirmation before the shipment to ensure the compliance of the package with the standards.</i></p> <ul style="list-style-type: none"> <i>• Regarding land transport of nuclear fuel materials etc., 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. 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.</i> <i>• 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.</i> <p><i>(Enforcement)</i></p> <ul style="list-style-type: none"> <i>• Regarding land transport of nuclear source material, nuclear fuel material and radioisotopes, the system has been provided and established in which the authorities may request a business operator etc. to report in the event of non-compliance, execute an on-the-Spot inspection as needed to confirm the status and order to take necessary rectification measures.</i> <i>• In the event of non-compliance that may affect transport, a framework called “Liaison Meeting for Countermeasure of related to Accident Transport of Radioactive Material” has been provided to facilitate a quick communication and adjustment between the relevant organizations responsible for transport of radioactive material. A framework called “Interagency Coordination Meeting for Safe Transport of Radioactive Material” has been provided so that the relevant organizations responsible for transport of radioactive materials can share the information on accident cases (including cases which had a risk to result in an accident), which provides the means of the multilateral information sharing between the relevant organizations as needed.</i> <i>• Regarding land transport of radiopharmaceuticals, MHLW specifies the rules/standards in order to incorporate IAEA safety standard pursuant to the Ministerial Ordinance/Notification on Pharmaceuticals and Medical Devices Act. In the case where</i> |
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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

(Regulations and Guidance)

- *Regarding the regulations etc. with respect to land transport of nuclear fuel materials, the role division between the relevant domestic organizations is being clearly defined without being overlapped or unallocated and the applicable Acts and Ordinances have been set based on the said regulations, which demonstrates how the IAEA transport regulation is reflected in the national safety transport regulations.*

- *Associated with a formulation or revision of the IAEA Regulations of safe transport of the radioactive material (SSR-6) etc. and the relevant national Acts and Ordinances, a framework called "Coordination Committee for Safe Transport of Radioactive Materials" is provided to facilitate the information sharing and discussion etc. between the relevant organizations responsible for transport of radioactive material. The function of the framework has been appropriately maintained by being held on a regular basis at a coinciding timing with the TRANSSC meeting.*

- *Regarding the integration of a revision of the IAEA safe transport regulations etc. into the national Acts and Ordinances, the NRA draws up the proposals for the improvement jointly with the other relevant organizations, revises the said Acts and Ordinances based on the in-house discussions or public comments, and a revision is promulgated in the official gazette or published on the official HP.*

- *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 Pharmaceuticals and Medical Devices Act, similarly as the RI Act. In the case of amendment of IAEA safety standards etc., similarly 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.*

(Emergency Response)

- *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. and furthermore,*

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| | <i>the framework is provided in which the relevant competent authorities cooperate with one another called “Interagency Coordination Meeting for the Safe Transport of Radioactive Material” consisting of the departments in charge of the said organizations.</i> |
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WEAKNESSES FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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| W1 | <p><i>(Review and Evaluation), (Regulations and Guidance)</i></p> <ul style="list-style-type: none"> • <i>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.</i> • <i>There is room for NRA to 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.</i> |
| | <p><i>(Training)</i></p> <ul style="list-style-type: none"> • <i>Since there are plural regulatory organizations in charge of the approval of transport of radioactive materials etc., maintaining consistency and compliance in the management of authorization related to transport of radioactive materials is important. However, the Nuclear Regulation Authority provides not sufficient opportunities such as a study meeting related to their regulation to improve the efficiencies of personnels together with the personnels of the other relevant regulatory bodies.</i> |
| | <p><i>(Emergency Response)</i></p> <ul style="list-style-type: none"> • <i>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, 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. are not clear.</i> • <i>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 by NRA.</i> |
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OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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| O1 | <p><i>(Regulations and Guidance)</i></p> <ul style="list-style-type: none"> • <i>The relevant regulatory organizations responsible for transport of radioactive materials may set an issuance of a revision of the IAEA Regulations of safe transport of the radioactive material (SSR-6) as an opportunity to review their regulatory requirements.</i> |
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THREATS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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| T1 | <p><i>(Regulations and Guidance)</i></p> <ul style="list-style-type: none"> • <i>The latest edition (2018 Edition) of the IAEA Regulations for safe transport of the radioactive material (SSR-6) has already been published, which the relevant regulatory authorities responsible for the transport of radioactive materials needs to adopted under national Acts and Ordinances by January 2021.</i> |
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CONCLUSIONS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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| C1 | <p><i>(The competent authority approval)</i></p> <ul style="list-style-type: none"> • <i>Regarding land transport of nuclear fuel material etc. and radioisotope etc., it finds that the Reactor Regulation Act and the RI 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, NRA identifies that the framework and measures for authorizations are in principle in accordance with relevant IAEA safety requirements</i> • <i>Regarding land transport of nuclear source material, 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.</i> • <i>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, it identifies that MHLW performs necessary regulations appropriately by specifying rules/standard to incorporate IAEA safety standards.</i> • <i>Regarding transport by post etc., pursuant to the Ministerial Ordinance/Notifications based on the Postal Act etc., it identifies that MIC performs necessary regulations</i> |
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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.

(Registration of packaging)

- N RA evaluates that, under the the Reactor Regulation Act and the RI Act, the packagings used for land transport of nuclear fuel material and radioisotope requiring the competent authority confirmation (approval) is appropriately managed.*

(Review and Evaluation)

- It finds that the Reactor Regulation Act and the RI Act 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 for the factor identified as "weakness".*

- Regarding review and assessment on land transport of radiopharmaceuticals, pursuant to Ministerial Ordinance/Notification based on the provision of 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.*

- Under the Postal Act etc., handling of nuclear fuel materials that require authorizations etc. specified in IAEA safety standard is prohibited. Therefore, MIC identifies as compliance with IAEA safety standard.*

(Special arrangement approval)

- Regarding land transport of nuclear fuel material etc. and radioisotope etc., it finds that the Reactor Regulation Act and the RI 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,*

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| | <p><i>NRA identifies that the framework and measures for authorizations are in principle in accordance with relevant IAEA safety requirements</i></p> <ul style="list-style-type: none"> <i>• 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, it identified that MHLW performs necessary regulations appropriately by specifying rules/standard to incorporate IAEA safety standards.</i> <p><i>(Inspection)</i></p> <ul style="list-style-type: none"> <i>• Regarding 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, NRA identifies that the framework is in principle in accordance with relevant IAEA safety requirements.</i> <i>• Regarding the inspection related to transport of nuclear source materials etc., 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, NAR identifies that the framework is in principle in accordance with relevant IAEA safety requirements.</i> <i>• Regarding 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, NRA identifies that the framework is in principle in accordance with relevant IAEA safety requirements.</i> <i>• 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.</i> <i>• 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, MIC identifies that the framework is in principle in accordance with relevant IAEA safety requirements.</i> |
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(Radiation Protection)

• *Regarding radiation protection associated with land transport of radioisotopes, nuclear source material and nuclear fuel material etc., it finds that the requirements such as standards are based on graded approach according to radiation risk under the Reactor Regulation Act and the RI 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.*

• *Regarding radiation protection in land 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 safe standard*

• *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.*

(Enforcement)

• *It finds that the Reactor Regulation Act and the RI Act clearly provide the requirements for the enforcement actions for land transport of radioisotopes, nuclear source materials and nuclear fuel materials etc. and the conditions for such enforcement actions and allow the NRA to decide on these enforcement actions for noncompliance and emergency measures. Therefore, NRA concludes that the framework and measures for enforcement are in principle in accordance with relevant IAEA safety requirements.*

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

• *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, MIC identifies that enforcement in transport by post etc. is in compliance with IAEA safety standard*

(Regulations and Guidance)

• , It finds that the Reactor Regulation Act and the RI Act requires the regulation according to the types of transport of radioisotopes, nuclear source materials and nuclear fuel materials etc. and specify and publish as the ordinances/instructions of NRA. Therefore, NRA concludes that the framework and measures for the regulations and guides are in principle in accordance with relevant IAEA safety requirements, except for the factor identified as “Weakness”.

• Regarding land transport of radiopharmaceuticals, pursuant to Ministerial Ordinance/Notifications based on the provisions of 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.

• 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.

(Training)

• Regarding land transport of nuclear fuel material etc. and radioisotope etc., the training of personnel engaged in transport is required as part of the quality management, therefore the NRA evaluates that it is basically conformable to the IAEA safety standards.

• For improvement of the competence of the staff of regulatory body related to transport of nuclear fuel materials etc., 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. Therefore, NRA evaluate that it is in principle in accordance with relevant IAEA safety requirements, except for the factor identified as “Weakness”.

• MHLW identifies that the appropriate education and training is practiced Regarding land transport of radiopharmaceuticals.

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| | <p><i>(Emergency Response)</i></p> <ul style="list-style-type: none"> • <i>It found that the regulatory framework is well established in advance to regulate emergency response including collaboration with the relevant bodies. Therefore, MIC, MHLW and NRA identify that the framework and measures for emergency response is in accordance with relevant IAEA safety requirements, except for the factor identified as “Weakness”.</i> |
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RECOMMENDATIONS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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| R1 | <p><i>(Regulations and Guidance)</i></p> <ul style="list-style-type: none"> • <i>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.</i> • <i>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.</i> <p><i>(Training)</i></p> <ul style="list-style-type: none"> • <i>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.</i> <p><i>(Emergency Response)</i></p> <ul style="list-style-type: none"> • <i>In the existing system in land transport of nuclear fuel materials, despite the results of risk assessment, 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.</i> • <i>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</i> |
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| | <i>organizations for more appropriate response based on the framework of the existing laws and regulations etc.</i> |
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REMARKS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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| RM1 | <p><i>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). The responsibility division for each relevant organization is as follows:</i></p> <ul style="list-style-type: none"> <i>• 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.</i> <i>• 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.</i> <i>• 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.</i> <i>• 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.”).</i> <i>• 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.</i> <i>• 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</i> |
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| | <p><i>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).</i></p> |
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ACTION PLANS FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS

Action Plan: Safety Requirements for Transport of Radioactive Material

| Recommendation No | Action No | Action Required | Responsible Person (s) | Start Date | End Date | Acceptance Date | Remarks |
|-------------------|-----------|-------------------------------------------------------------------|------------------------|------------|----------|-----------------|---------|
| R1 | A1 | (See the Action Plan A1 in the SARIS Summary Report for details.) | | | | | |
| | A2 | (See the Action Plan A2 in the SARIS Summary Report for details.) | | | | | |
| | A3 | (See the Action Plan A3 in the SARIS Summary Report for details.) | | | | | |
| | A4 | (See the Action Plan A4 in the SARIS Summary Report for details.) | | | | | |

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|--|----|-------------------------------------------------------------------|--|--|--|--|--|
| | A5 | (See the Action Plan A5 in the SARIS Summary Report for details.) | | | | | |
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ELECTRONICALLY GENERATED CONCLUSION FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS

Module: Safety Requirements for Transport of Radioactive Material

Good Compliance

Answers to this module suggest good compliance with the relevant IAEA standards and international undertakings. Thus, relative to other areas addressed during the self-assessment, this topic area may have a lower priority for improvement actions.

PRIORITIES ASSIGNMENT (PA) VALUES FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS

| Priority Assignment (PA) value by Module | PA |
|-----------------------------------------------------------|-----------|
| Safety Requirements for Transport of Radioactive Material | 3 |

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| Overall Priority Assignment (PA) value for all completed Modules | |
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Appendix

Information

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| Enter the full name of your country | <i>Japan</i> |
| Give the full name(s) of the national body or bodies having responsibility for the regulatory oversight of nuclear and/or radiation safety. | <i>Nuclear Regulation Authority, Ministry of Internal Affairs and Communications Ministry of Health, Labour and Welfare</i> |
| To whom (or to which body within the governmental organisational structure) is the above-named regulatory body (or bodies collectively) accountable? | <i>NRA, as an independent administrative authority, is accountable to the Japanese Diet. For example, presents to the Diet its annual report on the state of nuclear safety and radiation protection.</i> |
| List the type and number of Nuclear facilities (e.g. Nuclear Power Plants, Research Reactors, Nuclear fuel cycle facilities, waste management facilities, etc) | <i>Nuclear Power Plants:45 Commercial power reactors in the research and development phase: 2 Fabrication facilities:6 Research and test reactor facilities:22 Spent fuel interim storage facility:1 Reprocessing facilities:2 Category 2 waste disposal facilities:2 Waste interim storage facilities :2</i> |
| List the type and number of radiation facilities. e.g. Medical (diagnostic/interventional radiology, dental), Waste management facilities, Industrial facilities (irradiation, well-logging, NDT), Mining and milling facilities, Research facilities, etc | <i>Medical institution:1129 Research institute:439 Educational institution:515 Civilian agency:4593 Others:1045 (Including manufacturing site of radiopharmaceuticals: 23)</i> |
| Enter the type and number of activities (e.g. transport of radioactive material, decommissioning, remediation activities, waste management activities such as discharge of effluents, etc | <i>NRA requested the IAEA for IPPAS follow-up mission, which was completed in December 2018.</i> |
| List and describe any facilities and activities not otherwise addressed above | - |
| Enter the number of authorizations: • Issued • Renewed • Suspended or revoked in the last one year | <i>(April 1, 2018~May 31, 2019)</i> <i>From Nuclear Facility operator</i> •Issued:132 •Renewed:167 •Suspended or revoked:0 <i>For Radiation operator</i> |

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| | <ul style="list-style-type: none"> •<i>Issued:27</i> •<i>Renewed:260</i> •<i>Suspended or revoked:78</i> <p><i>License for manufacturing site of radiopharmaceuticals (by MHLW)</i></p> <ul style="list-style-type: none"> •<i>Issued: 1</i> •<i>Renewed: 0</i> •<i>Suspended or revoked: 0</i> |
| <p>Enter the number of:</p> <ul style="list-style-type: none"> • planned inspections • Completed planned inspections • Unplanned inspections <p>in the last one year</p> | <p><i>(April 1, 2018~May 31, 2019)</i></p> <p><i>For Nuclear Facilities:</i></p> <ul style="list-style-type: none"> •<i>planned inspections:437</i> •<i>Completed planned inspections:437</i> •<i>Unplanned inspections:91 topics</i> <p><i>For Radiation Facilities:</i></p> <ul style="list-style-type: none"> •<i>planned inspections: 257</i> •<i>Completed planned inspections:257</i> •<i>Unplanned inspections:0</i> <p><i>For Manufacturing Sites of radiopharmaceuticals (by MHLW):</i></p> <ul style="list-style-type: none"> •<i>planned inspections:1</i> •<i>Completed planned inspections: 0</i> •<i>Unplanned inspections:1</i> |
| List and briefly describe the national and international safety reviews and/or appraisals received by the regulatory body or State over the last three years | <i>NRA requested the IAEA for IPPAS follow-up mission, which was completed in December 2018.</i> |
| List and briefly describe the ranks, roles, relevant qualifications, experience and numbers of staff engaged in all activities assigned to the regulatory body. | <p><i>NRA commissioners</i></p> <p><i>Chairman:1</i></p> <p><i>Commissioner:4</i></p> <p><i>The secretariat of the nuclear Regulation Authority</i></p> <p><i>Secretary-General:1</i></p> <p><i>Deputy Secretary-General:1</i></p> <p><i>Deputy Secretary-General for Technical Affairs:1</i></p> <p><i>Director-General for Emergency Response:1</i></p> <p><i>Director-General for Radiation protection Strategy and Security:1</i></p> <p><i>Director-General:3</i></p> <p><i>Director-General, Nuclear Regulation Department:1</i></p> <p><i>Counsellor for Evidence-based policymaking:1</i></p> <p><i>Director for Cybersecurity and Information Technology: 1</i></p> |

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| | <p><i>Special Coordinator for International Collaboration on Nuclear Regulation:1</i> <i>Director for Evidence-based Policymaking:4</i></p> <p><i>Secretary-General's Secretariat Policy Planning and Coordination Division:72</i> <i>Public information office:12</i> <i>International Affairs office:17</i> <i>Accidents Response office:9</i> <i>Litigation Office:24</i> <i>Personnel division:25</i> <i>Counsellor for Budget and Accounting:38</i> <i>Division of Legal Affairs:12</i></p> <p><i>Regulatory Standard and Research Department</i> <i>Regulatory Standard and Research Division:22</i> <i>Division of Research for Reactor System Safety:45</i> <i>Division of Research for Severe Accident:29</i> <i>Division of Research for Nuclear Fuel Cycle and Radioactive Waste:35</i> <i>Division of Research for Earthquake and Tsunami:39</i></p> <p><i>Radiation Protection Department</i> <i>Radiation Protection Policy Planning Division:19</i> <i>Safeguards Office:20</i> <i>Radiation Monitoring Division:34</i> <i>Environment Radioactivity Office:11</i> <i>Division of Nuclear Security:38</i> <i>Division of Regulation for Radiation:34</i></p> <p><i>Nuclear Regulation Department</i> <i>Nuclear Regulation Policy Planning Division:17</i> <i>Fire management office:2</i></p> <p><i>Division of Licensing for Nuclear Power Plants:84</i> <i>Division of Licensing for Research Reactors, Use of Nuclear Material and Specified Nuclear Facilities:33</i> <i>Division of Licensing for Nuclear Fuel Facilities:23</i> <i>Division of Licensing for Earthquake and Tsunami Measures:31</i></p> |
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| | <p><i>Oversight Planning and Coordination Division: 10</i></p> <p><i>Risk Management Office:6</i></p> <p><i>Division of Oversight of Nuclear Power Plants:111</i></p> <p><i>Division of Nuclear Fuel Related Facilities and Research Reactors:68</i></p> <p><i>Division of Specified Oversight:72</i></p> <p><i>NRA Human Resource Development Center:48</i></p> <p><i>Relevant Qualifications</i></p> <p><i>Nuclear Inspection(Basic, Middle, and Upper -level)</i></p> <p><i>Safety Review(Basic, Middle, and Upper -level)</i></p> <p><i>Safeguard Inspection(Basic, Middle, and Upper -level</i></p> <p><i>Emergency Preparedness(Basic, Middle, and Upper -level)</i></p> <p><i>Radiation Regulation(Basic, Middle, and Upper -level)</i></p> <p><i>Postal Services Policy Department, MIC Director-General:1</i></p> <p><i>Postal Policy Division:10</i></p> <p><i>International Affairs Office:7</i></p> <p><i>Correspondence Delivery Business Division:7</i></p> <p><i>Pharmaceutical Safety and Environmental Health Bureau, MHLW</i></p> <p><i>Director:1</i></p> <p><i>Councilor of Minister's Secretariat (for pharmaceutical safety) :1</i></p> <p><i>Compliance and Narcotics Division: 29</i></p> |
| Use this field to enter any further information relating to the national regulatory infrastructure for safety | - |
| Project Manager Given Name | <i>Masakazu</i> |
| Family name | <i>Shima</i> |
| Job title | <i>Senior Coordinator</i> |
| Department | <i>Regulatory Reform Office, Secretary-Geneneral's Secretariat</i> |
| Organisation | <i>Nuclear Regulation Authority</i> |
| Enter the date of completion of this self-assessment cycle. | <i>01, Nov, 2019</i> |