IAEA Safety Standards Applications — TranSAS-7

Provision for the Application of the IAEA Safety Standards

Appraisal for Japan of the Safety of the Transport of Radioactive Material

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APPRAISAL FOR JAPAN OF THE SAFETY OF THE TRANSPORT OF RADIOACTIVE MATERIAL

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IAEA SAFETY STANDARDS APPLICATIONS – TRANSAS-7

APPRAISAL FOR JAPAN OF THE SAFETY OF THE TRANSPORT OF RADIOACTIVE MATERIAL

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2006

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P.O. Box 100
A-1400 Vienna
Austria
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tel.: +43 1 2600 22417
http://www.iaea.org/books

Printed by the IAEA in Austria
September 2006
STI/PUB/1267

IAEA Library Cataloguing in Publication Data

Appraisal for Japan of the safety of the transport of radioactive material. — Vienna : International Atomic Energy Agency, 2006.
p. ; 24 cm. — (Safety standards applications, ISSN 1684–7520; TranSAS-7)
STI/PUB/1267
ISBN 92–0–109506–6
Includes bibliographical references.

1. Radioactive substances — Transportation — Japan. 2. Radioactivity — Safety measures. I. International Atomic Energy Agency. II. Series.

IAEAL 06–00449

FOREWORD

Within the family of the United Nations, the IAEA has the specific statutory function of establishing standards of safety for the protection of health against exposure to ionizing radiation. As a result, in 1959 the United Nations Economic and Social Council requested that the IAEA be entrusted with the drafting of recommendations on the transport of radioactive substances. Within its statutory mandate and pursuant to this request, in 1961 the IAEA issued the Regulations for the Safe Transport of Radioactive Material (the Transport Regulations). The Transport Regulations have been periodically reviewed and, as appropriate, amended or revised. Moreover, several guides and technical documents supporting the Transport Regulations have been issued by the IAEA. The latest version of the Transport Regulations was issued in 2005 by the IAEA as Safety Standards Series No. TS-R-1.

On 25 September 1998 the IAEA General Conference adopted resolution GC(42)/RES/13 on the Safety of Transport of Radioactive Materials. In adopting that resolution the General Conference recognized that "*compliance with regulations which take account of the Transport Regulations is providing a high level of safety during the transport of radioactive materials...*"

The IAEA's Statute also authorizes it to provide for the application of its standards at the request of any State. The IAEA discharges this statutory function through a number of mechanisms, including rendering independent peer review appraisal services to determine the status of compliance with its standards. Consistent with this statutory function, resolution GC(42)/RES/13 requested the IAEA Secretariat to provide for the application of the Transport Regulations by, inter alia, providing a service for carrying out, at the request of any State, an appraisal of the implementation of the Transport Regulations by that State.

In response to this request, on 10 December 1998 the IAEA offered to render such an appraisal service to all States. The service was termed the Transport Safety Appraisal Service (TranSAS). Since then, the IAEA General Conference, through resolutions GC(43)/RES/11, GC(44)/RES/17, GC(45)/RES/10, GC(46)/RES/9, GC(47)/RES/7 and, most recently, GC(49)/RES/9B in 2005 has commended the Secretariat for establishing TranSAS, commended those Member States that had requested an appraisal, and encouraged other Member States to avail themselves of the appraisal.

The objective of a TranSAS appraisal is to assist any requesting State to achieve a high level of safety in the transport of radioactive material by reviewing its implementation of the Transport Regulations and by making recommendations for improvement where appropriate.

Since TranSAS was established, appraisals have been fielded to Slovenia (1999), Brazil (April 2002), the United Kingdom (June 2002), Turkey (March 2003), Panama (June 2003) and France (March–April 2004).

The appraisal for Japan in December 2005 of the safety of the transport of radioactive material is the seventh TranSAS appraisal since the inception of the service. This report presents its findings.

CONTENTS

SUMMARY, FINDINGS AND CONCLUSIONS

SUMMARY

Background

S01. In July 2004, the IAEA received a request from the Government of Japan for a Transport Safety Appraisal Service (TranSAS) appraisal. To lay the groundwork for the appraisal, preparatory visits were undertaken in December 2004 and May 2005. A preliminary memorandum addressing the scope of the appraisal and the tasks and activities to be undertaken prior to and during the appraisal was developed during the preparatory visit in December 2004.

Objective

S02. The TranSAS appraisal was intended to assist Japan to improve its transport safety regulatory programme by:

(a) Appraising Japan's transport safety regulatory practices with regard to the requirements of Refs [1–3] and related international standards and guidelines;
(b) Providing recommendations and suggestions, as appropriate, in areas in which Japan's transport safety regulatory programme might be improved;
(c) Recognizing good practices that could serve as models for the regulatory programmes of other Member States.

Scope

S03. A TranSAS appraisal covers all modes of transport (i.e. road, rail, maritime and air). In accordance with the request from Japan, the team reviewed the road and maritime transport of nuclear fuel material and waste in more detail.

S04. The appraisal considered in detail all relevant aspects of the regulation of the transport of radioactive material in Japan on the basis of the requirements specified in the IAEA requirements documents, the guidance provided in other IAEA documents and other relevant international regulatory documents, with special attention paid to the land and maritime transport of nuclear material.

TranSAS questionnaire

S05. A detailed TranSAS questionnaire was developed by the IAEA in 1999, and revised in 2005, in order to facilitate the appraisal process in a consistent manner. The questionnaire covers:

(a) Legislative and governmental responsibilities: general.
(b) Legislative and governmental responsibilities: legislative.
(c) The responsibilities and function of the regulatory body.
(d) The organization of the regulatory body.
(e) The activities of the regulatory body.
(f) Emergency preparedness for transport.
(g) Maritime transport.
(h) Air transport.
(i) Road and rail transport.

S06. Prior to the TranSAS appraisal, Japan provided the completed TranSAS questionnaire to the IAEA. It was used by the TranSAS team as a working document for the appraisal and by representatives of the host organization to prepare for interviews and to develop presentations.

Appraisal team

S07. The 13 member team for the appraisal in Japan was composed of eight independent experts from regulatory authorities responsible for the transport of radioactive material in Australia, Canada, France, Germany, Ireland, Panama, the United Kingdom and the United States of America, a maritime transport expert from the International Maritime Organization (IMO), another maritime transport expert (consultant) and a legal consultant from Germany with experience in the transport of radioactive material. In addition, the team included a transport safety expert (mission coordinator) from the IAEA and a technical writer. The team was led by the expert from the United Kingdom.

Appraisal process

S08. The appraisal process included:

(a) A preparatory session for the appraisal team to meet their counterparts from Japan and to review the programme for the appraisal, the

procedures to be followed, the reference material to be used and the work to be carried out;

(b) An entrance meeting involving presentations by key representatives of the Government of Japan and the regulatory bodies concerning their responsibilities for the safe transport of radioactive material;

(c) Discussions to obtain clarifications and additional or more detailed information;

(d) Preparation of the draft findings;

(e) Ongoing feedback on updates to the draft findings;

(f) Visits to regulatory authorities in Tokyo and to the Ibaraki Nuclear Off-site Centre (a local emergency response centre), the Nuclear Emergency Assistance and Training (NEAT) Centre, the Mitsubishi Nuclear Fuel Co. Ltd (MNF) and the Japan Atomic Power Company (JAPC) in the Tokai area, Ibaraki prefecture, and to Narita airport in the Chiba prefecture;

(g) An exit meeting to present and discuss the findings;

(h) Finalization of the appraisal report.

Appraisal report

S09. The appraisal report includes, in Section 3, the findings for each area considered in the appraisal, together with a background discussion and a basis for each finding. The findings are presented as recommendations, suggestions and good practices, which, for the purposes of a TranSAS appraisal, have been defined as follows:

(a) A recommendation is advice on improvement in the reviewed area. It can, but need not, be an indication of shortcomings either in the national statutory legislative and regulatory regime or in the methods of fulfilling the regulatory requirements.

(b) A suggestion may be an additional proposal in conjunction with a recommendation or it may stand on its own. A suggestion should stimulate the regulatory body's management and staff to consider ways and means of enhancing performance.

(c) A good practice is recognition of a current practice that is superior enough to be worth bringing to the attention of other nuclear regulatory bodies as a model in the general drive for excellence.

FINDINGS OF THE TRANSAS APPRAISAL FOR JAPAN

S10. Background information and the basis for the findings are presented together with the findings in Section 3 of this report. Each finding has a basis in the Regulations for the Safe Transport of Radioactive Material (the Transport Regulations) [1], in the modal international regulations and/or in other relevant international regulatory documents and standards.

S11. An overview of the findings is summarized here for the key areas of review, presented in the order in which they appear in Section 3 of this report. Appendix I is a synopsis of the TranSAS appraisal's findings.

S12. The findings of the appraisal include two recommendations and eight suggestions for areas in which the implementation of the IAEA's requirements can be streamlined or improved. The appraisal also identified 14 good practices that can serve as a model for other regulatory bodies in the radioactive material transport sector to emulate.

Legislative and governmental responsibilities

S13. The system of legislation concerning the transport of radioactive material is, in general, satisfactory. There are clear and comprehensive definitions of the terms 'vehicle shipment' and 'simple shipment', which leads to precise application of the law. Moreover, the legislation provides that the public is enabled to be informed directly by the government. Nevertheless, a smaller number of laws and regulations could be useful for daily work in regulatory and operational practice.

Responsibilities and functions of the regulatory body

S14. The compliance assurance arrangements as they relate to the interlinked responsibilities of the regulatory bodies concerned seem to be well organized. The Cabinet Office Legislative Bureau ensures that there is no overlap in the government's laws and ordinances. The Interagency Coordination Meeting for the Safe Transport of Radioactive Material is an informal working arrangement involving interfacing governmental bodies and organizations that have responsibilities in the transport of radioactive material. As a result of these mechanisms, formal agreements covering the responsibilities of each authority are not required.

Organization of the regulatory body

S15. The application of management systems varies throughout individual organizations, and not all have implemented the required quality management or management systems necessary to ensure that all phases of radioactive material transport are covered. Additionally, the availability of transport safety training varies according to the individual organization. Consequently, a defined training programme for the staff specifically engaged in transport safety activities should be implemented.

Activities of the regulatory body

S16. Authorization activities take the form of approvals and confirmations for package designs, packaging, consignments and methods of transport. A good practice was identified in the approval and registration of packagings for regulatory body approved package designs. It was suggested that the contents of the English version of certificates for regulatory body approved package designs include the paragraphs listed in the Transport Regulations, and that options for simplifying the multiple certificates issued for the same package design be investigated.

S17. Review and assessment activities included a good practice with regard to the timely review and approval of package designs according to the 1996 edition of the Transport Regulations. With regard to the thermal test requirements for regulatory body approved package designs, it was suggested that the regulatory structure include the additional details specified in the Transport Regulations.

S18. Systematic inspections (unique in Japan) of packaging, packages and transport methods lead to a high level of safety in the transport of uranium hexafluoride, fresh fuel, spent fuel, vitrified waste and high level activity sources. For nuclear fuel material and radioisotopes, non-regulatory-body approved package design inspections are performed. Still, the regulatory body could review, and correct if necessary, its compliance programme for non-regulatory-body approved package designs to ensure that it also covers radiopharmaceuticals.

S19. The enforcement provisions in place appear to be sufficient to meet the requirements of para. 311 of the Transport Regulations [1]. The fact that no breach of Japan's requirements has been recorded indicates that appropriate compliance has been achieved.

Maritime transport

S20. A high level of safety has been achieved. One of the key elements for achieving the high level of safety is the strict application of Japan's regulations, which include the relevant requirements of the International Code for the Safe Carriage of Packaged Irradiated Nuclear Fuel, Plutonium and High-level Radioactive Wastes on Board Ships (INF Code), the International Maritime Dangerous Goods Code (IMDG Code) and other international regulations for the safe carriage of radioactive material by sea.

Air transport

S21. According to Japan's transport regulations, Type C packages, low dispersible material and packages containing fissile material shall not be transported by air. The Ministry of Land, Infrastructure and Transport has notified the International Civil Aviation Organization to include these restrictions in the State deviations from the Technical Instructions for the Safe Transport of Dangerous Goods by Air. Regarding radiation protection, specific actions are prescribed within a Civil Aviation Bureau generic letter in order to limit exposure of workers. In fact, the Civil Aviation Bureau verifies that the exposure limit for workers is not more than 1 mSv per year, which is the same as the dose limit for members of the public.

Road and rail transport

S22. Most of the requirements applicable to road and rail transport in the Transport Regulations are clearly taken into account in Japan's transport regulations. Moreover, Japan's transport regulations limit the maximum dose rate to 0.1 mSv/h at 1 m from a vehicle instead of the 2 m required by the Transport Regulations, in order to reduce the public dose as much as possible. Nevertheless, Japan's transport regulations could more comprehensively incorporate a mandatory quality assurance programme for the transport of radioactive material and could make stowage and segregation applicable not only to transport but also to transit operations for radioisotopes and radiopharmaceuticals.

GENERAL CONCLUSIONS

S23. The TranSAS appraisal team completed a comprehensive appraisal of the implementation of the Transport Regulations in Japan. The cooperation of

the authorities in Japan, and of all those who participated in the discussions, was excellent and contributed to the success of the appraisal.

S24. The comprehensive legal framework, with responsibilities identified in considerable detail and with clear lines of authority to minimize overlap of responsibilities, provides a sound basis for the implementation of the Transport Regulations.

S25. Generally, the Transport Regulations are implemented in accordance with IAEA requirements. Some areas for possible improvement have been identified. These areas relate mainly to reduction of regulations, quality management systems, training, compliance assurance and lessening the administration burden for incorporating amendments to the IMDG Code.

S26. The findings include a considerable number of good practices, in particular in the area of maritime transport.

1. INTRODUCTION

BACKGROUND

1.1. In order to facilitate safety in the transport of radioactive material throughout the world, the IAEA, pursuant to its statutory authority, has established the Regulations for the Safe Transport of Radioactive Material (the Transport Regulations). The latest edition of the Transport Regulations was published in 2005 [1]. In addition to providing the Transport Regulations, the IAEA also issues various guidance documents [4–7].

1.2. Details regarding the manner in which the Transport Regulations are incorporated into international regulatory documents are provided in Section 2 of this report. Effective implementation of the Transport Regulations at the State level is essential for ensuring a high level of safety during the transport of radioactive material. Other key documents that should be considered by a State in regulating its transport of radioactive material are discussed in Section 2.

1.3. In 1998 the IAEA General Conference, pursuant to its resolution GC(42)/RES/13 on the Safety of Transport of Radioactive Materials, requested the IAEA Secretariat to provide a service for carrying out, at the request of any State, an appraisal of the implementation of the Transport Regulations by that State.

1.4. In response to this request, the IAEA Director General offered the Transport Safety Appraisal Service (TranSAS) to all States. The first TranSAS was undertaken and completed at the request of Slovenia in 1999. Japan is the seventh State to have requested a TranSAS appraisal.

REQUEST FROM JAPAN

1.5. In July 2004 the IAEA received a request from the Government of Japan for a TranSAS appraisal. At a pre-appraisal meeting on 6–9 December 2004 in Tokyo — attended by key representatives of Japan's regulatory authorities and major organizations involved in the transport of radioactive material and the IAEA — and at a preparatory meeting on 23 May 2005, a preliminary memorandum was developed and finalized that covered the scope

of the appraisal and the tasks and activities to be completed prior to and during the appraisal.

1.6. The preliminary memorandum addressed:

(a) The objective and scope of the appraisal;
(b) The tentative dates and locations of the appraisal;
(c) Funding for the appraisal;
(d) The activities to be completed by the IAEA and by Japan prior to the appraisal;
(e) The activities to be undertaken during the appraisal;
(f) The formation of the TranSAS team and related requirements;
(g) The facilities required during the appraisal.

OBJECTIVE

1.7. The TranSAS appraisal was intended to assist Japan to improve its transport safety regulatory programme by:

(a) Appraising Japan's transport safety regulatory practices with regard to the requirements of the Regulations for the Safe Transport of Radioactive Material (the Transport Regulations) [1], Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [2], Preparedness and Response for a Nuclear or Radiological Emergency [3] and related international standards and guidelines;
(b) Providing recommendations and suggestions, as appropriate, in areas in which Japan's transport safety regulatory programme might be improved;
(c) Recognizing good practices that could serve as models for the regulatory programmes of other Member States.

SCOPE

1.8. The general scope of any TranSAS appraisal includes an appraisal of the State's regulatory practices for transport safety, addressing all modes of transport (road, rail, maritime and air) with regard to the IAEA requirements, which include the Transport Regulations, and related international standards and guidelines.

1.9. The more specific scope for Japan, pursuant to its request and to additional considerations that arose during the preparatory visit, included more in-depth attention to the evaluation of the road and maritime transport of nuclear fuel material and waste.

1.10. The appraisal considered in detail all relevant aspects of the regulation of the transport of radioactive material in Japan on the basis of the requirements specified in the IAEA requirements documents, the guidance provided in other IAEA documents and other relevant international regulatory documents. At the request of the Government of Japan, neither physical protection nor legal liability, which are not component parts of transport safety, were addressed in the TranSAS appraisal.

ACTIVITIES COMPLETED PRIOR TO THE APPRAISAL

1.11. Preparations completed by Japan included:

(a) The completion and transmittal to the IAEA of the detailed TranSAS questionnaire and related supporting material;
(b) Ensuring the availability of key personnel from the authorities during the appraisal;
(c) Arranging the logistics for the appraisal, including accommodation and local transport for the team members, and some translation services during the appraisal.

1.12. Preparations completed by the IAEA included:

(a) Recruiting the appraisal team members (and arranging for the necessary approvals);
(b) Providing the team with relevant documentation and the TranSAS guidelines;
(c) Arranging for the travel of the team members to and from Japan.

APPRAISAL TEAM

1.13. The 13 member team for the appraisal in Japan was composed of eight independent experts from regulatory authorities responsible for the transport of radioactive material in Australia, Canada, France, Germany, Ireland, Panama, the United Kingdom and the United States of America, a maritime

transport expert from the International Maritime Organization (IMO), another maritime transport expert (consultant) and a legal consultant from Germany with experience in the transport of radioactive material. In addition, the team included a transport safety expert (mission coordinator) from the IAEA and a technical writer. The team was led by the expert from the United Kingdom. Further biographical details on the members of the appraisal team are provided in Appendix III of this report.

1.14. The expertise of the appraisal team was broad and covered all aspects of the implementation of regulations for the safe transport of radioactive material. Specific experience was taken into account in the assignment of lead responsibilities for appraising the topical areas addressed in the TranSAS questionnaire.

APPRAISAL PROCESS

1.15. The appraisal process included:

(a) A preparatory session for the appraisal team to meet their counterparts from Japan and to review the programme for the appraisal, the procedures to be followed, the reference material to be used and the work to be carried out. Team members' specific experience was taken into account in the assignment of lead responsibilities for appraising the topical areas addressed in the TranSAS questionnaire.
(b) An entrance meeting involving presentations by key representatives of the Government of Japan and the regulatory bodies concerning their responsibilities for the safe transport of radioactive material.
(c) Discussions to obtain clarifications and additional or more detailed information.
(d) Preparation of the draft findings.
(e) Ongoing feedback on updates to the draft findings.
(f) Visits to regulatory authorities in Tokyo and to the Ibaraki Nuclear Off-site Centre (a local emergency response centre), the Nuclear Emergency Assistance and Training (NEAT) Centre, Mitsubishi Nuclear Fuel Co. Ltd (MNF) and the Japan Atomic Power Company (JAPC) in the Tokai area, Ibaraki prefecture, and to Narita airport in the Chiba prefecture.
(g) An exit meeting to present and discuss the findings.
(h) Finalization of the appraisal report.

APPRAISAL REPORT

1.16. This report documents the results of the appraisal conducted during the TranSAS appraisal of Japan. It includes, in Section 3, the findings for each area considered in the appraisal, together with a background discussion and a basis for any finding (tied to an international regulatory requirement or recommendation). The findings are presented as recommendations, suggestions and good practices, which for the purposes of a TranSAS appraisal have been defined as follows:

(a) A recommendation is advice on improvement in the reviewed area. It can, but need not, be an indication of shortcomings either in the national statutory legislative and regulatory regime or in the methods of fulfilling the regulatory requirements.
(b) A suggestion may be an additional proposal in conjunction with a recommendation or it may stand on its own. A suggestion should stimulate the regulatory body's management and staff to consider ways and means of enhancing performance.
(c) A good practice is recognition of a current practice that is superior enough to be worth bringing to the attention of other nuclear regulatory bodies as a model in the general drive for excellence.

Final remarks concerning the findings are presented in Section 4 of this report.

2. DOCUMENTS RELEVANT FOR THE TRANSAS APPRAISAL

IAEA SAFETY STANDARDS

2.1. The IAEA safety standards are key to the development of a regulatory regime for the safe transport of radioactive material. The safety standards serve as a basis for appraising the regulatory activities for the transport of radioactive material. There are three key documents in the Safety Standards Series that provide for the application of the Transport Regulations in a State. The major document is the IAEA publication Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [2], which

discusses in detail the legislative and governmental responsibilities of a State and the responsibilities, functions, organization and activities of a regulatory body. The second, equally important, document is Preparedness and Response for a Nuclear or Radiological Emergency [3], which establishes the requirements for an adequate level of preparedness and response for a nuclear or radiological emergency in any State.

2.2. Finally, the Regulations for the Safe Transport of Radioactive Material, usually referred to as the Transport Regulations, establish standards of safety that provide an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the transport of radioactive material. These Transport Regulations utilize the principles set forth in both Radiation Protection and the Safety of Radiation Sources [8] and the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [9]. Thus, compliance with the Transport Regulations is deemed to satisfy the principles of the BSS in respect of transport.

2.3. These safety standards provide a sound basis for regulatory bodies in States to regulate the transport of radioactive material. Specifically, the Transport Regulations [1] provide a model to be followed by relevant international organizations and States in developing binding regulations for the international and domestic transport of radioactive material. The guidance publications [4–7] also are valuable tools for regulatory bodies, consignors, carriers and consignees for describing how they may apply specific requirements of the regulations; for example, Ref. [4] provides insight into why various regulatory requirements have been established and defines ‘a way’, or ‘ways’, but not ‘the way’, in which specific requirements may be satisfied in practice. Guidance is also provided in specific key areas, inter alia planning and preparing for emergencies [5], compliance assurance [6] and quality assurance [7].

2.4. In striving to foster a consistent basis for communicating these recommended requirements to its Member States, the IAEA also issues a standard glossary [10].

INTERNATIONAL REGULATORY DOCUMENTS AND STANDARDS

2.5. The Transport Regulations serve as the model for the radioactive material portions of international regulations for the transport of dangerous

goods by the various modes of transport. These regulations were first developed in the late 1950s at the request of the United Nations Economic and Social Council. The first edition of the Transport Regulations was published in 1961, and has been updated regularly. The latest edition of the Transport Regulations was issued in 2005 [1]. Additional guidance publications are issued by the IAEA to support the application of the Transport Regulations by regulators and users [4–7].

2.6. The first step in applying the Transport Regulations to the international transport of radioactive material was the incorporation of their requirements into the recommendations on the transport of dangerous goods drawn up by the United Nations Committee of Experts on the Transport of Dangerous Goods and published as the 'model regulations' [11]. Dangerous goods are classified into nine classes. Radioactive material is Class 7 in these regulations. The United Nations model regulations serve as a basis for international regulations for the transport of dangerous goods by the various modes of transport.

2.7. Accordingly, the International Civil Aviation Organization (ICAO) publishes its regulations as the Technical Instructions for the Safe Transport of Dangerous Goods by Air [12] (the ICAO Technical Instructions). These Technical Instructions are mandatory upon all Member States of the ICAO. In addition, the International Air Transport Association (IATA) publishes its Dangerous Goods Regulations [13], which incorporate all the requirements of the ICAO Technical Instructions and additional operator variations.

2.8. The IMO publishes the International Maritime Dangerous Goods Code [14] (the IMDG Code) for the transport of dangerous goods by sea. Many of the detailed requirements of the IMDG Code became mandatory for all IMO Member States on 1 January 2004. In addition, the IMO has published the International Code for the Safe Carriage of Packaged Irradiated Nuclear Fuel, Plutonium and High-level Radioactive Wastes on Board Ships (the INF Code). The INF Code is mandatory under the International Convention for the Safety of Life at Sea (SOLAS Convention) and entered into force on 1 January 2001.

3. APPRAISAL OF THE IMPLEMENTATION OF THE TRANSPORT REGULATIONS IN JAPAN

INTRODUCTION

3.1. This section of the report is structured around the key topical areas covered in the TranSAS questionnaire (and, in addition, road and rail transport):

(a) Legislative and governmental responsibilities: general.
(b) Legislative and governmental responsibilities: legislative.
(c) The responsibilities and function of the regulatory body.
(d) The organization of the regulatory body.
(e) The activities of the regulatory body.
(f) Emergency preparedness for transport.
(g) Maritime transport.
(h) Air transport.
(i) Road and rail transport.

3.2. This section provides, for each of these areas, an overview of relevant information followed by the findings for that area. Each finding is preceded by an underpinning (basis) from appropriate international regulatory and guidance documents. The findings are presented in terms of recommendations, suggestions and good practices (see para. 1.16), as applicable.

LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES: GENERAL

Overview

3.3. The legislative framework and governmental responsibilities of the authorities in Japan are described taking into account the legislative hierarchy (Fig. 1). For the purposes of this appraisal, the legal system that regulates the transport of radioactive material — as far as it relates to the aspects of the safety of transport — has been reviewed against the requirements relevant to the transport of radioactive material as specified in paras 2.2 and 2.4 of Ref. [2]. Paragraph 2.2 of Ref. [2] addresses the legislative and governmental mechanisms that are prerequisites for the safe transport of radioactive

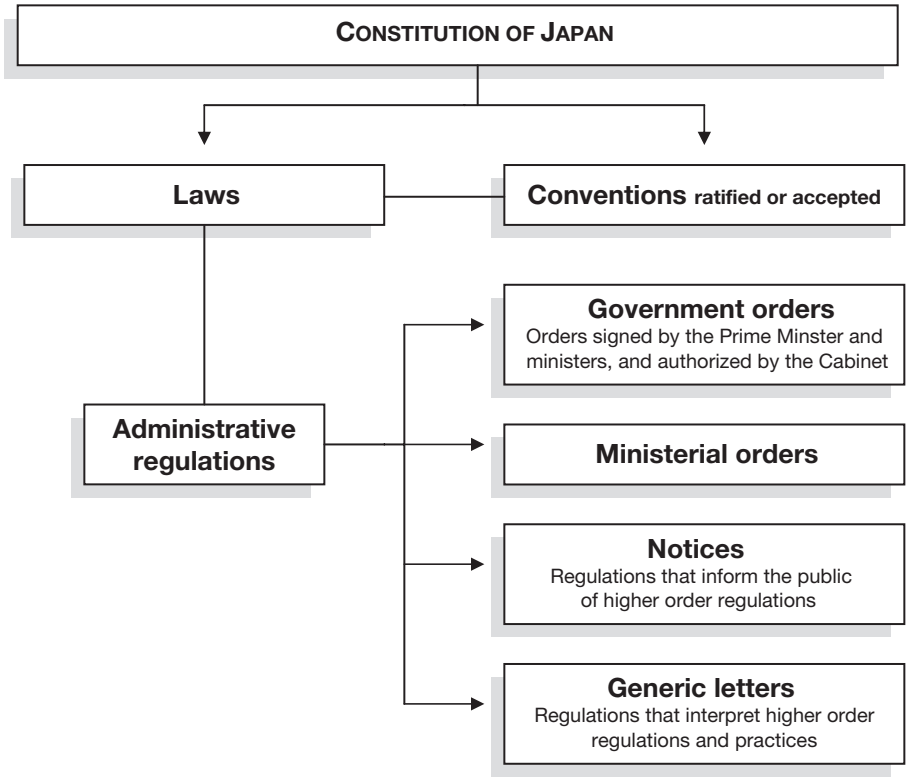

FIG. 1. Legal hierarchy and sources of law in Japan.

material. Paragraph 2.4 of Ref. [2] addresses the specific legislative requirements concerning transport safety.

3.4. Reference [2] states, inter alia, in para. 1.5, that "*This publication establishes legal and governmental responsibilities which are common to a broad range of facilities and activities…*" These activities include "*the transport of radioactive materials…*" Reference [2] states, inter alia, in para. 2.2, that there are "*certain prerequisites for the safety of facilities and activities.*" These prerequisites are addressed in certain subparagraphs of para. 2.2.

3.5. Reference [2] requires, inter alia, in para. 2.2, that "*(1) A legislative and statutory framework shall be established to regulate the safety of facilities and activities.*"

Legal framework and sources of law for the transport of radioactive material

3.6. Legislation applies abstract rules to facts. Facts are the basis for the application of different types of abstract rules within the legal system. The facts for applying Japan's legislative rules on the transport of radioactive material are that in Japan there are 54 commercial nuclear power reactors (as of 8 December 2005), 23 test and research reactors (as of 13 December 2005), 200 facilities using nuclear fuel material (as of 13 December 2005) and 4844 facilities using radioisotopes (as of 1 December 2005). Nevertheless, as Japan is short of natural resources such as uranium, international transport of nuclear fuel material is carried out very often for imports of natural uranium hexafluoride, enriched uranium hexafluoride and uranium dioxide powder for fuel. Furthermore, radioisotopes and radiopharmaceuticals are also transported.

3.7. The legislative basis for the appraisal in the field of this section is included in the list of legislation in Appendix VI [A–L-2].[1]

3.8. It is also noted that although [C-7, D-3, I-3] provide definitions of the terms 'vehicle shipment' and 'vehicle' that include transport by railway and cableway, these modes are not used for the transport of radioactive material in Japan. Radioactive material is transported only by sea, air, road and, in rare cases, post and correspondence delivery (hereinafter abbreviated for convenience to 'post' as a general term to include correspondence delivery as well). Also, inland waterways are not used to transport radioactive material.

3.9. Furthermore, it should be noted that the legislation and governmental responsibility for aspects of nuclear liability (see Ref. [2], para. 2.4 (11), (12)) and physical protection concerning the transport of radioactive material were excluded from the scope of this appraisal for Japan.

3.10. Japan's legal system is hierarchical in structure. The Constitution formally declares that the Diet (parliament) is the sole law making organ of Japan. Legislation is, therefore, created by the Diet.

3.11. The legal framework for the transport of radioactive material in Japan is provided by the Constitution, binding international conventions and treaties,

[1] Relevant Japanese legislation (referenced by letters of the alphabet, or letters and numbers, in square brackets) is listed in Appendix VI.

national laws and various types of executive regulations. Figure 1 provides an overview of the legal hierarchy and the law sources in Japan.

3.12. The legal framework and the sources of law for the transport of radioactive material in Japan may be summarized as follows:

— Constitution of Japan (promulgated on 3 November 1946). The Constitution of Japan is the supreme law of the nation and no law, ordinance, imperial prescript or other act of government or part thereof contrary to its provisions shall have legal force or validity.
— Laws. Pursuant to the procedures set out by the Constitution of Japan (Article 59) and laws such as the Diet Law, laws are enacted via resolutions of the Diet, the legislative body, and are then promulgated by the Emperor.
— Government orders. Government orders are issued by the Cabinet, a body with administrative powers, and are issued to implement the provisions of the Constitution and its laws or are issued as mandated by law. However, penal regulations cannot be established, obligations cannot be imposed, nor can the rights of the people be restricted without a legal mandate for a government order (Clause 6, Article 73, of the Constitution, and Article 11 of the Cabinet Law).
— Ministerial orders. Ministerial orders are orders prescribed by the heads of the respective administrative bodies (ministries) for implementing laws or government orders, or by special mandate of a law or order (Clause 1, Article 12, of the National Government Organization Law). Penal regulations cannot be established, obligations cannot be imposed, nor can the rights of the people be restricted without a legal mandate for a ministerial order (Clause 3, Article 12, of the National Government Organization Law).

3.13. In addition, the following also possess the force of law:

— Notices. Notices serve to inform the public of the details of decisions of ministers, committees and agency directors pertaining to the administrative work of their government bodies (Articles 7 and 58 of the Cabinet Law and Article 14 of the National Government Organization Law).
— Generic letters. Generic letters are issued by ministers, heads of committees and agencies to provide the various bodies and staff under their jurisdiction with information such as details of the administrative work of their bodies, explanations of legislation and operating policies

(Articles 7 and 58 of the Cabinet Law and Article 14 of the National Government Organization Law).

Relationship between domestic laws and treaties

3.14. The relationship between legislation and treaties is as follows:

— The Constitution of Japan and treaties. The Constitution of Japan is generally understood to take precedence over international law. Nonetheless, given that the Constitution stipulates that treaties and other international legislation ratified by Japan are to be faithfully observed (Clause 2, Article 98, of the Constitution of Japan) when Japan (the Cabinet) concludes a treaty, it thoroughly studies it to see that no conflict with domestic law will ensue, and it obtains prior or, depending upon the circumstances, subsequent approval of the Diet.
— Treaties, international law and domestic law. Treaties are understood to take precedence over law in the order of primacy between treaties and law. When a treaty is concluded by Japan, in order to give the treaty legal force over the nation it is common that the Government of Japan enacts or amends domestic laws or orders so that they satisfy its requirements.

Prerequisites for the safe transport of radioactive material according to the requirements of the Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety

3.15. Reference [2] states, inter alia, in para. 2.2, that "*(1) A legislative and statutory framework shall be established to regulate the safety of facilities and activities.*" The transport of radioactive material is subject to a wide and diverse legislative and statutory framework in Japan for the different modes of transport (road, air, sea and post) and different types of radioactive material (Fig. 2).

3.16. Japan incorporated the Transport Regulations in the 1973, 1985, 1996, 2000 and 2003 editions into its relevant legislation in 1978, 1990, 2001, 2003 and 2005, respectively, and has implemented safety regulations in conformity with them (see Fig. 3).

3.17. The geography of Japan, an archipelago, obviously excludes any kind of international land transport.

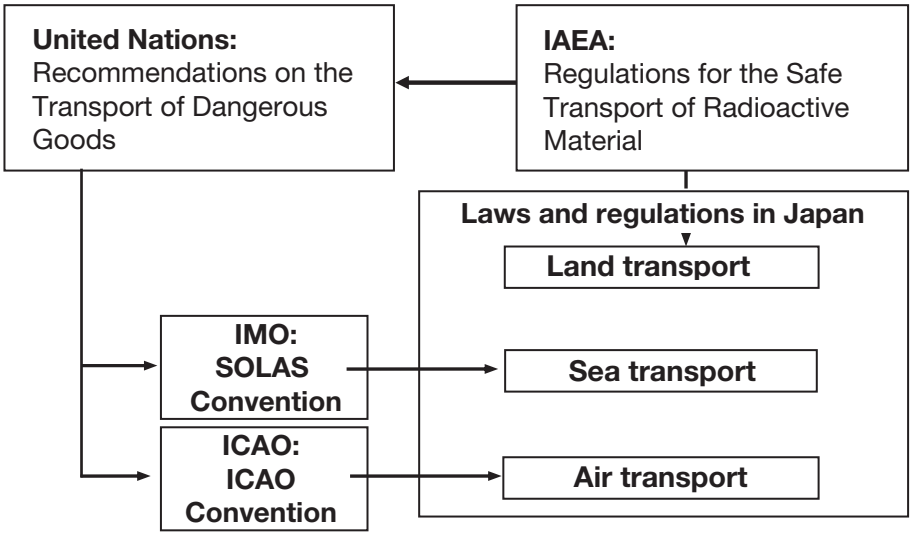

FIG. 2. Incorporation of international regulations into Japan's legislation.

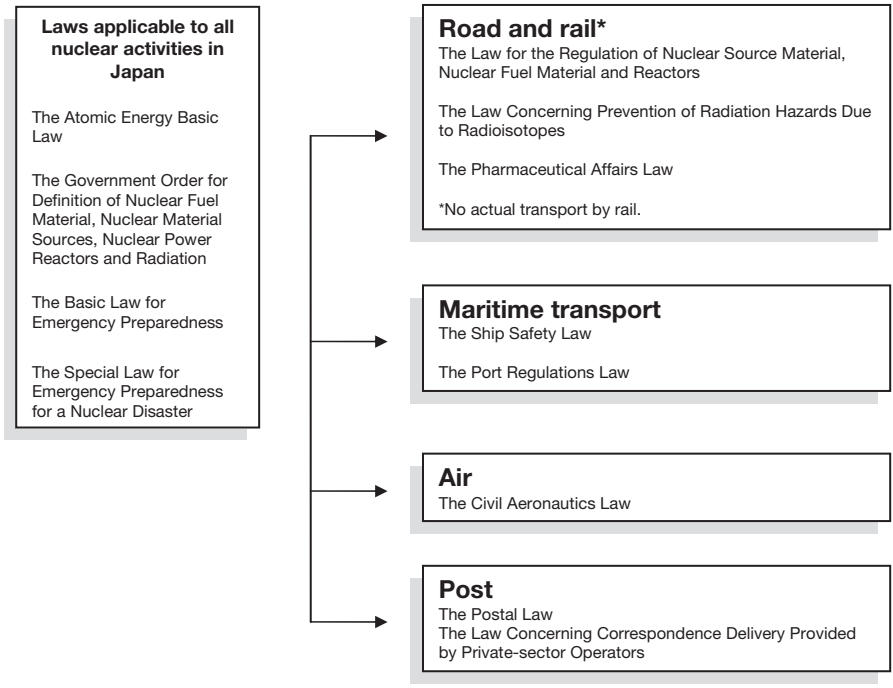

FIG. 3. Adoption of the Transport Regulations within the legal system of Japan.

3.18. Japan is a Member State of the Convention on International Civil Aviation (Chicago Convention or ICAO Convention). Regarding international air transport, the ICAO Technical Instructions (Annex 18), which incorporate the Transport Regulations, are linked with the Civil Aeronautics Law.

3.19. Japan is a Member State of the International Convention for the Safety of Life at Sea (SOLAS Convention), and, for sea transport, the IMDG Code, which incorporate the Transport Regulations, and the INF Code of the SOLAS Convention are incorporated into the Ship Safety Law.

3.20. Japan is a Member State of the Universal Postal Union (UPU), which incorporates the Transport Regulations into its postal requirements.

System of the transport of radioactive material in Japan

3.21. Japan's laws on the transport of radioactive material are separately established for each transport mode (sea, air and land). More legal prerequisites are established in regulations addressing the different types of radioactive material.

Laws applicable to all nuclear activities

3.22. The laws applicable to all nuclear activities are the:

(a) Atomic Energy Basic Law;
(b) Government Order for Definition of Nuclear Fuel Material, Nuclear Material Sources, Nuclear Power Reactors and Radiation;
(c) Basic Law for Emergency Preparedness;
(d) Special Law for Emergency Preparedness for a Nuclear Disaster.

Road and rail

3.23. Land transport is regulated by different laws; each law defines its own scope of radioactive material, radioactive nuclides and quantities. These laws refer to the terms defined in the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Reactor Regulation Law), the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes (Radiation Hazard Prevention Law) and the Pharmaceutical Affairs Law. The specific requirements to be met during road transport are stipulated in various regulations.

Nuclear fuel material

3.24. The following are regulatory documents that apply to nuclear fuel material:

(a) Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors;
(b) Government Order for the Enforcement of the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors;
(c) Regulations for Transport of Nuclear Fuel Material Outside Plants;
(d) Regulations for Vehicle Transport of Nuclear Fuel Material, Etc.;
(e) Notice on the Details of Technical Standards for Transport of Nuclear Fuel Material in Accordance with the Provisions of Article 3 of the Regulations for Transport of Nuclear Fuel Material Outside Plants;
(f) Notice on the Details of the Regulations for Vehicle Transport of Nuclear Fuel Material, Etc.;
(g) Regulations for Actions in Emergencies Concerning Transport of Nuclear Fuel Material Outside Plants;
(h) Cabinet Office Order for the Notification of Transportation of Nuclear Fuel Material, Etc.

Radioisotopes

3.25. The following are regulatory documents that apply to radioisotopes:

(a) Law Concerning Prevention of Radiation Hazards Due to Radioisotopes;
(b) Government Order for the Enforcement of the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes;
(c) Regulations for the Enforcement of the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes, Etc.;
(d) Notice on the Details of Technical Standards for Transport of Radioisotopes or Material Contaminated with Radioisotopes Outside Plants;
(e) Regulations for Vehicle Transport of Radioisotopes;
(f) Notice on the Details of the Regulations for Vehicle Transport of Radioisotopes;
(g) Regulations for Actions in Emergencies Concerning Transport of Radioisotopes Outside Plants;
(h) Cabinet Office Order for the Notification of Transportation of Radioisotopes.

Radiopharmaceuticals

3.26. The following are regulatory documents that apply to radiopharmaceuticals:

(a) Pharmaceutical Affairs Law;
(b) Regulations for Manufacturing and Handling of Radiopharmaceuticals;
(c) Standard for Transport of Radioactive Material.

Sea transport

3.27. The following are regulatory documents that apply to sea transport:

(a) Ship Safety Law;
(b) Regulations for the Carriage and Storage of Dangerous Goods by Ships;
(c) Notice on the Details of Standards Concerning the Carriage of Radioactive Material by Ships;
(d) Notice on the Carriage of Dangerous Goods by Ships;
(e) Port Regulations Law;
(f) Regulations for the Enforcement of the Port Regulations Law;
(g) Notice to Define the Kinds of Dangerous Goods Under the Regulations for the Enforcement of the Port Regulations Law.

Air transport

3.28. The following are regulatory documents that apply to air transport:

(a) Article 86 of the Civil Aeronautics Law;
(b) Article 194 of the Regulations for the Enforcement of Civil Aeronautics (Civil Aeronautics Regulations);
(c) Notice of Standard for Transport of Radioactive Material by Air.

Post

3.29. The following are regulatory documents that apply to the postal system:

(a) Postal Law;
(b) Notice No. 384 of the Ministry of Communications, 1947, to Define Explosive, Inflammable or Other Dangerous Substances Pursuant to the Provisions of the Postal Law, Article 14, Subpara. 1;

(c) Law Concerning Correspondence Delivery Provided by Private-sector Operators (Correspondence Delivery Law);
(d) Notice No. 203 of 2003 to Define Explosive, Inflammable or Other Dangerous Substances Pursuant to the Provisions of the Law Concerning Correspondence Delivery Provided by Private-sector Operators;
(e) Letter Post Regulations (Notice);
(f) Parcel Post Regulations (Notice).

3.30. Reference [2] states, inter alia, in para. 2.2, that "*(2) A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for… activities. This is so that regulatory judgments can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.*" Japan's legislation establishes various authorities that — apart from scientific and consulting institutions — are generally empowered, according to their specific responsibility given by law, to discharge appropriate measures for licensing, inspection and enforcement.

3.31. The Nuclear and Industrial Safety Agency (NISA) was established as a special agency in the Ministry of Economy, Trade and Industry (METI) in January 2001. NISA is effectively separated in the decision making process from the Agency for Natural Resources and Energy, which is concerned with the promotion or utilization of nuclear technologies development. Decisions by METI are supervised by the Nuclear Safety Commission, a high level body within Japan's governmental administrative system.

3.32. Although the Ministry of Education, Culture, Sports, Science and Technology (MEXT) regulates nuclear related science and technology, regulatory policies for nuclear safety are established independently by regulatory organizations (Office of Nuclear Regulation and Office of Radiation Regulation of the Science and Technology Policy Bureau), which are separate from other organizations promoting the development of nuclear technologies (Research and Development Bureau). Policy decided by MEXT is supervised by the Nuclear Safety Commission.

3.33. Reference [2] states, inter alia, in para. 2.2, that "*(3) Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides.*" The responsibilities are fulfilled by diverse regulatory bodies in accordance with the legislation.

3.34. Reference [2] states, inter alia, in para. 2.2, that "*(5) No other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety.*" The responsibilities given to the diverse regulatory bodies are defined in several laws and administrative regulations. No internal conflicts could be found that affect the exclusive responsibility of a responsible regulatory body for the safety of transport.

3.35. Reference [2] states, inter alia, in para. 2.2, that "*(7) Adequate infrastructural arrangements shall be made for the safe transport of radioactive material.*" Reference [2] also states, in para. 2.2, that "*(4) The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities.*"

3.36. The number of national government personnel and the number of personnel for each ministry and agency are stipulated in the Law for the Fixed Number of Personnel of Administrative Organizations and the relevant Order for the Fixed Number of Administrative Organizations. Moreover, the number of personnel for each bureau is defined by official instructions, and their allocation is ensured depending on the work to be performed. Financial resources are determined and provided by the national budget of each fiscal year. The legal framework and the regulatory body for the safe transport of radioactive material are clearly prescribed, and the responsible organization and the personnel and financial resources are fully ensured.

3.37. Reference [2] states, inter alia, in para. 2.2, that "*(8) An effective system of governmental emergency response and intervention capabilities shall be established and emergency preparedness shall be ensured.*" This topic is addressed in detail in the section of this report on emergency preparedness for transport.

Land transport

Nuclear fuel material

3.38. The responsibility for the safe transport of nuclear fuel material is assigned to operators in accordance with the Reactor Regulation Law.

Radioisotopes

3.39. The responsibility for the safe transport of radioisotopes is assigned to users in accordance with the Radiation Hazard Prevention Law.

Radiopharmaceuticals

3.40. The responsibility for the safe transport of radiopharmaceuticals is assigned to manufacturers in accordance with the Regulations for Manufacturing and Handling of Radiopharmaceuticals.

Sea transport

3.41. The person responsible for confirmation of consignment is defined in the Regulations for the Carriage and Storage of Dangerous Goods by Ships as the person who prepares the packages. The person who takes responsibility for confirmation of the safety of the transport method is defined in the same regulations as the ship's captain.

Air transport

3.42. The person who takes responsibility for the packages is defined in the Civil Aeronautics Law as the shipper. The person who takes responsibility for the transport method is defined as the captain, air transport operator, etc.

Post

3.43. The person who takes responsibility for post is defined in the Postal Law, Universal Postal Convention and Correspondence Delivery Law as the sender.

LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES: LEGISLATIVE

3.44. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(1) shall set out objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future*".

3.45. The Transport Regulations state at the outset that an acceptable level of control of radiation should be one of the main principles of safety to be

established (Ref. [1], paras 301–303). The aim is to ensure that doses to person shall be below the relevant dose limits. Provisions to prevent radiation hazards have been incorporated into the legislation for land, air, sea and postal transport.

3.46. The objectives are defined in several regulations:

(a) Law Concerning Prevention of Radiation Hazards Due to Radioisotopes;
(b) Regulations for Vehicle Transport of Nuclear Fuel Material, Etc. (dose rate for a container or on an overpack, transport index and criticality index, placards and labels, loading limit dose rate for vehicles);
(c) Regulations for Transport of Nuclear Fuel Material Outside Plants;
(d) Notice on the Details of Technical Standards for Transport of Radioisotopes or Material Contaminated with Radioisotopes Outside Plants;
(e) Regulations for Vehicle Transport of Radioisotopes;
(f) Articles 101, 102 and 103 of the Regulations for the Carriage and Storage of Dangerous Goods by Ships;
(g) Generic Letter on Regulations for Transport of Radioactive Material (generic letter by the Director General of the Civil Aviation Bureau of the Ministry of Land, Infrastructure and Transport (MLIT));
(h) Notice No. 384 of the Ministry of Communications, 1947, to Define Explosive, Inflammable or Other Dangerous Substances Pursuant to the Provisions of the Postal Law, Article 14;
(i) Notice No. 203 of 2003 to Define Explosive, Inflammable or Other Dangerous Substances Pursuant to the Law Concerning Correspondence Delivery Provided by Private-sector Operators (subpara. (i) of para. 1 of Article 47).

3.47. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation*".

Land transport

3.48. The Reactor Regulation Law and related laws refer to the transport of nuclear fuel material by conveyance other than ship or aircraft. The exemption value is not defined for nuclear fuel material on the grounds that the scope of the law is limited to nuclear fuel material rather than radioactive material. The Radiation Hazard Prevention Law and related laws refer to the transport of

radioisotopes by conveyance other than ship or aircraft. The exemption values in the Transport Regulations are fundamentally incorporated for radioisotopes.

3.49. The Pharmaceutical Affairs Law and related legislation provide for the transport of radiopharmaceuticals by conveyance other than ship or aircraft. The exemption values for radiopharmaceuticals given in the Transport Regulations are fundamentally incorporated by this law.

Sea transport

3.50. The Ship Safety Law and related legislation refer to the transport of radioactive material by ships, to which the IMDG Code and, where appropriate, the INF Code are applied. The same exemption values as those specified in the IMDG Code are defined for radioactive material.

Air transport

3.51. The Civil Aeronautics Law and related legislation refer to the transport of radioactive material by aircraft. The same exemption values as those specified in the ICAO Technical Instructions in accordance with the Convention on International Civil Aviation (Chicago Convention) are defined for radioactive material.

Post

3.52. The Postal Law, the Correspondence Delivery Law and related legislation refer to the transport of radioactive material by post (provision of item 9, explosive substances, combustible substances and other dangerous substances, described in Ministry of Communications Notice No. 384 of 1947 pursuant to subpara. (i) of Article 14 of the Postal Law, and described in the Ministry of Internal Affairs and Communications (MIC) Notice No. 203 of 2003 pursuant to subpara. (i) of para. 1 of Article 47 of the Correspondence Delivery Law).

3.53. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(3) shall establish authorization and other processes (such as notification and exemption), with account taken of the potential magnitude and nature of the hazard associated with the facility or activity, and shall specify the steps of the processes*". Depending on the mode of transport, the requirements for procedures for confirmation of consignment, approval of packaging, approval

of package design, confirmation of transport method, reporting, etc., are defined by the corresponding relevant laws.

Land transport

3.54. NISA, MEXT and the MLIT are the regulatory bodies for nuclear fuel material, and operators are required to take the necessary actions to preserve safety in accordance with para. 1 of Article 59-2 of the Reactor Regulation Law. The operators have obligations to obtain confirmation by the competent minister in accordance with para. 2 of Article 59-2 of the said law. Issuance of approval certificates (a certificate for confirmation of consignment, a certificate for approval of the packaging and package or a certificate for confirmation of transport method) is provided in Articles 17 and 17-3 of the Regulations for Transport of Nuclear Fuel Material Outside Plants and Article 22 of the Regulations for Vehicle Transport of Nuclear Fuel Material, Etc., to issue the approval certificate whenever any confirmation or approval is given. (Other approval certificates are currently defined in generic letters, but will be provided for in the legislation at the amendment of orders and notices by the ministries in the future.)

3.55. A notice for shipment of nuclear fuel material as defined by government order must be submitted in accordance with the Cabinet Office order pursuant to para. 5 of Article 59-2 of the Reactor Regulation Law (paras 2 and 3 of Article 59-2 of the Reactor Regulation Law provide that any person who intends to obtain a licence or confirmation shall submit an application for consignment attached with explanatory documents to the competent minister in accordance with Articles 16 and 17-2 of the Regulations for Transport of Nuclear Fuel Material Outside Plants, and shall also submit a plan for the transport method to the Minister of the MLIT in accordance with Article 21 of the Regulations for Vehicle Transport of Nuclear Fuel Material, Etc.).

3.56. For the transport of radioisotopes according to the Radiation Hazard Prevention Law, similar regulations are in force that oblige applicants to obtain the appropriate confirmation or licence from the regulatory body. For the transport of radiopharmaceuticals, the Ministry of Health, Labour and Welfare (MHLW) is the regulatory body, and applicants are obliged to take the necessary action to prevent radiation hazards in accordance with paras 6 and 7 of Article 2 of the Regulations for Manufacturing and Handling of Radiopharmaceuticals relating to para. 2 of Article 18 of the Pharmaceutical Affairs Law.

Sea transport

3.57. The MLIT is the regulatory body for regulating the safety of sea transport of nuclear radioactive material. The consignor is obliged to transport radioactive material in packaged form in accordance with Article 80 of the Regulations for the Carriage and Storage of Dangerous Goods by Ships.

3.58. The person who prepares packages is required to obtain approval from the MLIT for package design compatibility in accordance with Article 86 of the Regulations for the Carriage and Storage of Dangerous Goods by Ships and to obtain confirmation by the Minister of the MLIT or the Director General of the District Transport Bureau for package compatibility in accordance with these regulations.

3.59. The provision concerning issuance of approval certificates (a certificate of approval of the package design, confirmation of consignment and confirmation of transport method), which is conducted whenever any approval or confirmation is given, is included in a generic letter (Generic Letter No. 64 by the Inspection and Measurement Division, Maritime Bureau, MLIT, 2 March 1987).

Air transport

3.60. Air transport of radioactive material is regulated by the MLIT as the regulatory body (subpara. (ii) of para. 2 of Article 194 of the Civil Aeronautics Regulations). Additionally, the applicant has to obtain confirmation by the competent minister in accordance with items C–E of subpara. (ii) of para. 2 of Article 194 of the said regulations. An approval certificate (a certificate of confirmation of consignment and a certificate of confirmation of transport method) is issued when confirmation is given.

Postal law

3.61. The MIC is the regulatory body for the postal system. Conditions for radioactive material to be sent by post are specified in Notice No. 384 of the Ministry of Communications, 1947, in accordance with subpara. (i) of Article 14 of the Postal Law, and Notice No. 203 of the MIC, 2003, in accordance with subpara. (i) of para. 1 of Article 47 of the Correspondence Delivery Law. In addition, provisions of Articles 25 and 26 of the Universal Postal Convention are applied to international post in accordance with Article 13 of the Postal Law.

3.62. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(4) shall establish a regulatory body with the authority outlined in para. 2.6*" and "*(5) shall arrange for adequate funding of the regulatory body*".

3.63. As to the resources provided to the regulatory body and the means used to make them available: according to the Law for the Fixed Number of Personnel of Administrative Organizations and the Government Order for the Fixed Number of Administrative Organizations, the budget bills are approved by the Diet, which sets the basis for the arrangement of funding of the regulatory body.

3.64. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(7) shall establish a procedure for review of, and appeal against, regulatory decisions (without compromising safety)*". The procedure is in accordance with the Administrative Appeal Law, which is a general law. In addition, reports to be used in the decision making process are open to the public for comment before finalization.

3.65. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(8) shall provide for continuity of responsibility when activities are carried out by several operators successively and for the recording of the transfers of responsibility*". The responsibilities of operators are specified for every mode of transport and for every item (e.g. package, transport method). The responsible operator does not change for multimodal shipment of a package. According to national Japanese legislation, an approval by one regulatory body for one transport mode is considered to be approval by another regulatory body in charge of another mode of transport.

3.66. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(9) shall allow for the creation of independent advisory bodies to provide expert opinion to, and for consultation by, the government and regulatory body*". According to several laws and regulations, such as the Law for the Atomic Energy Commission and the Nuclear Safety Commission, Articles 1 and 6 of the Law for Technical Standards for Prevention of Radiation Hazards, Article 19 of the Law for the Ministry of Economy, Trade und Industry, Article 13 of the Law for the Incorporated Administrative Agency, Japan Nuclear Energy Safety Organization, subpara. 72 of Article 4 of the Law for the Ministry of Education, Culture, Sports, Science and Technology and the Generic Letter on Procedures for Establishment of Technical Adviser System for the Transport of Radioactive Material by Ships (23 January 1981), the

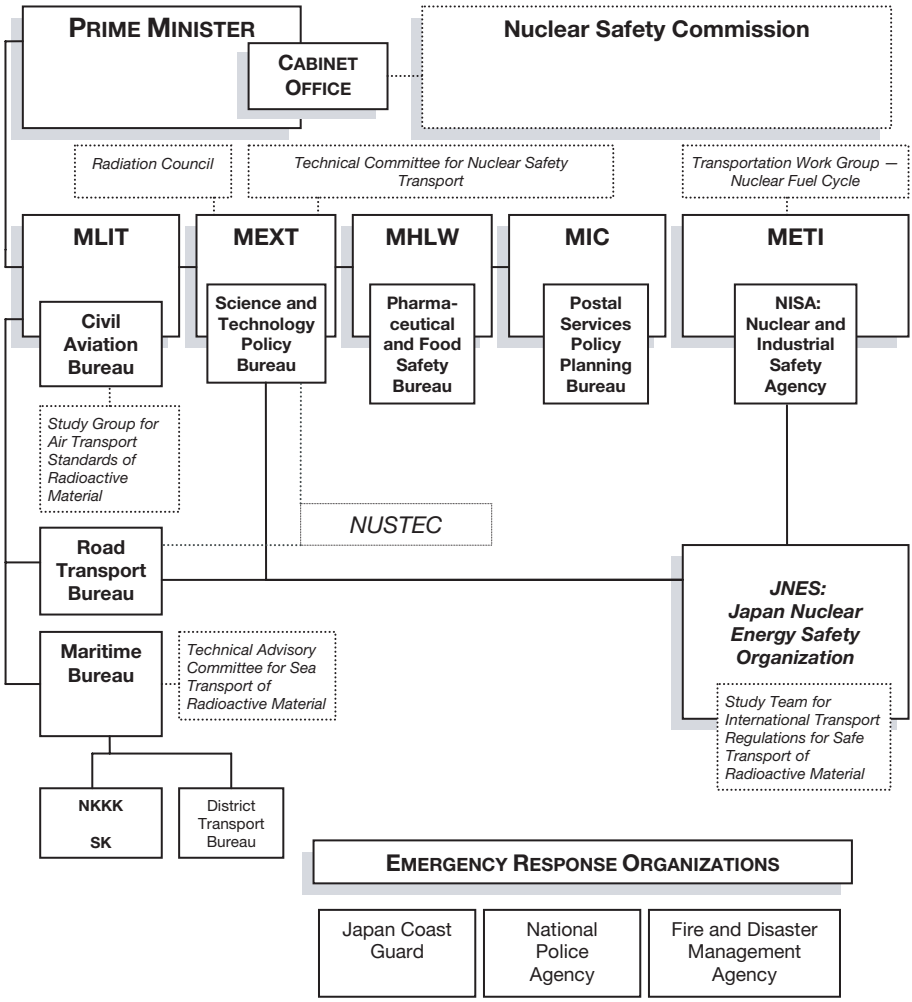

FIG. 4. Organization of the responsible authorities and their advisory organizations.

bodies/persons responsible for advice on transport issues related to specific governmental authorities (see Fig. 4) are:

(a) The Nuclear Safety Commission;
(b) The Radiation Council;
(c) The Transportation Work Group — Nuclear Fuel Cycle Subcommittee;
(d) The International Transport Regulation Board of Inquiry;
(e) Transport specialists;
(f) The Technical Committee for Nuclear Safety Transport;

(g) The Technical Advisory Committee for Sea Transport of Radioactive Material;
(h) The Study Group for Air Transport Standards of Radioactive Material.

3.67. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(10) shall set up a means whereby research and development work is undertaken in important areas of safety*". The safety of transport is included in the Nuclear Safety Research Programme prepared by the Nuclear Safety Commission, which identifies research to be carried out at national government institutes.

3.68. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(14) shall define what is an offence and the corresponding penalties*". Offences and their penalties are defined in several laws and corresponding orders. According to the regulatory system in Japan, this subject is defined in every law regulating each mode of transport (land, sea, air and post) and for each type of radioactive material. For example, the operator faces a fine of up to 500 000 yen in any case of shipment undertaken without obtaining the applicable confirmation or notification.

3.69. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(15) shall implement any obligations under international treaties, conventions or agreements*". All international treaties concerning the transport of radioactive material relevant to the scope of this appraisal are implemented in the legal system of Japan. For sea transport, it is obligatory to completely implement the IMDG Code and the INF Code in accordance with the provisions of the SOLAS Convention. For air transport, implementation is in accordance with the Chicago Convention.

3.70. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(16) shall define how the public and other bodies are involved in the regulatory process*". Generally, the public is invited to comment on the establishment, amendment and repeal of regulations other than those requiring Diet deliberation. This is implemented in accordance with the Generic Letter on the Procedure for Submitting Opinions Relating to Establishment, Amendment or Abrogation of Regulations (Cabinet decision, 23 March 1999). According to this decision, a public comment procedure is implemented. Therefore, any administrative organ that expresses its intentions shall — through this procedure — disclose the drafts thereof before making its final decision. Administrative organs shall disclose additional material related to the body of drafts in order to clarify them to the public.

3.71. Reference [2] states, inter alia, in para. 2.4, that this legislation "*(17) shall specify the nature and extent of the application of newly established requirements to existing facilities and current activities*". The nature and extent of application of the newly established requirements are defined clearly in the legislation. Generally, the transitional arrangements are defined in supplementary provisions of the legislation. For example, when uranium hexafluoride was categorized as a nuclear fuel material for the purposes of the Regulations for Transport of Nuclear Fuel Material Outside Plants to reflect the new technical requirements for packages containing uranium hexafluoride in the 1996 revision, a transitional provision was added to the regulations to avoid the situation in which the package would be subject to confirmation, as required by Article 15, before entry into force of the 1996 revision of the Transport Regulations. In addition, transitional arrangements up to 1 January 2004 were made for existing approved packaging in the supplementary provisions of Order No. 1, 15 June 2001, which was under the co-jurisdiction of the relevant three ministries and agencies.

3.72. Requirements for authority and responsibilities of the regulatory bodies can be found in both the Transport Regulations and Ref. [2].

3.73. The Transport Regulations specify, in para. 103, that "*In certain parts of these Regulations, a particular action is prescribed, but the responsibility for carrying out the action is not specifically assigned to any particular legal person. Such responsibility may vary according to the laws and customs of different countries and the international conventions into which these countries have entered. For the purpose of these Regulations, it is not necessary to make this assignment, but only to identify the action itself. It remains the prerogative of each government to assign this responsibility.*" The appraisal evaluated the authority, responsibilities and functions of Japan's transport regulatory bodies through a variety of means (presentations, interviews and a detailed study of documents). The authorities for transport were found to comply with paras 2.4 and 2.6 of Ref. [2].

3.74. Regarding the allocation of responsibility, pursuant to para. 103 of the Transport Regulations [1], Japan has set out responsibilities as shown in Fig. 4; this allocation was determined by the appraisal team to be adequate and complete. The functions of the regulatory bodies are set forth according to the laws shown in Fig. 3.

3.75. Reference [2] states, in para. 2.6, that:

> "*The regulatory body shall have the authority*:
> *(1) to develop safety principles and criteria*".

3.76. The safety principles according to the Transport Regulations are incorporated within the relevant regulations and laws. During the appraisal, it was shown that Japan met the further requirements based on Ref. [2], para. 2.6, in particular:

> "*(2) to establish regulations and issue guidance;*
> *(3) to require any operator to conduct a safety assessment;*
> *(4) to require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;*
> *(5) to issue, amend, suspend or revoke authorizations and to set conditions;*
> *(6) to require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;*
> *(7) to enter a site or facility at any time to carry out an inspection;*
> *(8) to enforce regulatory requirements*".

3.77. Reference [2] states, inter alia, in para. 2.6, that the regulatory body shall have the authority "*(9) to communicate directly with governmental authorities at higher levels when such communication is considered to be necessary for exercising effectively the functions of the body*". It was confirmed during the interviews that the authorities, including local branch offices, can directly communicate with higher level authorities.

3.78. Reference [2] states, inter alia, in para. 2.6, that the regulatory body shall have the authority "*(10) to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate*". Reference [2] further states, in para. 2.6, that the regulatory body shall have the authority "*(11) to communicate independently its regulatory requirements, decisions and opinions and their basis to the public*". Press releases, web sites and periodical publications are available to communicate with the public.

3.79. Reference [2] states, inter alia, in para. 2.6, that the regulatory body shall have the authority "*(12) to make available, to other governmental bodies, national and international organizations, and to the public, information on*

incidents and abnormal occurrences, and other information, as appropriate". For national organizations, all legislation includes the obligation to report on accidents (Article 67 of the Reactor Regulation Law, Article 42 of the Radiation Hazard Prevention Law, Article 23 of the Regulations for Vehicle Transport of Nuclear Fuel Material, Etc., Article 22 of the Regulations for Vehicle Transport of Radioisotopes, Article 13 of the Regulations for Manufacturing and Handling of Radiopharmaceuticals), and notification and report to the competent ministry and agency, or to the police, are obligatory. For governmental organizations, there is a communication system for accidents, in accordance with the agreement of the Interagency Coordination Meeting for the Safe Transport of Radioactive Material. At the international level, Japan has ratified the Convention on Early Notification of a Nuclear Accident. The notification is made in accordance with the International Nuclear Event Scale (INES). Press releases and news briefings by each competent ministry and agency are available to communicate with the public.

3.80. Reference [2] states, inter alia, in para. 2.6, that the regulatory body shall have the authority "*(13) to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods*". The Interagency Coordination Meeting for the Safe Transport of Radioactive Material ensures close coordination.

3.81. Reference [2] states, inter alia, in para. 2.6, that the regulatory body shall have the authority "*(14) to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information*". Japan liaises with the United Nations Economic and Social Council (ECOSOC), IMO, ICAO, IAEA and UPU.

3.82. NISA has concluded a bilateral agreement and exchanges safety information with:

(a) The USA (Nuclear Regulatory Commission);
(b) France (Direction générale de la sûreté nucléaire et de la radioprotection);
(c) The Republic of Korea (Ministry of Science and Technology);
(d) China (National Nuclear Safety Administration);
(e) The United Kingdom (Health and Safety Executive);
(f) Sweden (Swedish Nuclear Power Inspectorate).

In addition, training programmes on nuclear safety for Asian and east European countries are being held.

3.83. MEXT has concluded bilateral agreements and exchanges safety information with:

(a) The USA (Nuclear Regulatory Commission);
(b) France (Direction générale de la sûreté nucléaire et de la radioprotection);
(c) Germany (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety);
(d) The Republic of Korea (Ministry of Science and Technology);
(e) China (National Nuclear Safety Administration);
(f) The United Kingdom (Health and Safety Executive);
(g) Italy (National Environmental Protection Agency).

Findings

3.84. Basis: Ref. [2] states, inter alia, in para. 2.4, that this legislation "*(2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation*".

Good practice: The clear and comprehensive definitions of the terms 'vehicle shipment' and 'simple shipment' in the Regulations for Transport of Nuclear Fuel Material Outside Plants (Article 1 (i), (ii)) apply to any kind of transport. In accordance with the purpose of regulation in general — to protect the public, workers and the environment from the hazards of radiation — it is clear that any transport without exemption is under the jurisdiction and surveillance of the responsible regulatory body.

3.85. Basis: Ref. [2] states, inter alia, in para. 2.4, that legislation "*(16) shall define how the public and other bodies are involved in the regulatory process*". According to Article 3 of the Information Disclosure Law for Information Possessed by Administrative Bodies and also the Generic Letter on Procedure for Submitting Opinions Relating to Establishment, Amendment or Abrogation of Regulations, every person may request heads of administrative organs to disclose administrative documents held by the administrative organ. Administrative organs must disclose as much material as possible in addition to the body of drafts in order to clarify them to the public and must gather a wide

spectrum of public opinion and use information and expertise in order to ensure fairness and improve the transparency of the process.

Good practice: The public is enabled to be informed directly, so that people and non-governmental institutions can play an active role in the process of submitting opinions relating to the establishment, amendment or abrogation of regulations.

3.86. Basis: Ref. [2] states, inter alia, in para. 2.4, that this legislation "*(2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation*".

Good practice: Any user of nuclear source material has to report to the responsible minister immediately if hazards arise when using nuclear source material or if the exposure of personnel engaged in radiation work has exceeded or is feared to exceed prescribed limits. Also, the operator of shipments of radioactive material (transport in general) is obliged to report to the competent minister not only in the event of specific incidents such as theft or unusual leakage but any event that is or is likely to be a hazard to people.

3.87. Basis: Ref. [2] states, inter alia, in para. 2.4, that this legislation "*(2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation*". The basis for the regulation of land transport covers 17 specific regulations for nuclear fuel [C-7–C-23] and ten additional regulations for radio-isotopes [D-4–D-13], which are linked with higher level laws (e.g. [A, D-1, I-1, C-1]). For the purpose of having a clear, concise and homogeneous approach to the safety of transport, there seems to be no necessity to establish such numerous regulations dealing sometimes with similar topics. To achieve the goal of harmonizing Japan's regulations relating to transport safety, it may be helpful to reduce the total number of regulations (e.g. [C-16] and [C-18], referring explicitly to the Transport Regulations, 1996 edition).

Suggestion: A smaller number of regulations could be useful for daily work in regulatory and operational practice, so it is suggested that the regulatory body could try to reduce or merge them to the extent possible.

RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.88. The responsibility for regulating the transport of radioactive material is spread among five ministries of the Government of Japan (see Fig. 4). These responsibilities are divided on the basis of:

(a) The type of material (i.e. nuclear fuel material, radioisotopes, radiopharmaceuticals);
(b) The mode of transport (such as land, sea, air or post);
(c) Emergency response.

Many of these ministries have established governmental offices and support organizations to assist in performing their respective responsibilities.

3.89. METI is the principal regulatory body for the safe transport of radioactive material as mandated by the Law for the Ministry of Economy, Trade and Industry. METI administers affairs related to regulations for nuclear power plants and nuclear fuel cycle facilities. This ministry has established NISA to operate as an independent support agency, removed from ministerial concerns of promoting or utilizing nuclear technology. NISA, through its Nuclear Fuel Transport and Storage Regulations Division, is the regulatory body on matters related to the road transport of nuclear material packages through the issuance of approval certificates, as appropriate, and for international cooperation in the transport of radioactive material, such as working with the IAEA. The Government of Japan has created the Japan Nuclear Energy Safety Organization (JNES), an incorporated administrative agency, to act on behalf of METI in conducting safety analyses and evaluations of nuclear facilities and to conduct on-site inspections.

3.90. METI also has responsibility for nuclear emergency preparedness through NISA's Nuclear Emergency Preparedness Division. The Special Law on Emergency Preparedness for a Nuclear Disaster clarifies the responsibilities and roles of the national government. The Japan Coast Guard, the National Police Agency and the Fire and Disaster Management Agency also have defined functions for emergency response purposes (see the section on emergency preparedness for transport).

3.91. MEXT is the regulatory authority on matters related to the safety — for land transport — of nuclear fuel material from test and research reactors and also facilities using the material, and of radioisotopes for industrial and research applications. The Nuclear Safety Division of the Science and

Technology Policy Bureau of MEXT is responsible for authorizing approval certificates for packages containing these types of radioactive material for land transport.

3.92. MEXT also has responsibility for nuclear emergency preparedness through the Office of Emergency Planning and Environmental Radioactivity. The Special Law on Emergency Preparedness for a Nuclear Disaster clarifies the responsibilities and roles of the national government. The Japan Coast Guard, the National Police Agency and the Fire and Disaster Management Agency also have defined functions for emergency response purposes (see the section on emergency preparedness for transport).

3.93. The Pharmaceutical and Food Safety Bureau of the MHLW is responsible for developing and administrating regulations applicable to radiopharmaceutical packages for land transport.

3.94. The MLIT is divided into four bureaus responsible for the transport of radioactive material: the Road Transport Bureau, the Railway Bureau, the Maritime Bureau and the Civil Aviation Bureau. Each of these bureaus regulates the respective transport mode for nuclear fuel material and radioisotopes, and, in the case of the Maritime Bureau and Civil Aviation Bureau, approves the packages as well. The Maritime Bureau of the MLIT is supported by Nippon Kaiji Kentei Kyokai (NKKK) and Shin Nihon Kentei Kyokai (SK), registered organizations that conduct stowage and container inspections on its behalf.

3.95. The Postal Services Policy Planning Bureau of the MIC administers regulations for the shipment of radioactive material by post. The JNES, an incorporated administrative agency, supports METI, MEXT and the MLIT in the confirmation of packages and the shipment method for nuclear fuel material. The Nuclear Safety Technology Centre (NUSTEC), as a registered organization, supports MEXT and the MLIT in the confirmation of packages and the transport method for radioisotopes.

3.96. The regulatory bodies or their respective technical support organizations conduct inspections of packages, the transport method, or both, as applicable. Necessary corrective actions are ordered for the land transport of nuclear material, radioisotopes and radiopharmaceuticals, sea transport, air transport and postal items. Appropriate enforcement actions are undertaken as required when safety requirements have been violated.

3.97. The Nuclear Safety Commission, established as a body within the Cabinet Office of the Government of Japan as authorized under the Law for the Atomic Energy Commission and the Nuclear Safety Commission, supervises regulatory activities by requiring, if necessary, the heads of relevant ministries to provide reports, submit material, present opinions and explanations, and provide necessary cooperation.

3.98. The Transport Regulations [1] state, inter alia, in para. 311, that "*The [regulatory body] is responsible for assuring compliance with these Regulations*". Reference [6] states, inter alia, in para. 203, that "*More than one organization may be responsible for the regulatory control of transport in a country, depending on the existing regulations, as well as the mode of transport and the type of radioactive material… Where there are several responsible authorities, close co-operation between them is essential, and there should be formal agreements covering the responsibilities of each authority. Each [regulatory body] should establish and maintain liaison with the other governmental and non-governmental organizations having related responsibilities.*" The Government of Japan has created both formal and informal mechanisms to eliminate regulatory responsibility overlap or duplication. The Government of Japan has created a legal structure to ensure that the responsibilities and functions of ministries do not conflict with one another. The Cabinet Office Legislative Bureau ensures that there is no overlap in the government's laws and ordinances.

3.99. Several ministries and agencies regulate the safe transport of radioactive material in accordance with multiple laws. In 1983 these concerned ministries and agencies established the Interagency Coordination Meeting for the Safe Transport of Radioactive Material. The functions of this body were revised in 2004 by the Outline of the Interagency Coordination Meeting for the Safe Transport of Radioactive Material. This agreement defines the membership and names NISA as the chair of the body. Other ministries and agencies may attend as required. The Interagency Coordination Meeting is convened in principle every month to exchange views on relevant regulatory and policy issues. These coordination meetings discuss proposed changes to the Transport Regulations, Japanese participation at IAEA technical meetings on the Transport Regulations and emergency response. A summary of deliberations at the monthly Interagency Coordination Meetings is recorded.

3.100. Compliance assurance arrangements as they relate to the interlinked responsibilities of the regulatory bodies concerned seem to be well organized. NISA has well established informal working arrangements with the interfacing

governmental bodies and organizations that have responsibilities in the transport of radioactive material. As a result of the legal structure in Japan, formal agreements covering the responsibilities of each authority are not required.

ORGANIZATION OF THE REGULATORY BODY

General

3.101. The regulatory body must be structured so as to be capable of discharging its responsibilities and have an organizational structure and size commensurate with the extent and nature of the facilities and activities that it will regulate. The extent of the transport programme in Japan is as follows (see also Tables 1–4):

(a) Number of airlines that transport radioactive packages: ten domestic airlines, 15 foreign airlines (including both domestic and international shipments, in 2002).
(b) For sea transport there is no registration system of ships/companies transporting radioactive material in Japan. The actual number of ships/companies, obtained through confirmation of the transport method of radioactive packages by the government, is 33 ships and 11 companies (in 2004).
(c) Special arrangements in 2004: none.

3.102. Thus industry in Japan transports approximately 707 000 packages per year. The regulatory bodies issue shipment package confirmations for these packages. About 9000 packages are subject to the additional confirmation of consignment. The relevant regulatory body issues its confirmations and fulfils its other functions related to safety of the transport of radioactive material through a number of individual organizations whose infrastructure is specified in legislative instruments. Package design approvals are issued by METI, MEXT and the MLIT for nuclear fuel material, by MEXT for radioisotopes and by the MHLW for radiopharmaceuticals. Additionally, the MLIT issues all confirmations for transport methods. Figure 4 describes the regulatory body. The areas of responsibility of the individual organizations are depicted in Table 5. Each of these organizations is established by national legislation, and the specific responsibilities are defined therein. In the case of the MLIT, outstations support the regulatory function. Legislation ensures independence from organizations that promote nuclear or radiation related technologies.

TABLE 1. ANNUAL NUMBER OF PACKAGES SUBJECT TO CONFIRMATION OF CONSIGNMENT (NUCLEAR MATERIAL AND RADIOISOTOPES)

	Type IP(F)	Type A(F)	Type B	Total
Road	106	4890	667 (533)	5663
Sea	350	2690	149 (46)	3189
Air	0	0	371 (371)	371
Total	456	7580	1187 (950)	9223

Note: The numbers in parentheses indicate the number of packages containing radioisotopes subject to confirmation of consignment. The data for road and air transport were obtained through confirmation of consignment.

TABLE 2. QUANTITY (TONNES OF URANIUM)

	Type IP(F)	Type A(F)	Type B	Total
Road	216.2	1987.0	599.9	2803.1
Sea	195.2	1132.0	548.4	1875.6
Air	0	0	0	0
Total	411.4	3119.0	1148.3	4678.7

TABLE 3. ANNUAL NUMBER OF CONFIRMATIONS OF CONSIGNMENT (IN 2004)

Type IP(F)	Type A(F)	Type B	Total
8	137	571 (535)	716

Note: The number in parentheses is the number of radioisotopes actually transported.

TABLE 4. NUMBER OF PACKAGES CONTAINING RADIOISOTOPES IN 2004

Type of package	Pharmaceutical	Research purposes	Total
Type L (excepted)	37 563	49 611	87 174
Type A	589 050	21 649	610 699
Type B	0	485	485
Total	626 613	71 745	698 358

TABLE 5. RESPONSIBILITIES OF ORGANIZATIONS FOR THE TRANSPORT OF RADIOACTIVE MATERIAL

	Land transport		Sea transport packages/ transport method	Air transport packages/ transport method
	Packages	Transport method		
Nuclear fuel material	Reactor Regulation Law Regulations for Transport of Nuclear Fuel Material Outside Plants (METI, MEXT, MLIT)	Reactor Regulation Law Regulations for Vehicle Transport of Nuclear Fuel Material, Etc. (MLIT)	Ship Safety Law (MLIT)	Civil Aeronautics Law (MLIT)
Radioisotopes	Radiation Hazards Prevention Law Regulations for the Enforcement of the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes (MEXT)	Radiation Hazards Prevention Law Regulations for Vehicle Transport of Radioisotopes (MLIT)		
Radiopharmaceuticals	Pharmaceutical Affairs Law (MHLW)			

Note: Postal items are transported under the Postal Law (MIC).

3.103. The Government of Japan has effectively reduced the potential for overlapping responsibilities through national legislation. The main functions are clearly identified, which minimizes the potential for an operator to have conflicting requirements. Additionally, the organizations are consistent in the application of regulations and there is feedback and exchange of information through the Interagency Coordination Meeting for the Safe Transport of Radioactive Material. This meeting is convened monthly and ensures that the responsible organizations meet their mandates under the national legislation.

3.104. To perform its functions, an individual organization might require technical support. This support is effectively independent of activities that are performed by an operator regulated by the responsible organization. The technical support frequently comes from public institutions and incorporated administrative agencies in order that independence can be reviewed and ensured.

3.105. Finally, the regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management that extend throughout the range of responsibilities and functions undertaken. To satisfy this requirement, through national legislation the Government of Japan requires a systematic approach to quality management for regulatory objectives to achieve safety. According to the government, individual organizations are currently reviewing their regulatory programmes to ensure that quality in management systems is ensured.

3.106. Basis: Ref. [2], in para. 4.5, requires that "*The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken.*" Although individual regulatory bodies were able to refer to activities that addressed quality management, an overall approach to a consistent system could not be identified. A consistent programme of quality management has not yet been formulated. Each regulatory body should improve its quality management programmes.

Recommendation: Each regulatory body should review, and improve if necessary, its arrangements for implementing quality management in order to ensure that all regulatory activities related to radioactive material transport are covered.

Staffing and training of the regulatory body

3.107. The regulatory body employs a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. The Government of Japan employs a body of experts whose qualifications are fixed by legislation. Although they are not reproduced in this report, the numbers of personnel employed by the regulatory body were available during the appraisal and are appropriate.

3.108. To ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body ensures that its

staff members participate in well defined training programmes. This training ensures that staff members are aware of technological developments and new safety principles and concepts. By legislation, the Government of Japan requires that the staff members of individual programmes possess specified qualifications for their jobs. The personnel of national government regulatory organizations are generally required to possess a university degree in science and/or engineering and relevant experience. Additionally, many employees have received training specific to their job functions.

3.109. Staff members of NISA are generally required to have a capability and knowledge equivalent to that of graduates possessing degrees in science or engineering. Although NISA does not have mandatory training programmes for those involved in the regulation of nuclear fuel material transport, it strongly recommends that staff members take the programmes defined by NISA in the light of their importance to NISA's continuous efforts to enhance abilities that enable comprehensive judgement through obtaining knowledge on nuclear sites and their related facilities. For those who will be posted as nuclear safety inspectors or nuclear facility inspectors, NISA mandates classroom training courses for those who have never taken any. However, the syllabus for classroom training did not identify radioactive material transport safety as a component of the training programme.

3.110. Similarly, staff members of MEXT are generally required to possess a capability and knowledge equivalent to that of science or engineering graduates. Furthermore, those engaged in the safety regulation of radioactive material transport are strongly recommended to take training programmes. In addition, those involved in the transport of radioactive material include persons with experience as nuclear safety inspectors, who are required to have knowledge about reactors and other facilities using nuclear material. Also included are experienced specialists in nuclear emergency preparedness. All these individuals are required to undertake training. Additionally, they participate in various training sponsored by the Japan Atomic Energy Agency (JAEA).

3.111. In this regard, the aforementioned people engaged in transport regulation have sufficient knowledge of radiation protection, nuclear emergency preparedness and so forth. Moreover, MEXT also employs, on a fixed term basis, professionals with knowledge of radiation protection through their involvement in nuclear research.

3.112. The MLIT's Road Transport Bureau staff members also must possess specified qualifications. Although the MLIT does not specify mandatory training programmes for those involved in safety regulation activities for road transport, the MLIT posts staff members who have experience in safety regulation activities such as vehicle inspections. In addition, they are to undertake the training given by related organizations such as the Japanese Radioisotope Association (JRIA), with a view to acquiring basic knowledge of radioactive material and its transport. They also have a system that enables them to acquire required knowledge through participation in technical meetings and on-site inspection conducted by qualified staff.

3.113. In the MLIT's Maritime Bureau, the technical/professional staff members undertake the training course for dangerous goods transport by sea, including lectures on nuclear basics and nuclear emergency preparedness. This training course is held every year and is obligatory for some staff of the District Transport Bureau. The training programme includes lectures on the latest editions of the Transport Regulations and on Japan's transport regulations, in order to update their knowledge continuously.

3.114. The MLIT's Civil Aviation Bureau has mandatory training programmes for those involved in the regulation of radioactive material air transport; furthermore, the majority of staff members must attend IATA's dangerous goods training seminar.

3.115. The MHLW, which regulates the transport of radiopharmaceuticals, requires staff to have experience in pharmaceutical regulation activities such as inspections for compliance with good manufacturing practice. Also, staff are required to attend transport training courses provided by related organizations such as the JRIA, and to participate in technical meetings.

3.116. At the MIC, staff members who regulate carriage by post (and correspondence delivery) are responsible for incorporating the requirements of the Transport Regulations into the postal requirements. Under the postal requirements that incorporate safe transport regulations [H-1] and the UPU Convention, radioactive material is allowed to be transported by post only if it is below specified limits. Although no specific training is required for engaging in radioactive material transport by post, MIC staff are trained to fulfil this function and they participate in the regular meetings of the Interagency Coordination Meeting for the Safe Transport of Radioactive Material to acquire the relevant specialized knowledge.

3.117. At the JNES, classroom and on the job training on relevant laws for the consignment and the transport method and related facilities have been given to the relevant personnel.

3.118. The NUSTEC has an education and training programme for personnel for confirmation of packages and of the transport method. This programme has been implemented as the ISO 9001:2000 system of quality management, including desk study of relevant laws, radiation measurement practice in accordance with the operating rules, administrative instructions and training rules.

3.119. Finally, NKKK, which supports the MLIT's Maritime Bureau, provides its inspectors with training on the safe transport of dangerous goods, including radioactive material. The training programme includes lectures on the latest Transport Regulations and on Japan's transport regulations. It is carried out in accordance with a quality management system certified under ISO 9001:2000.

3.120. Basis: Ref. [2] states, inter alia, in para. 4.7, that "*In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes.*"

3.121. Currently, the availability of transport safety training varies according to the individual organization. Some organizations specifically require training, others make it voluntary and some do not require training. The lack of a consistent approach to training across organizational lines does not ensure that staff members are aware of existing and changing regulatory requirements, technological developments or new safety principles and concepts.

Recommendation: All individual organizations that have not already done so should implement an appropriately defined training programme for those staff who are specifically engaged in transport safety activities.

Advisory bodies to the regulatory body

3.122. The regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. The Government of Japan uses advisers to assist in its decisions on policies, development and amendment of regulations, examination of applications for authorization, advice on packaging tests and inspection. Recom-

mendations from advisory bodies are not legally binding to the government and the regulatory organizations; however, the recommendations are carefully considered during governmental decisions. The advice is not published in many cases, but minutes of the meeting are prepared and maintained for reference in the organization.

Relations between the regulatory body and the operator

3.123. Mutual understanding and respect between the regulatory body and the operator and a frank, open and yet formal relationship are essential for conveying information. The Government of Japan conducts informal meetings for discussion of mutually important regulatory and technical issues. These meetings provide the opportunity for organizations to meet with operators to listen to concerns about operational issues, exchange opinions on regulatory decisions and request advice on compliance with the regulatory requirements.

International cooperation

3.124. The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, must establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote cooperation. The Government of Japan achieves this through bilateral information exchanges with organizations in other States, such as the US Nuclear Regulatory Commission, the Direction générale de la sûreté nucléaire et de la radioprotection of France, the Health and Safety Executive of the United Kingdom and other similar bodies. Additionally, the government works closely with international organizations such as the IAEA, IMO, ICAO and UPU. Bilateral agreements ensure that the latest technical information and state of the art technology is available to the relevant organizations.

ACTIVITIES OF THE REGULATORY BODY: AUTHORIZATION

Overview

3.125. When radioactive material is transported, the safety of transport personnel, the general public, property and the environment can be ensured

only through compliance with the accepted transport regulations. Although all packages for radioactive material are subject to regulatory requirements, a key function of the regulatory body within the field of authorization is the conduct of a systematic programme for issuing documents that approve the transport of radioactive material. Examples of these approval documents, often referred to as certificates of approval, include design approvals for packages containing fissile material, Type B(U) and Type B(M) package design approvals, design approvals for packages containing uranium hexafluoride, certain shipment approvals and special arrangement approvals.

3.126. In Japan, the regulatory body requires all packages to comply with technical standards set by ministry order, and if packages contain specific nuclear fuel material, these packages are under the strict control of a confirmation system that consists of package design approval, packaging approval and package confirmation. The regulatory body issues certificates, or approvals, based on this confirmation system. This confirmation system is described in detail below.

3.127. A review of the information provided during the TranSAS appraisal has confirmed that the responsibility for issuing approvals in Japan rests with several organizations. According to the regulatory framework in Japan these responsibilities are, in general, assigned depending on the kind of radioactive material and the mode of transport as follows:

(a) METI for approval of package designs for the land transport of nuclear fuel material for the operation of nuclear power plants and other facilities of the nuclear fuel cycle;
(b) MEXT for approval of package designs for the land transport of nuclear fuel material for the operation of nuclear test and research reactors and facilities using nuclear fuel material, and also for approval of packages containing radioisotopes for industrial and research applications;
(c) The MLIT for approval of package designs for the land transport of nuclear fuel material for the operation of commercial nuclear ship reactors (no such ships have been built), for approval of packages used for sea and air transport and for approval of shipment methods, including special arrangements for sea, air and land transport for radioisotope shipments, except for radioisotope shipments of radiopharmaceuticals.

3.128. According to the regulatory requirements in Japan, the following special provisions must be observed in relation to approval processes:

(a) Nuclear fuel material is subject to approval without exemption values for land transport;
(b) Fissile material, low dispersible material and Type C packages may not be transported by air.

3.129. On the basis of this regulatory framework and special requirements, regulatory bodies are assigned in Japan to issue approvals for:

(a) Radioactive material in special form;
(b) All packages containing fissile material;
(c) Packages containing 0.1 kg or more of uranium hexafluoride;
(d) Type B(U) and Type B(M) packages;
(e) Special arrangements;
(f) Certain shipments.

3.130. These types of approval are in compliance with the Transport Regulations. In addition to these approval processes, the following types of approval are required in Japan:

(a) Approval of all the aforementioned shipments of nuclear fuel material for land transport;
(b) Approval of shipments under exclusive use with an increased radiation level at the package surface (>2 mSv/h) or at a distance of 1 m from the package surface (>0.1 mSv/h);
(c) Approval of IP-2 and IP-3 packages described in paras 625–628 of the Transport Regulations [1];
(d) Approval of IP-2 packages described in para. 624 of the Transport Regulations [1].

3.131. Japan has a highly developed and varied nuclear industry. There are 54 commercial nuclear power reactors in Japan (as of 8 December 2005), a number of test and research reactors and several hundred facilities that use nuclear fuel material. There are several thousand additional facilities that use radioisotopes for industrial, research or other purposes, and several manufacturing facilities for radiopharmaceuticals.

3.132. Commensurate with this broad and mature nuclear industry, there are a large number of transports of radioactive material in Japan. These shipments include nuclear fuel material, defined as natural, depleted and enriched uranium, ^{233}U, thorium and plutonium, radioisotopes for industrial, research and medical purposes, and radiopharmaceuticals.

3.133. To ensure safety in transport, Japan has a robust regulatory oversight and approval system, as described above. This system includes:

(a) Approval of package design as described above. METI, MEXT and the MLIT all have an approval process for regulatory body approved package designs. Package design certificates are issued primarily by METI and MEXT. The certificates are issued for a period not exceeding three years, and may be renewed at the request of the applicant. The certificates are renewed automatically if there are no changes in regulations or package design, or are renewed with a safety review conducted if there are changes.

(b) Approval of packaging. METI, MEXT and the MLIT may also approve specific packaging by serial number. The approval is based on a review of the manufacturing of these packagings. The approval confirms that each packaging is manufactured and maintained according to the approved design, and that each packaging is registered. A certificate is also issued for approval of the packaging, which also has a period of three years (for most certificates) and may also be renewed.

(c) Confirmation of consignment. Japan has instituted a regulation whereby the consignment must be approved for fissile material and Type B packages as well as packages containing more than 0.1 kg of uranium hexafluoride. The confirmation of consignment means that the packaging of a specific design, with its contents, must be confirmed by the regulator. For confirmation of consignment, the regulator, prior to the first shipment of a specific consignment, must inspect the consignment and confirm that the packaging is manufactured according to the package design approved by the regulatory body, that the radioactive contents are within the limits of the design approval and that the package complies with operational provisions such as the surface dose rate and contamination levels. A certificate is also issued to show confirmation of consignment. After the initial consignment, the regulator may authorize additional transports or may delegate the authority to provide confirmation of future shipments of that consignment.

(d) Confirmation of shipment method. Japan has also instituted a regulation whereby the consignment, together with the conveyance, must be approved for fissile material having a total criticality safety index greater than 50, for Type B packages and for packages containing 0.1 kg or more of uranium hexafluoride. The confirmation of shipment method means that the shipment configuration must be confirmed by the regulator, by direct inspection of the shipment. This includes such

features as loading methods, stowage on the conveyance, package tie downs, dose rates and contamination level on the package surface and on other areas of the conveyance. A certificate is also issued for the confirmation of shipment method, and this certificate expires upon completion of the transport.

3.134. This comprehensive system of approvals provides additional assurance of compliance with the regulatory requirements, and has been developed in Japan based on its history of the development of the laws governing nuclear activities.

Findings

3.135. Basis: According to para. 819 of the Transport Regulations [1], "*The [regulatory body] shall be informed of the serial number of each packaging manufactured to a design approved under paras 806, 809, 812, and 816–817. The [regulatory body] should, consistent with para. 311, maintain a register of such serial numbers.*" METI, MEXT and the MLIT go beyond this and have implemented a comprehensive system that registers any packaging produced according to a packaging approval system that provides updated information on all owners of approved package designs in Japan. Furthermore, this system enables METI, MEXT and the MLIT to be informed about any change to a packaging, because the certificate holder must apply for it. In this way, the latest status of the packaging is always known and approved by the regulatory body.

Good practice: The packaging approval system established by METI and MEXT provides a comprehensive and updated register of serial numbers of approved package designs for all owners in Japan. It goes beyond the requirements of para. 819 of the Transport Regulations by providing more information. It confirms also that each manufactured packaging complies with the approved package design and documents any change to this packaging during its use so that the regulatory body is always informed about the actual status of the packaging.

3.136. Basis: A package design approval certificate shall include the information as listed under para. 833 of the Transport Regulations [1]. A review of a Japanese package design certificate during the TranSAS appraisal showed that not all of this information was included directly in the English version of the certificate. In particular, the information on the packaging and the design as required under para. 833 (j) and (k) and the reference to the

documentation that demonstrates the criticality safety of the contents according to para. 833 (m) (iii) were not included. It is noted that the Japanese certificate includes this information. Since the English certificate is accompanied by the safety analysis report for the package, the information, although not directly contained in the certificate, is indirectly available. Compliance of the English version of the certificate with para. 833 is important to support and harmonize multilateral approval procedures for international shipments.

Suggestion: METI, MEXT and the MLIT could review their certificates, including the English version, regarding the information to be included according to para. 833 of the Transport Regulations and revise them accordingly.

3.137. Basis: Para. 203 of Ref. [6] states, inter alia, that "*More than one organization may be responsible for the regulatory control of transport in a country, depending on the existing regulations, as well as the mode of transport and the type of radioactive material (e.g. mode dependent package design, fissile or non-fissile material). Usually, at least radiation protection bodies and government transport offices are involved in the control activities. Where there are several responsible authorities, close co-operation between them is essential, and there should be formal agreements covering the responsibilities of each authority. Each [regulatory body] should establish and maintain liaison with the other governmental and non-governmental organizations having related responsibilities.*" Such an interlinked responsibility was found for approval of package designs used for land transport and air transport of radioisotopes. In this case MEXT is responsible for issuing the package design certificate for land transport and the MLIT is responsible for issuing the package design certificate for air transport. In this process the MLIT's review and assessment work is focusing on the air mode specific requirements only and relies on the MEXT certificate regarding demonstration of compliance with all the other applicable requirements for the package design. Review of the MLIT certificate showed that this direct interlink between these two certificates is not included as information on the certificate itself. However, applications submitted to the MLIT for approval refer to information on the MEXT certificate.

Suggestion: The MLIT could revise its certificate in such a way that a direct reference to the MEXT certificate for the same package design is included. Alternatively, it could investigate the option of issuing a single certificate valid for both modes of transport.

ACTIVITIES OF THE REGULATORY BODY: REVIEW AND ASSESSMENT

Overview

3.138. Although it is the role of the users of the Transport Regulations, including applicants, to evaluate and ensure compliance with all relevant regulatory documents, the regulatory body also has a key responsibility: to review and assess compliance. The Transport Regulations stipulate that for the most safety significant transport activities, packages require regulatory body approval and package design assessments prior to their use. Furthermore, for certain shipments and special arrangements, not only the package designs themselves but also specific shipment provisions need pre-approval by the regulatory body.

3.139. In performing the required review and assessment work the regulatory body may rely on technical support provided by outside agencies supported by the government or by other technical experts. Since the nuclear industry in Japan is mature, and because a number of transport packages have been developed to serve the industry and there is significant experience with their use, the number of requests for new designs for regulatory body approved packages or significant design modifications is small. The total number of certificates for package designs in Japan was 63 at the time of the TranSAS appraisal, as shown in Table 6. Most of the package design certificates are issued by MEXT and METI. Validations of foreign approved designs are not given; instead, these are subject to review and approval by the regulatory bodies in Japan.

3.140. Since the number of applications for new designs or major design modifications is small, currently the review and assessment work is primarily completed by the regulatory bodies themselves. Previously, significant work was performed to update package designs to incorporate the changes in the Transport Regulations introduced in the 1996 edition. Each agency makes use of review guidance for assessors in the form of checklists that identify applicable regulatory requirements and allow for comments to be made during the review. Each item includes a space for a confirmation check, which is marked only when the regulatory conclusion has been reached. Regulations are in place for approval of special form radioactive material; however, currently no special form approvals are given.

TABLE 6. NUMBER OF PACKAGE DESIGN APPROVAL CERTIFICATES

Type	H(U)	IF	AF	B(M)	B(M)F	B(U)	B(U)F	Total
Number	1	5	17	2	22	1	15	63

3.141. For new package designs or for major design modifications that would necessitate additional technical resources, both METI and MEXT can request technical support from the JNES, which is a government supported organization that employs technical staff in the Safety Analysis and Evaluation Division. The JNES technical staff members, who have expertise in mechanical, thermal, radiation protection and nuclear engineering disciplines, are available to provide technical assessment, including independent confirmatory analyses, to MEXT and METI. The JNES provides a technical report to the regulatory body documenting the results of the review.

3.142. It is noted that the technical staff members of the JNES provide technical expertise on the entire range of nuclear fuel cycle activities and facilities. The JNES also includes a Safety Standards Division and a Safety Information Research Division. The research group may support transport activities, for example by providing technical information regarding emergent technical issues, such as the characteristics of spent fuel with very high burnup. MEXT and METI may also request additional outside review of technical information from experts such as university faculty.

3.143. The relevant regulatory body is responsible for the issuance of the package design approval. Each agency has written administrative procedures that specify who is authorized to sign for the minister with respect to approvals granted in accordance with the Transport Regulations. Applicable written documents, including certificates with supporting technical review checklists, are reviewed and stamped by the responsible staff members.

3.144. The use of package designs approved by Japan has resulted in an exceptional safety record, both domestically and around the world. There has never been an accident resulting in loss of material from a package nor injury attributable to the radioactive nature of the contents.

Findings

3.145. Basis: Para. 817 of the Transport Regulations specifies transitional arrangements for the continued use of packages approved under previous editions of the regulations. For implementation of the 1996 edition of the Transport Regulations, Japan instituted a process whereby all regulatory body approved package designs were updated on an accelerated basis. Associated with this process, applicants submitted a complete updated safety analysis report that addressed all applicable regulatory changes. This was reviewed by the regulatory bodies and provided the basis for design approval according to the 1996 edition. This systematic and comprehensive evaluation of all package designs against the newest regulatory standards in a timely manner is notable. In this way, the use of packages under the transitional arrangements was minimized.

Good practice: The process used by Japan to ensure that all packages are in compliance with the most recent edition of the Transport Regulations in a timely fashion was found to be outstanding compared with those processes observed elsewhere.

3.146. Basis: Para. 728 of the Transport Regulations specifies conditions for use in evaluating the performance of a package under the accident conditions thermal test. Specifically, para. 728 states, inter alia, that "*(a) Exposure of a specimen for a period of 30 minutes to a thermal environment which provides a heat flux at least equivalent to that of a hydrocarbon fuel/air fire in sufficiently quiescent ambient conditions to give a minimum average flame emissivity coefficient of 0.9 and an average temperature of at least 800°C, fully engulfing the specimen, with a surface absorptivity coefficient of 0.8 or that value which the package may be demonstrated to possess if exposed to the fire specified…*" Japan's regulatory framework (law, regulations, orders, notices and generic letters) includes the requirements for the thermal test for regulatory body approved packages but does not include certain details. The review of Japan's regulatory framework indicated that the specifications in para. 728 (a) of the Transport Regulations were not included. These specifications are considered to be important in demonstrating compliance with package design requirements. The test details are in the checklist used for design review; however, this information must be included in the regulatory framework to be consistent with the Transport Regulations.

Suggestion: The specifications for the thermal test according to para. 728 (a) of the Transport Regulations could be introduced into Japan's regulatory framework.

ACTIVITIES OF THE REGULATORY BODY: INSPECTION

Overview

3.147. Consistent with the Transport Regulations and supporting documents, the regulatory body performs inspection according to its own jurisdiction [C-7–C-10, C-21–C-23, D-5, E-1, E-3, I-1, I-2].

3.148. For every Type B(U) and Type B(M) package, for every package containing fissile material and for every package containing 0.1 kg or more of uranium hexafluoride, Japan's regulations require that the regulatory bodies inspect and confirm prior to consignment that the:

(a) Packaging is manufactured and maintained in accordance with the package design;
(b) Radioactive contents are within the acceptable limits of the package design;
(c) Radiation level and the contamination on the external surface of the package satisfy the technical standards.

These controls, based on documents and on the spot inspections, are systematically conducted for each transport of the above mentioned packages within the system of confirmation of consignment implemented in Japan's regulations.

3.149. For land transport, once the registration of the packaging has been obtained, the organization designated or registered by the government (the JNES for the transport of nuclear fuel material and the NUSTEC for the transport of radioisotopes) is empowered to inspect for package confirmation on behalf of the government.

3.150. In addition, for every Type B(U) and Type B(M) package, for every consignment containing fissile material with a total criticality safety index greater than 50 and for every package containing 0.1 kg or more of uranium hexafluoride, the regulatory body (the MLIT) assesses documents and conducts on-site inspections in order to control the shipment method prior to

consignment. In this way, the regulatory body's inspection includes items related to:

(a) External aspects of packages;
(b) Stowage;
(c) Radiation level of the vehicle and non-contamination;
(d) Transport indices and criticality safety indices for each vehicle;
(e) Marking, labelling and placarding, as applicable;
(f) Carrying equipment;
(g) Segregation during transport from persons and from other dangerous goods;
(h) Segregation of packages containing fissile material during transport;
(i) Certificates, instructions and transport documents;
(j) Radiation protection programme;
(k) Emergency measures;
(l) Education and training.

3.151. In the event that the regulatory body (the MLIT) has inspected a shipment method previously for land transport, the organization designated or registered by the government (the JNES for the transport of nuclear fuel material and the NUSTEC for the transport of radioisotopes) is empowered to inspect the method on behalf of the government under the condition that a registered packaging is used in the repeat transport.

3.152. Specifically for maritime transport, inspections of stowage and inspections of container packaging are performed in accordance with Articles 111 and 112 of the Regulations for the Carriage and Storage of Dangerous Goods by Ships. Therefore, stowage and segregation of packages in ships are covered by on the spot inspection of the package shipment vessel.

3.153. Some special inspections can be conducted. When a specific problem is identified or in the event of an abnormal occurrence, a special inspection is implemented if necessary.

3.154. A report is prepared for each inspection. This report describes mainly the inspection findings. Any non-compliance is reviewed and submitted to the regulation process. The report is originally issued as an internal document and is used within the regulatory body. It is kept at the department as administrative information.

3.155. An example of package inspection witnessed by the registered organization (the JNES) was given. The inspected items comprise:

(a) Contents (check by visual inspection and data sheet on the external condition of spent fuel, contents specification and water level in the cask);
(b) Criticality safety;
(c) Pressure measurement;
(d) Leaktightness;
(e) External condition;
(f) Weight;
(g) Lifting;
(h) Radiation level (the acceptance criteria are 2 mSv/h at the surface and 0.1 mSv/h at 1 m from the package);
(i) Surface contamination;
(j) Temperature measurement.

3.156. A presentation also described the JAPC's quality management system: all work for the packaging procedure at the power plant is based on the ISO 9001 quality management system. The regulatory body checks the quality management system activity by periodic audit.

3.157. A presentation by the Nuclear Fuel Transport Co. (NFT) was very instructive: the quality management system is ISO 9001 (2000 version) certified, but its use is not mandatory. In addition, the NFT has developed a radiation protection programme for sea and road transport, including the following items based on the IAEA's provisional guidance:

(a) Scope and definitions;
(b) Roles and responsibilities;
(c) Dose control measures during transport;
(d) Emergency response;
(e) Training;
(f) Quality assurance.

3.158. Concerning air transport, the TranSAS team examined an inspection report by the Civil Aviation Bureau at the MLIT offices. This inspection conducted at Narita airport was related to a Type B(U) package loaded with ^{99}Mo. The inspection report was clearly written and gave precise details of, for example, radiation measurements, control of tie down, document assessments, and marking and labelling; illustrations were also included.

FIG. 5. Package containing uranium hexafluoride.

Findings

3.159. Basis: Ref. [9] states, inter alia, in para. 462, that "*A major feature of any [regulatory body's] compliance assurance programme will be the performance of inspections of the transport operations, since these inspections can be used to monitor both the adequacy of the various regulations and the degree of compliance with those regulations by the user, as well as to produce evidence of compliance.*" Paragraph 463 states that "*Transport inspections should be carried out by the [regulatory body] or by its nominated agent. In some countries such inspections are carried out on a modal basis, by examining all types of dangerous goods, with the aviation authority inspecting air shipments, the maritime department inspecting marine shipments, etc. The [regulatory body] acts as an adviser and co-ordinator. It is important that all types and aspects of transport, consistent with the size of the radioactive material transport industry within a country, are periodically inspected.*"

3.160. The regulatory body conducts a systematic detailed inspection of every Type B(U) and Type B(M) package, every package containing fissile material and every package containing 0.1 kg or more of uranium hexafluoride prior to shipment (see Fig. 5). The inspection covers many features of the transport, such as manufacture and maintenance of the packaging, conformity of the contents of the packages, radiation level and contamination. Transport methods are also inspected for packages containing fissile material. This

inspection is applicable if the total criticality safety index exceeds 50, and it includes lifting, labelling and placarding, equipment, radiation level on the vehicle, stowage and documents.

Good practice: The systematic controls on packaging, packages and transport methods lead to a high level of safety in the transport of uranium hexafluoride, fresh fuel, spent fuel, vitrified waste and high activity sources.

3.161. Basis: Ref. [6] states, in para. 441, that "*The compliance assurance programme should also cover the design, manufacture and use of packages and the maintenance of packagings that does not require [regulatory body] approval*." Moreover, para. 442 states that "*Despite the reduced involvement of the [regulatory body] in respect of packages not requiring certification, the following subjects should be considered in a compliance assurance programme*:

— *quality assurance programme*
— *design and internal approval process*
— *manufacturing control*
— *maintenance programme…*"

3.162. In Japan, non-regulatory-body approved package designs (Type A and Type IP) for radioisotopes and radiopharmaceuticals are tested by the JRIA, whose establishment was authorized by MEXT to confirm that the design satisfies the technical standards stipulated by the law and regulations. Furthermore, MEXT conducts periodical confirmations at the JRIA based upon Article 12-10 of the Radiation Hazards Protection Law and on-site inspections on the basis of Article 43-2 of the same law. For nuclear fuel material, on the spot inspections are performed of non-regulatory-body approved package designs.

Suggestion: The regulatory body could review, and correct if necessary, its compliance programme for non-regulatory-body approved package designs to ensure that it also covers radiopharmaceuticals.

ACTIVITIES OF THE REGULATORY BODY: ENFORCEMENT

Overview

3.163. The regulatory bodies have several methods of enforcement available to them within the legislation and they have several penalty provisions open to

them to impose on an operator where a contravention has occurred. These are summarized in Table 7. The level of penalty imposed for a contravention is commensurate with the seriousness of the offence in relation to safety.

3.164. Where the non-compliance is considered to be slight, a written direction or order is given to the operator to take remedial action. For more serious violations, an order to take remedial action can be issued or interdiction of shipment can be imposed. A very serious non-compliance could result in the cancellation of the operator's business licence or another similar penalty.

3.165. Generally, the operator is notified in writing of the enforcement measures required. In the case of an administrative guidance without the need for enforcement measures, however, the operator may be notified of the guidance orally.

3.166. An order to take corrective action issued to an operator includes the date by which the corrective action must be completed. The operator is required to conduct a complete investigation of the non-compliance and to take all measures to prevent a recurrence.

3.167. The implementation of corrective action is confirmed in a report submitted by the operator and, where considered necessary, an on the spot investigation by the relevant regulatory body.

3.168. Depending on the degree of enforcement measures required, the minister (in the case of important measures) or the director general (for less important measures) of the relevant regulatory body will make the enforcement decisions. A decision to extend the due date is authorized by the same decision making person as the enforcement measures.

3.169. Inspectors are not authorized to take on the spot enforcement action and must inform the public security agency and those directly associated with the non-compliance event to promptly take the necessary enforcement measures.

3.170. The operator has a right to appeal against the enforcement decisions in accordance with the Administrative Appeal Law, which provides a legal forum to mediate between both parties.

3.171. The appraisal team was informed that there had been no recorded contravention of the legislation at the time of the appraisal.

TABLE 7. METHODS OF ENFORCEMENT AVAILABLE TO THE REGULATORY BODY

Principal legislation	Enforcement action	Relevant clauses
Reactor Regulation Law	Repeal of licence, interdiction of shipment, order of remedial action	Subparagraph 12 of para. 2 of Article 33, subpara. 13 of Article 56 and para. 4 of Article 59-2 of the Reactor Regulation Law
Radiation Hazard Prevention Law	Repeal of licence, interdiction of shipment, order of remedial action, penalties	Subparagraphs 9 and 10 of para. 1 of Article 26, para. 4 of Article 18 and Article 54 of the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes
Ship Safety Law and Regulations for the Carriage and Storage of Dangerous Goods by Ships	Detention for a major deficiency or other administrative disposition, instructions for ensuring the safety of the carriage as required, penalties	Paragraph 3 of Article 14 of the Ship Safety Law, para. 4 of Article 87, para. 2 of Article 99 and Articles 392, 394–396 and 399 of the Regulations for the Carriage and Storage of Dangerous Goods by Ships
Civil Aeronautics Law	Order of operation improvement, penalties	Article 112 of the Civil Aeronautics Law, subpara. (xiii) of para. 1 of Article 145, (i) of para. 1 of Article 157, Article 158 and Article 159 of the Civil Aeronautics Law
Pharmaceutical Affairs Law	Order of remedial action, penalties, cancellation of the licence or business suspension	Paragraph 1 of Article 72-3, para. 1 of Article 75, subpara. 6 of Article 85 and subpara. 15 of para. 1 of Article 86 of the Pharmaceutical Affairs Law

3.172. Where an incident or accident has occurred, the operator must submit a report about that incident or accident to the relevant regulatory body in accordance with the legislation. Where required, the relevant ministry will establish a council, subcommittee or study group to investigate the cause of the incident or accident and deliberate the measures to be taken to mitigate the circumstances and avoid recurrence. The results are made public.

3.173. Table 8 summarizes the basic arrangements and requirements for the operator in relation to:

(a) Non-compliance and incident reporting;
(b) Reports that the operator must submit to the relevant regulatory body;
(c) Records that the operator must retain, and for how long;
(d) Notification of shipments.

3.174. Transport regulations and the procedures for their implementation are provided in laws, Cabinet orders, ministerial orders, notices and generic letters. Approvals are required for:

(a) Laws by the Diet;
(b) Cabinet orders by the Cabinet;
(c) Ministerial orders and notices by the relevant ministers;
(d) Generic letters by the director generals, directors of the competent bureau, etc.

3.175. Specialist subcommittees and study groups are organized within the relevant ministries and government offices to develop regulations or guidelines. Some of these groups are established by legislation, such as the Radiation Council, which was formed to create harmonized technical standards for prevention of radiation hazards. Moreover, drafts of regulations for establishment, amendment or abolition are released to the public for comment for a period of one month. The public can access the relevant documents via the Internet. Where a particular public comment is not considered suitable for inclusion, the person making the submission is contacted with an explanation as to why the suggestion was rejected.

3.176. The scope of application and the features of proposed regulations are clearly specified. The transitional arrangements in the event of major amendments are defined as necessary. An example of this occurred when supplementary provisions for transitional arrangements were created following the incorporation of the 1996 edition of the Transport Regulations into national legislation, whereby approved packaging under the existing regulations had been exempt from the new requirements until 31 December 2003.

3.177. Individual licence conditions are provided for by ministerial orders, whereas detailed requirements are defined by notices or generic letters. These are incorporated into legislation through:

TABLE 8. ARRANGEMENTS AND REQUIREMENTS FOR THE OPERATOR IN RELATION TO INCIDENT REPORTING, RECORDS AND NOTIFICATION OF SHIPMENTS

Relevant legislation	Relevant area			
	Non-compliance and incident reporting	Reports that the operator must submit to the relevant regulatory body	Records that the operator must retain, and for how long	Notification of shipments
Reactor Regulation Law	Reports of emergency measures, occurrence of unusual leakage, hazard, etc.	Report as required by the regulatory bodies in accordance with the legislation	Items to be recorded and the preservation time period are specified in each business law	For packages above the specified level, the record must be reported to the regulatory bodies
Radiation Hazard Prevention Law	Emergency measures are taken and reported to the regulatory bodies in accordance with the legislation, etc.	The responsible party is requested to submit a report to the extent that the regulatory body requires in accordance with the legislation	Items to be recorded and the period to retain them are specified in the legislation, etc.	Records of shipment are defined to be preserved and the regulatory bodies collect the reports as needed
Ship Safety Law	Non-compliance: if there is any possibility of degradation in performance of the packaging, the owner of the packaging is required to report to the Director of the Inspection and Measure Division in accordance with the generic letter Incident: the operator is obliged to report promptly to the maritime authority in accordance with the regulations	Reporting forms for incident are specified	Nothing other than logbooks of vessels	For packages above the specified level, the carriage must be reported to the Japan Coast Guard

TABLE 8. ARRANGEMENTS AND REQUIREMENTS FOR THE OPERATOR IN RELATION TO INCIDENT REPORTING, RECORDS AND NOTIFICATION OF SHIPMENTS (cont.)

Relevant legislation	Relevant area			
	Non-compliance and incident reporting	Reports that the operator must submit to the relevant regulatory body	Records that the operator must retain, and for how long	Notification of shipments
Civil Aeronautics Law	The operator is obligated to report in accordance with the generic letter	Reports as required in accordance with the legislation	Items to be recorded and the period to retain them are specified in the legislation	For packages above the specified level, the record must be reported to the regulatory bodies
Pharmaceutical Affairs Law	Reports of emergency measures, occurrence of unusual leakage, hazard, etc., in accordance with the legislation	Report as required by the regulatory bodies in accordance with the legislation	Items to be recorded and the period to retain them are specified in the legislation	Records of shipment are defined to be preserved and the regulatory bodies collect the reports as needed

(a) Paragraph 2 of Article 59-2 of the Reactor Regulation Law for land transport under METI, MEXT and the MLIT;
(b) Paragraph 2 of Article 18 of the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes for land transport under MEXT and the MLIT;
(c) Articles 87 and 99 of the Regulations for the Carriage and Storage of Dangerous Goods by Ships for sea transport under the MLIT;
(d) Subparagraph 2 (c)–(e) of Article 194 of the Regulations for the Enforcement of Civil Aeronautics for air transport under the MLIT.

3.178. The regulatory body has also developed a series of non-mandatory guidance documents, usually issued as generic letters, relating to particular aspects of transport. These guidance documents are not legally binding. Drafts of legislation and regulations are distributed to relevant internal departments, reviewed by councils and study groups as required, and examined by the responsible internal officers.

3.179. The enforcement provisions in place would appear to be sufficient to meet the requirements of para. 311 of the Transport Regulations. The fact that no breach of Japan's requirements has been recorded would indicate that appropriate compliance has been achieved.

EMERGENCY PREPAREDNESS FOR TRANSPORT

Infrastructure for emergency preparedness

3.180. The Government of Japan's regulatory organizations responsible for the transport of radioactive material are separated into two groups:

(a) Regulatory bodies for radioactive material transport;
(b) Organizations for initial emergency preparedness and response.

3.181. The organizations with jurisdiction over regulations mainly for emergency response are the:

(a) Japan Coast Guard;
(b) National Police Agency;
(c) Fire and Disaster Management Agency.

Emergency response to unusual events in transport (general)

3.182. Where an unusual event occurs during the transport of radioactive material, the operator must notify the relevant government offices immediately and take emergency measures for safety as necessary — such as deployment of watchpersons, enforcement of no-entry measures, decontamination, relief measures — in accordance with the laws and regulations (Article 64 of the Reactor Regulation Law and Article 33 of the Radiation Hazard Prevention Law).

3.183. The relevant government agencies — METI, MEXT, the MLIT, the MHLW, the National Police Agency, the Fire and Disaster Management Agency and the Japan Coast Guard, which are the responsible bodies for the safe transport of radioactive material — have authority to order the operator to take the necessary measures for disaster prevention. Furthermore, with a view to enabling prompt response as a team in any emergency, they have an official agreement to:

(a) Communicate with and notify each other;
(b) Call conferences to coordinate emergency measures;
(c) Allocate duties of related government offices;
(d) Register emergency response specialists;
(e) Define the measures to be taken at the site of the accident.

3.184. The agreement provides that, if an unusual event occurs, a conference to discuss the countermeasures to be taken is to be held in order to initiate the necessary measures in accordance with the agreement (Fig. 6). The objective of the conference is to promote coordination among the ministries concerned and to assign the different responsibilities depending on the material/modes of transport.

Emergency response to a nuclear disaster

3.185. In Japan, various measures are to be taken, in accordance with the basic response scheme mentioned above, if extraordinary circumstances occur during the transport of radioactive material. Furthermore, if a nuclear disaster occurs resulting in radioactive material release or radiation emission above a specified level from a package, measures are also taken in accordance with the system shown in Fig. 7.

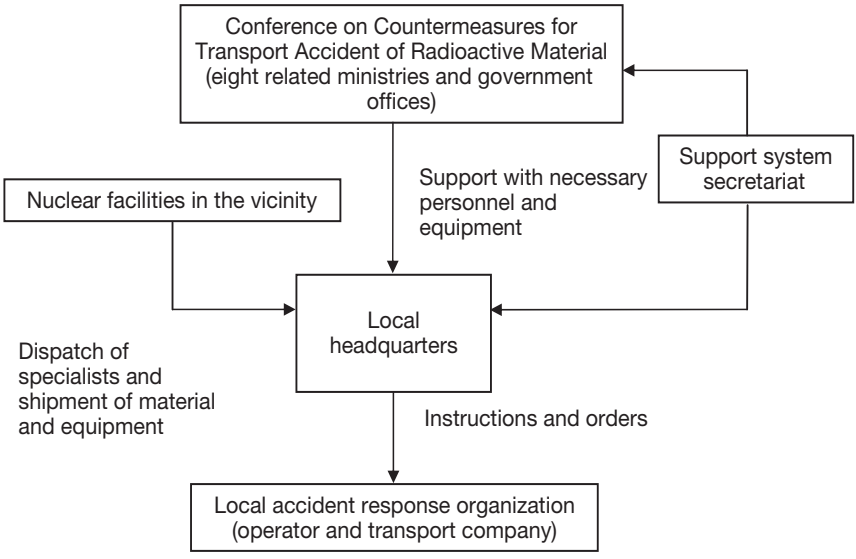

FIG. 6. Emergency preparedness system for unusual events during transport.

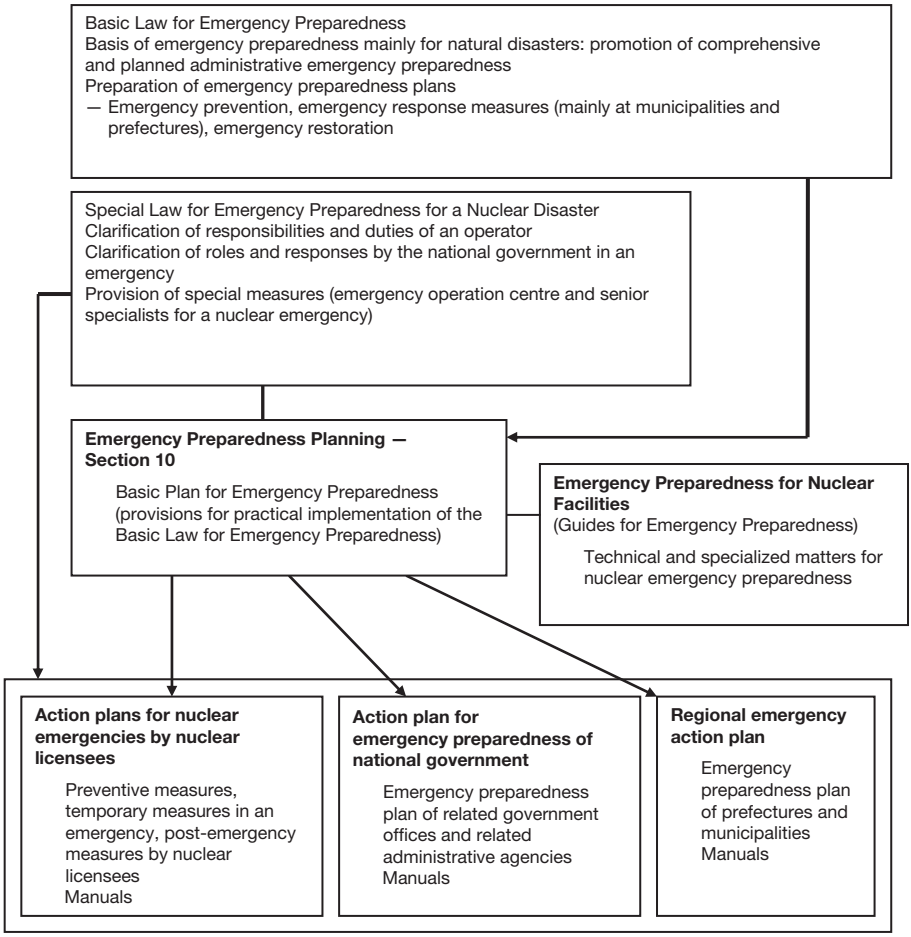

FIG. 7. Emergency preparedness system for a nuclear disaster.

3.186. The fundamental framework for emergency response systems is defined by the following laws:

(a) Basic Law for Emergency Preparedness: general law for emergencies to arrange and promote disaster prevention administration in a comprehensive and systematic manner.

(b) Special Law for Emergency Preparedness for a Nuclear Disaster: special law for nuclear operators to take all possible measures to prevent nuclear disasters, to prevent their escalation and to conduct rehabilitation from them.

(c) Emergency Preparedness Planning — Section 10, Emergency Preparedness for a Nuclear Disaster.
(d) Emergency Preparedness for Nuclear Facilities (Guides for Emergency Preparedness): Decision by the Nuclear Safety Commission.

3.187. Additional national legislation referring to emergency response and preparedness includes:

(a) Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors;
(b) Regulations for Actions in Emergencies Concerning Transport of Nuclear Fuel Material Outside Plants;
(c) Law Concerning Prevention of Radiation Hazards Due to Radioisotopes;
(d) Regulations for Actions in Emergencies Concerning Transport of Radioisotopes Outside Plants;
(e) Regulations for the Carriage and Storage of Dangerous Goods by Ships;
(f) Civil Aeronautics Law;
(g) Pharmaceutical Affairs Law;
(h) Operational Plan for Disaster Prevention;
(i) Outline of the Interagency Coordination Meeting for the Safe Transport of Radioactive Material;
(j) Provisions for Safety Measures Against a Transport Accident of Radioactive Material;
(k) Dispatch of Expert for Transport Accident of Radioactive Material.

3.188. There are various emergency preparedness plans:

(a) Action plans for emergency preparedness of designated administrative organizations (prepared by MEXT, METI, the MLIT, Japan Coast Guard, Fire and Disaster Management Agency, National Police Agency, Defence Agency);
(b) Regional emergency preparedness plans (prepared by each related prefecture and related municipality);
(c) Action plans for nuclear emergencies by nuclear licensees (prepared by each nuclear operator);
(d) Action plans for emergency preparedness of designated public institutions (prepared by the Japan Red Cross, JAEA, utilities).

3.189. There are various emergency preparedness manuals:

(a) Manuals for actual concrete matters for emergency preparedness by the national government, local governments, nuclear operators;
(b) Manuals of related government offices (METI, MEXT, the MLIT and related ministries).

Emergency preparedness at the international, national and local levels

3.190. Japan ratified the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency in 2003. A Basic Plan for Emergency Preparedness has been developed by the government and a Manual for Nuclear Emergency Preparedness has been prepared for coordination by relevant ministries. An Action Plan for Emergency Preparedness has also been prepared. Regional emergency plans are prepared at a local level. Japan also contributes to the IAEA Illicit Trafficking Database Office Programme and the EVTRAM (Events in the Transport of Radioactive Material) database as required.

3.191. A comprehensive training programme by the relevant ministries is well established and includes training for senior specialists in nuclear emergency management (METI), training on emergency response (MEXT) and information on nuclear disasters (JAEA). The training covers the various modes, multiple scenarios and drills. Exercises and training are also undertaken by operators, and the ministries participate in these as required. Resources such as specialists, budgets for drills and exercises, equipment for emergency response centres, communication networks and off-site centres are available.

3.192. MNF: The emergency response arrangements reported by MNF cover internal training, a detailed emergency response manual specific for pre-shipment protocols and the arrangements to be adopted in the event of uranium hexafluoride transport accidents. These include:

(a) Dispatch of nominated relevant staff.
(b) Education and training.
(c) Contacts with relevant organizations such as the:
    (i) Police;
    (ii) Fire services;
    (iii) Mayor;

(iv) Governor of the prefecture;
(v) All the ministries concerned.

(d) Established communications systems.

3.193. These arrangements appear to be satisfactory. As of December 2005, more than 5000 packages of uranium hexafluoride and 16 000 fuel assemblies have been transported by land and by domestic and international sea transport, and no transport incidents have been reported.

3.194. JAPC: The NFT transports spent fuel on behalf of utilities, including the JAPC. Training on spent fuel shipments includes lectures on emergency planning for marine transport and details on emergency communication protocols. This training is undertaken annually. An emergency communication drill is also undertaken each year in conjunction with the JAPC. Procedures for sea transport include:

(a) The implementation of a radiation protection programme;
(b) Measures to prevent disasters resulting from theft of the package;
(c) Detailed security measures;
(d) The establishment of a communications system for normal transport;
(e) Emergency conditions for each transport;
(f) Dispatch of experts to the ship in the event of an emergency;
(g) Suitable on the job communication training for emergency response.

3.195. The company takes stringent steps in managing the design, licensing, handling and transport of packages, and these processes and others are based on the ISO 9001 quality management system.

3.196. Japan Airlines International Co. Ltd (JAL): The contents of the emergency response action plan included in the dangerous goods manual are satisfactory for the volumes of Class 7 goods imported and exported. Moreover, the procedure for handling damaged cargo, the notification of incident requirements, the training programme and the presence of a comprehensive emergency kit with radiation monitoring equipment (see Fig. 8) is consistent with that of other international airlines.

Findings

3.197. Japan has well established emergency preparedness and response capabilities covering all modes of transport. The arrangements meet the requirements as specified in Appendix V of the BSS and comply with the

Transport Regulations (1996 edition, as amended 2003), which set out the following requirements concerning emergency response, in paras 308 and 309:

> "*308. In the event of accidents or incidents during the transport of radioactive material, emergency provisions, as established by relevant national and/or international organizations, shall be observed to protect persons, property and the environment…*
>
> *309. Emergency procedures shall take into account the formation of other dangerous substances that may result from the reaction between the contents of a consignment and the environment in the event of an accident.*"

3.198. In addition, the arrangements address the recommendations and guidelines described in Ref. [5].

3.199. Basis: Para. 2.6 of Ref. [2] states, inter alia, that the practical goal of emergency preparedness is "*To ensure that arrangements are in place for a timely, managed, controlled, co-ordinated and effective response at the scene, and at the local, regional, national and international level, to any nuclear or radiological emergency.*" The JAEA provides technical support to the national and local government, the police and fire services, licence holders, the public and the media. It is a designated public organization conforming to the Basic Law for Emergency Preparedness and the Basic Plan for Disaster

FIG. 8. JAL emergency response kit.

Countermeasures. The NEAT Centre of the JAEA has been established in the Ibaraki and Fukui prefectures (Fig. 9). The appraisal team visited the centre at Ibaraki.

3.200. The NEAT Centre provides a comprehensive range of technical support activities to an off-site centre when an emergency occurs. Specifically, the NEAT Centre gives the Joint Council of Nuclear Disaster Countermeasures, which meets at the off-site centre, technical advice and information, provides for the dispatch of specialists as required, supplies emergency equipment, a command vehicle, a decontamination vehicle, a whole body counting vehicle and a body surface contamination monitoring vehicle and provides material and radiation measurement instrument support (Fig. 10).

3.201. An off-site centre is a nuclear emergency response operations facility and is used as a base in the event of a nuclear emergency to ensure a harmonized and coordinated response. The appraisal team visited the off-site centre at Ibaraki (located beside the NEAT Centre). Twenty-two off-site centres have been established throughout Japan. The typical equipment provided at the off-site centre include graphical display systems, video conference facilities, an emergency response support system, a prediction system for environmental emergency dose information, displays of radiation monitoring data, a meteorological information system, communication equipment (including satellite communication systems), personal protective equipment and radiological surveillance equipment.

3.202. In 2004 and 2005 the relevant ministries conducted drills involving the transport of nuclear material. In addition, drills to cover accident scenarios involving nuclear fuel material are also carried out on a regular basis (approximately 13 times per year). It was planned to hold further drills relating to transport accidents, although on a less frequent basis than other nuclear fuel material related accident scenarios. It should be noted that the off-site centre did not cover accidents involving the transport of radioisotopes, but was capable of doing so. Such accidents would be handled at the accident site by the operator and the relevant responsible body.

Good practice: The comprehensive equipment and systems available at the Ibaraki Off-site Centre and at the NEAT Centre could be considered to be a role model for such facilities.

FIG. 9. The NEAT Centre.

FIG. 10. Emergency vehicles at the Ibaraki Nuclear Off-site Centre.

MARITIME TRANSPORT

Overview

3.203. The review of the maritime operations addressed specifically the operational rules and practices of the MLIT concerning the carriage of radioactive material into and out of the ports of Japan.

3.204. In 2004 there were 154 confirmations of maritime shipments of radioactive material in Japan. There were 63 Type B, 77 Type A, nine Type IP-2 and five Type IP-1 shipments.

Nuclear fuel related material

3.205. New fuel: Natural uranium hexafluoride from which low enriched uranium fuel is produced for power generation. Uranium hexafluoride enriched outside Japan and uranium dioxide powder converted from enriched uranium hexafluoride are transported from abroad to Japan by foreign flagged ocean going container ships. This nuclear fuel material is processed into new fuel assemblies in processing plants in Japan, from which the fuel assemblies are transported to the nuclear power plants either by land or by sea in Japanese flagged ships covering exclusive use only.

3.206. Spent fuel: Spent fuel is transported by Japanese irradiated nuclear fuel (INF) ships from nuclear power plants to the Tokai reprocessing plant or the Rokkasho-mura reprocessing plant.

3.207. Radioactive waste: Low level radioactive waste for burial is transported by dedicated Japanese ships from the nuclear power plants to the low level radioactive waste disposal facility in Rokkasho-mura. High level radioactive waste, in the form of vitrified residue canisters, resulting from reprocessing in France, is transported to Japan by United Kingdom flagged INF Class 3 ships.

Radioisotopes

3.208. Cobalt-60 and ^{137}Cs are the radioisotopes that are transported by ocean going container ships from Seattle or Oakland, USA, or other places. There were 30 confirmations of this method of shipment in 2004.

Safety achievement

3.209. A high level of safety has been achieved. One of the key elements for achieving this high level of safety is the strict application of Japan's regulations, which include the relevant requirements of the INF Code and those of the IMDG Code and other international regulations for the safe carriage of radioactive material by sea.

Laws, regulations and procedures for the carriage of radioactive material in Japan

3.210. The maritime transport of radioactive material is regulated by the:

(a) Ship Safety Law;
(b) Regulations for the Carriage and Storage of Dangerous Goods by Ships;
(c) Ministerial Order Concerning Certification Under the International Convention for the Safety of Life at Sea;
(d) Regulations for Issuance of a Ship Management Certificate;
(e) Notice on the Details of Standards Concerning the Carriage of Radioactive Material by Ships;
(f) Notice on the Carriage of Dangerous Goods by Ships;
(g) Generic Letter on Amendments to the Generic Letter on Paperwork of Shipment Vessel for Irradiated Nuclear Fuel, KAISA No. 520, dated 19 September 1995.

SOLAS Convention

3.211. The provisions of chapter VII of the SOLAS Convention are relevant to the carriage of dangerous goods. Parts A and D of that chapter are respectively applicable to the carriage of dangerous goods in packaged form and to special requirements for the carriage of packaged INF, plutonium and high level radioactive waste on board ships.

3.212. Japan is a contracting party to the SOLAS Convention, and since the convention's entry into force on 25 May 1980 the provisions of the convention, including all amendments, have been incorporated into Japan's national legislation and implemented.

3.213. In addition, all IMO instruments, which have mandatory status under the umbrella of the SOLAS Convention, have been given that status in Japan

under the relevant Japanese legislation in accordance with the Constitution of Japan.

International Maritime Dangerous Goods Code (IMDG Code)

3.214. Basis: Under the umbrella of the SOLAS Convention, the IMDG Code, which was recommendatory since 1965, attained mandatory status under IMO Resolution MSC.123(75) and entered into force on 1 January 2004. Future biennial amendments to the mandatory IMDG Code are intended to enter into force on 1 January of an even numbered year; however, to facilitate the multimodal transport of dangerous goods, Member States are encouraged to apply them a year earlier, from the 1 January of an odd numbered year.

Good practice: Japan has incorporated the provisions of IMO Resolution MSC.123(75) into the national legislation (Regulations for the Carriage and Storage of Dangerous Goods by Ships) and made them effective from 1 January 2005, prior to their formal entry under the provisions of the SOLAS Convention.

3.215. Basis: The SOLAS Convention defines the IMDG Code as the International Maritime Dangerous Goods Code adopted by the Maritime Safety Committee of the organization by Resolution MSC.122(75), as may be amended by the organization, provided that such amendments are adopted, brought into force and take effect in accordance with the provisions of Article VIII of the SOLAS Convention, concerning the amendment procedures applicable to the annex other than chapter 1. However, there is no general updating provision in the national legislation of Japan whereby future amendments to the IMDG Code would enter into force on 1 January of an even numbered year and the voluntary application of those amendments would take place a year earlier, on 1 January of an odd numbered year. This requires a new ministerial order to be issued each time amendments to the IMDG Code need to be implemented in Japan.

Suggestion: Although the efforts of Japan in producing the amendments to the IMDG Code in the Japanese language well in time are commendable, there could be benefit from a general updating provision in the national legislation whereby future amendments to the IMDG Code would enter into force without the need for a ministerial order being issued each time those amendments need to be implemented in Japan. Implementation of this suggestion would lessen the administrative burden on the relevant agencies.

Quality and compliance assurance

3.216. The IMDG Code requires quality and compliance assurance programmes to be in place. In this context, Japan has in place the following:

(a) The regulatory body confirms the quality control system of the manufacturer of the packaging;
(b) Periodical self-inspection of the packaging is required and the results of the inspection are submitted to the regulatory body for record keeping purposes;
(c) Confirmation of packages and of shipping method is required;
(d) Inspection of stowage or inspection of container packing, as appropriate, is required;
(e) The quality control manual for the radiation protection programme during the transport of radioactive material should be kept on board the ship;
(f) For ships to which the International Safety Management (ISM) Code is not applicable, a voluntary certification system is in place to ensure that the relevant provisions of the ISM Code are met. The ISM Code of the IMO provides an international standard for the safe management and operation of ships and pollution prevention.

3.217. Additional quality and compliance assurance is carried out by the MLIT, NKKK and SK during inspection of the stowage and container packing of radioactive shipments.

IMDG Code training

3.218. Basis: Training of mariners serving on board ships is covered by the Convention on Standards for Training, Certification and Watchkeeping (STCW Convention) 1995, as amended. For shoreside personnel engaged in the transport of dangerous goods by sea, training in the handling of radioactive material is recommended under the IMDG Code as enumerated in its chapter 1.3. Japan is a signatory to the mandatory STCW Convention, as amended; thus the relevant provisions in it are obligatory.

3.219. Japan conducts regular lectures on the safe transport of radioactive material for all personnel associated with the transport of radioactive material, thus ensuring that they have the requisite knowledge to fulfil their functions and thus meeting the training provisions of the IMDG Code. Such lectures, conducted under the auspices of the MLIT, are intended not only for those

involved in the carriage of radioactive material by sea but also for those associated with other radioactive industries (workers at nuclear power plants, nuclear fuel fabrication facilities, researchers, dealers in measuring devices containing radioactive isotopes), and are held four times a year in Japan. The topics of the lectures include basic knowledge of nuclear power, technical standards provided in transport regulations, radiation protection and emergency response procedures.

3.220. Training and education of shoreside workers is covered by the Industrial Safety and Health Law (law number 57, dated 8 June 1972), under which the employer is required to provide education and training to all new and reassigned workers, including shoreside workers; this law stipulates that the education and training needs to be commensurate with the nature of the job those workers are intended to perform. Vital parts of such education and training are health and safety at work. In addition, representatives of the MHLW carry out on-site inspections to verify that workers are adequately and properly trained in the jobs they are expected to carry out.

Good practice: Japan requires mandatory education and training of all shoreside workers commensurate with their duties and responsibilities, including those associated with the handling of all dangerous goods.

Emergency response

3.221. Japan requires the ship owner to develop a handling manual, describing the measures to be taken in emergencies, to be carried on board ships carrying dangerous goods. This manual encompasses the salient features of the recommendatory Medical First Aid Guide for Use in Accidents Involving Dangerous Goods (MFA Guide) and Emergency Response Procedures for Ships Carrying Dangerous Goods (EmS Guide). The manual includes topics on how to deal with cargoes spilt and lost at sea, how to deal with fire in dangerous goods and the measures to be undertaken when in contact with dangerous goods. This manual is approved by the regulatory body for the carriage of Type B packages, fissile radioactive material or radioactive material exceeding certain limits.

International Code for the Safe Carriage of Packaged Irradiated Nuclear Fuel, Plutonium and High-level Radioactive Waste on Board Ships (INF Code)

3.222. Basis: The INF Code, under the umbrella of the SOLAS Convention, attained mandatory status and entered into force on 1 January 2001. The code has been incorporated in the national legislation of Japan and has been imple-

mented. In addition, a generic letter (Generic Letter KAISA No. 520 by the Director General of the Maritime Bureau) requires all ships carrying INF cargo, regardless of flag State, to meet higher standards for structure and equipment than those provided in the INF Code, taking into consideration the congestion of routes and the deep ocean spaces in the seas adjacent to Japan.

3.223. There has been no Japanese flagged ship, engaged in international trade, subject to the provisions of the INF Code, but there are ships of other flags to which the certificate, in accordance with the generic letter, has been issued and is likely to be issued in the future. The provisions of the INF Code apply to all ships, regardless of the date of construction and size, engaged in the carriage of INF cargo.

Good practice: Japan requires all INF ships to fully comply with the relevant provisions of the SOLAS Convention and, in addition, to meet higher standards for structure and equipment than those provided in the INF Code.

Inspections and surveys

3.224. The INF Code requires that before the carriage of INF cargo takes place, a ship intended to carry it shall be subject to an initial survey, which shall include a complete examination of its structure, equipment fittings, arrangements and material in so far as the ship is covered by that code. In order to ensure compliance with that provision of the INF Code, Japan examines in detail the drawings of structures, material, equipment and shielding at the design stage, and the ship is inspected during construction in accordance with the INF Code and the generic letter (Generic Letter KAISA No. 520 by the Director General of the Maritime Bureau). The examination is conducted in accordance with the views of the Technical Advisory Committee of the Director General of the Maritime Bureau, which includes academic experts. In accordance with the Japanese Ship Safety Law, Domestic Regulation, violation of the requirements imposes penalties on the ship owner that include detention of the ship, or a fine, or a combination of both. Subsequent inspections and surveys are carried out by Japan at appropriate times in accordance with the relevant provisions of the SOLAS Convention that have been incorporated into the national regulations.

Radiation protection

3.225. Depending upon the characteristics of the INF cargo to be carried and upon the design of the ship, the INF Code requires that additional arrange-

ments or equipment for radiological protection, if necessary, be provided to the satisfaction of the administration. Japan's regulations require all INF cargo ships to be provided with equipment for measuring dose equivalent rates at the accommodation space, the hull shell plates, etc. The dose equivalent rates are checked by inspection of stowage in order to confirm that the rates do not exceed certain levels stipulated in the national legislation. In accordance with the Japanese Ship Safety Law, Domestic Regulation, violation of the requirements imposes penalties on the ship owner, which include detention of the ship, or a fine, or a combination of both.

Management and training

3.226. Management and training for a ship carrying INF cargo need to satisfy the government. In accordance with Japan's national regulations, all ships engaged in international voyages are required to meet the provisions of the ISM Code. For other ships, there is a system to certify, on a voluntary basis, that they meet the provisions of the ISM Code. SOLAS Regulation IX/4 requires that a Safety Management Certificate be issued to every ship by the government or an organization recognized by the government. The government or organization recognized by it shall, before issuing the Safety Management Certificate, verify that the company and its shipboard management operate in accordance with the approved safety management system. The Government of Japan and Nippon Kaiji Kyokai (NK) have issued certificates to 563 ships, including the Hinoura Maru and the Rokuei Maru. These two ships are dedicated to the carriage of INF on domestic routes only.

3.227. Basis: Existing ships carrying INF cargo, plying on domestic routes, have undergone certification under the INF Code. The requirements are the development of a radiation protection programme, including training, education and quality assurance, and keeping the documents on board ship. In accordance with the Ship Safety Law, the regulatory body confirms the contents of the programme, which is prepared by the ship's owner, and its implementation, by means of routine and random inspections of entries in the ship's logbook.

Good practice: Japan requires the provisions of the ISM Code to be complied with by existing ships carrying INF cargo plying domestic routes.

Shipboard emergency plan

3.228. Every ship carrying INF cargo is required, in accordance with the provisions of the INF Code, to carry on board a shipboard emergency plan; if a ship is required to have a shipboard emergency plan by other international instruments, the various plans may be combined into a single plan entitled the Shipboard Marine Emergency Plan. The regulatory body is required to examine such a plan and the crew's familiarity with it at routine and random inspections. Japan requires all ships to carry an emergency preparedness and response guide, which is prepared on the basis of the relevant IMO Resolutions A.852(20) and A.854(20). This plan will be available on ships carrying INF cargo.

Notification of incidents involving INF cargo

3.229. The INF Code requires notification in the event of an incident involving INF cargo, and the reporting requirements of Regulation VII/6 (reporting of incidents involving dangerous goods) of the SOLAS Convention apply both to the loss or likely loss of INF cargo overboard and to any incident involving a release or probable release of INF cargo, whatever the reason for such a loss or release, including that of securing the safety of the ship or saving life at sea. Such a report also needs to be made in the event of damage, failure or breakdown of a ship carrying INF cargo that affects the safety of the ship, including collision, grounding, fire, explosion, structural failure, flooding and cargo shifting, or that results in the impairment of the safety of navigation, including the failure or breakdown of the steering gear, propulsion system, electricity generating system and essential shipborne navigational aids. Relevant to the aforementioned regulation, Japan's national regulations, promulgated by means of Article 5-10 of the Regulations for the Carriage and Storage of Dangerous Goods by Ships, require that whenever there is a release of dangerous goods, including radioactive material that is transported by methods other than loading in bulk, or a possibility of such a release, the master is required to notify the maritime safety agencies immediately. Generic Letter HOKEIBO No. 62 of 19 November 1987, issued by the Japan Coast Guard and directed at Japanese ship owners and masters of Japanese registered ships and ships in Japanese waters, specifies what is to be done in the event of an accident. The notification by the master shall be based upon general principles and guidelines developed by the IMO as enumerated in IMO Resolution A.851(20) on general principles for ship reporting systems and ship reporting requirements, including guidelines for reporting incidents involving dangerous goods, harmful substances and/or marine pollutants. In addition, the Ship

Safety Law of Japan requires such a report to be made in the event of damage, failure or breakdown of a ship carrying INF cargo that affects the safety of the ship, including, but not limited to, collision, grounding, fire, explosion, structural failure, flooding and cargo shifting, or results in the impairment of the safety of navigation, including the failure or breakdown of the steering gear, propulsion system, electricity generating system and essential shipborne navigational aids.

Code of Safe Practice for Solid Bulk Cargoes (BC Code), 2004

3.230. The recommendatory Code of Safe Practice for Solid Bulk Cargoes (BC Code), 2004, was adopted in December 2004 by means of Resolution MSC.193(79), and the provisions of that version of the BC Code have not, as yet, been incorporated into the national legislation of Japan. However, most provisions of the 1994 BC Code (as amended) concerning dangerous goods have been incorporated into the Regulations for the Carriage and Storage of Dangerous Goods by Ships, and many of the requirements concerning 'material which may liquefy' and 'material hazardous only in bulk (MHB)' of the 1994 BC Code have been incorporated into the Regulations for the Carriage of Special Cargo by Ships. For carriage of United Nations substance identification numbers UN 2912 and UN 2913 in bulk, the relevant provisions of the Transport Regulations [1] (para. 523) have been incorporated into the national legislation.

Port State control on operational requirements

3.231. Under SOLAS Convention Regulation XI-1/4, ships when in a port of another contracting government are subject to control by officers duly authorized by such a government concerning operational requirements in respect of the safety of ships. In that context, procedures relating to the port State control prescribed in SOLAS Convention Regulation I/19 shall apply. In accordance with Article 120-3 of the Mariners' Law of 1947, revised in 2005, provisions governing port State control on operational requirements, as enumerated in SOLAS Convention Regulation XI-I/4, have been given effect and, in addition, are implemented, by means of a generic letter, in accordance with the provisions of IMO Resolution A.787(19) on Procedures for Port State Control, as amended by IMO Resolution A.882(21). In 2004, the MLIT inspected 4896 ships, of which 23 had docked at Japanese ports on 57 occasions and had carried or were carrying radioactive material at some stage and which required confirmation of the transport methods by the MLIT. In 2004, none of the ships inspected that carried INF cargo had any deficiencies due to the nature of their radioactive cargo, reflecting the good safety record and status of

those ships. Also, the National Maritime Research Institute is developing an assessment system to evaluate the effects of incidents and accidents involving radioactive material on human life and the environment.

Transport tracking system

3.232. Basis: Regulation V-19 of the SOLAS Convention (carriage requirements for shipborne navigational systems and equipment) sets out the navigational equipment to be carried on board ships, according to ship type. In 2000, the IMO adopted a new requirement (as part of a revised new chapter V) for ships to carry automatic identification systems (AISs) capable of providing information about the ship to other ships and to coastal authorities automatically. This regulation requires AISs to be fitted, not later than 1 July 2008, aboard cargo ships of 500 gross tonnage and upwards not engaged on international voyages.

3.233. At present, the only tracking of packages required in Japan is to confirm consignments at the time of their shipment and for security purposes. However, the NFT has installed and put into operation a maritime navigation information system that can keep track of ship locations, displaying them on monitors in the NFT, that utilizes satellite communication. The tracking data are constantly displayed, both during voyage and port handling work. In addition, in an emergency the tracking data are also displayed in the emergency response room of the NFT. The maritime navigation information system includes package monitoring data, such as radiation and temperature information, and video data from in and around the vessel.

Good practice: The state of the art vessel tracking system established by the NFT is commendable. It was installed on vessels engaged in domestic voyages prior to the required date of 1 July 2008.

AIR TRANSPORT

Overview

3.234. Japan is a contracting party to the Convention on International Civil Aviation. The MLIT has overall responsibility for implementing and enforcing the air transport legislation according to the National Government Organization Law and the Law for the Ministry of Land, Infrastructure and Transport. This responsibility is delegated to the Civil Aviation Bureau of the MLIT.

FIG. 11. Loading an aircraft at Narita airport.

3.235. The area of competence of the Civil Aviation Bureau concerns the air carrier, transport authorizations, handling, storage at the airport, flight conditions, separation of radioactive material from other dangerous goods and stowage on board the aircraft (Fig. 11).

3.236. The Civil Aviation Bureau monitors the operation of aircraft in accordance with the Civil Aeronautics Law, the Regulations for the Enforcement of Civil Aeronautics and the Notice of Standards for Transport of Radioactive Material by Air, which provide the legal framework for the transport of radioactive material by air in Japan.

3.237. The Generic Letter on Education and Training Relating to Transport of Dangerous Goods is a guide relating to the education and training of those engaged in the transport of dangerous goods by air.

3.238. As mentioned in the general provisions of this generic letter, any air carrier or aircraft operator who makes or intends to make its employees conduct transport (including acceptance on trust, ground handling, storage, loading, unloading, delivery of cargo, in addition to transport by aircraft) of dangerous goods shall develop an education and training plan and obtain the

approval of the Director of Flight Standards, Engineering Department, Civil Aviation Bureau.

3.239. According to Japan's regulations, Type C packages, low dispersible material and packages containing fissile material shall not be transported by air. These requirements are more restrictive than the ICAO Technical Instructions [12]. In fact, Type L and Type A packages loaded with radionuclides with short half-lives are mainly transported. The transport by air of explosive radioactive material is also forbidden. In accordance with the Convention on Civil Aviation, the MLIT has notified the ICAO to include these restrictions in the State deviations of the ICAO Technical Instructions [12].

3.240. The TranSAS appraisal team visited the JAL facilities at Narita airport. The operator provided adequate information and procedures in its operations manual. The procedures are written sufficiently to enable the flight crew to carry out its related responsibilities. In addition, there are instructions for use in the event of emergencies involving radioactive material.

3.241. The operator inspects packages and containers containing radioactive material in accordance with the acceptance procedures. The acceptance checklist for radioactive material complies with the requirements of the ICAO Technical Instructions [12]. Moreover, packages and overpacks containing radioactive material are loaded and stowed on an aircraft in accordance with the provisions of the ICAO Technical Instructions. Specific separation and segregation requirements are included in the dangerous goods loading procedure (Fig. 12).

Findings

3.242. Basis: The Transport Regulations state, in para. 306, that:

> "*Radioactive material shall be segregated sufficiently from workers and from members of the public. The following values for dose shall be used for the purpose of calculating segregation distances or radiation levels:*
> *(a) for workers in regulatory occupied working areas a dose of 5 mSv in a year;*
> *(b) for member of the public, in areas where the public has regular access, a dose of 1 mSv in a year to the critical group, with account taken of exposures expected to be delivered by all other relevant sources and practices under control.*"

FIG. 12. Dangerous goods sign at Narita airport.

3.243. Specific actions are provided within the generic letter [G-4] in order to prevent exposure of workers. The annual exposure dose of aircraft and ground crew shall be calculated and the results shall be written up and reported to the Director of Flight Standards, Engineering Department, Civil Aviation Bureau of the MLIT, in order to verify that the radiation exposure of those who are engaged in the transport of radioactive material is not more than 1 mSv in a year.

Good practice: The regulatory body for air transport (the MLIT) verifies that the exposure limit for workers is not more than 1 mSv in a year, which is the same as the dose limit to members of the public.

ROAD AND RAIL TRANSPORT

Overview

3.244. The transport of radioactive material by land is only carried out using road vehicles; trains are not used. The two reasons for this are that:

(a) There are no railway tracks laid up to nuclear power plants or in their vicinity, and the construction of railway tracks up to plants is not economically viable;
(b) Ships are used to transport large sized packages or a large quantity of packages, since nuclear power plants in Japan are located in coastal areas.

3.245. The MLIT has jurisdiction over the vehicles and transport methods for the transport of nuclear fuel material and radioisotopes. Covering the transport of radioactive material by road and rail are:

(a) The Regulations for Vehicle Transport of Nuclear Fuel Material, Etc., and the Notice on the Details of the Regulations for Vehicle Transport of Nuclear Fuel Material, Etc.;
(b) The Regulations for Vehicle Transport of Radioisotopes and the Notice on the Details of the Regulations for Vehicle Transport of Radioisotopes.

3.246. The requirements for land transport of radiopharmaceuticals are detailed in the Regulations for Manufacturing and Handling of Radiopharmaceuticals and the Notice on the Standards for Transport of Radioactive Material. Only Type A and Type L packages for radiopharmaceutical purposes are transported by road, although these regulations also cover the transport of Type IP packages. Approximately 600 000 Type A and 38 000 Type L packages are transported by road each year.

3.247. In the above mentioned regulations, the Transport Regulations requirements applicable to road and rail transport are clearly taken into account, especially concerning:

(a) The radiation level on the vehicle;
(b) The sums of criticality safety indices and of transport indices;
(c) Marking, labelling and placarding, as applicable;
(d) Stowage;
(e) Carrying equipment;
(f) Segregation during the transport from persons and from other dangerous goods;
(g) Segregation of packages containing fissile material during transport;
(h) Certificates, instructions and transport documents;
(i) The radiation protection programme;

(j) Emergency measures;
(k) Education and training.

3.248. The loading methods are well specified in the regulations [C-9, D-5] and in the notice [I-3]. Loading and unloading of radioactive packages are carried out so that the safety of the packages is not impaired. Radioactive packages are loaded so that their safety is not impaired due to moving, overturning or falling during the shipment. In addition, radioactive material is loaded only in areas with access restricted to authorized personnel.

3.249. The radiation protection programme is defined in the notices [C-10, D-6, I-3] and includes:

(a) The transport implementation system;
(b) The methods of radiation dose assessment;
(c) The surface contamination of radioactive material packages;
(d) The segregation and protection of radioactive material packages;
(e) The response in an emergency;
(f) The training for an emergency;
(g) The quality assurance of the radiation protection programme;
(h) Other matters that the MLIT or the MHLW deem necessary.

3.250. These notices require that the transport operators implement education and training programmes to cover:

(a) The handling methods for packages;
(b) Training corresponding to duties;
(c) Safety exercises assuming a radiation hazard;
(d) Other matters that the MLIT or the MHLW deem necessary.

3.251. Packages are often transported by several vehicles. As these vehicles use ordinary public roads, a convoy system comprising several vehicles, including escort vehicles, is adopted upon instruction of the Prefectural Public Safety Commission.

3.252. There are no stipulations for convoy transport in the Regulations for Vehicle Transport of Nuclear Fuel Material/Radioisotopes. However, it is presupposed that the person responsible for the shipment of particular nuclear fuel material as prescribed in Article 17 of the regulations [C-9] shall ride in an escort vehicle. Restrictions on the number of vehicles in a fleet, vehicle arrangements and the distance between vehicles are prescribed in the bylaws of

the National Police Agency, and they are used when giving instructions to applicants who file a report of intended shipment.

3.253. An example of convoy transport was given by MNF relating to its shipment of fresh fuel from Tokai-mura, where pressurized water reactor fresh fuel assemblies are manufactured. A dedicated truck with shock absorber and thermal protection was used to transport MFC-1 packages loaded with fuel assemblies. The truck was part of an escorted convoy, which reduced the probability of an accident, all the more as weather conditions are taken into account prior to the confirmation of consignment. All these measures contribute to a high level of safety of the radioactive material transport. It is important to emphasize that more than 16 600 fuel assemblies and 5200 uranium hexafluoride packages have been transported by MNF without any accident.

Findings

3.254. Basis: The Transport Regulations [1] state, inter alia, in para. 572, that the radiation level shall not exceed "*(c) 0.1 mSv/h at any point 2 m from the vertical planes represented by the outer lateral surfaces of the vehicle, or, if the load is transported in an open vehicle, at any point 2 m from the vertical planes projected from the outer edges of the vehicle.*"

Good practice: In order to reduce the dose to members of the public, Japan's transport regulations limit the maximum dose rate to 0.1 mSv/h at 1 m from a vehicle, instead of 2 m as set out in the Transport Regulations.

3.255. Basis: The Transport Regulations [1] state that the requirements of paras 564–568 (stowage, accumulation of packages, segregation of packages containing fissile material) are applicable during transport and storage in transit. In practice, there is no storage in transit for the road transport of radioactive material in Japan. Still, storage in transit is not explicitly defined within Japan's transport regulations for vehicles. For the road transport of nuclear fuel material, regulations already exist that prohibit storage in transit. These regulations do not necessarily apply to radioisotopes or radiopharmaceuticals.

Suggestion: Japan's transport regulations could explicitly incorporate provisions making stowage and segregation applicable not only to transport but also to transit operations for radioisotopes and radiopharmaceuticals.

3.256. Basis: The Transport Regulations [1] state, inter alia, in para. 310, that "*Quality assurance programmes based on international, national or other standards acceptable to the [regulatory body] shall be established and implemented for the design, manufacture, testing, documentation, use, maintenance and inspection of all special form radioactive material, low dispersible material and packages and for transport and in-transit storage operations to ensure compliance with the relevant provisions of these Regulations. Certification that the design specification has been fully implemented shall be available to the [regulatory body].*" Japan's transport regulations include requirements for quality assurance, for example within the notices [C-10] Article 11.2, [D-6] Article 11.2 and [I-3] Article 26. Still, these provisions are related to the quality assurance of the radiation protection programme, while para. 310 of the Transport Regulations [1] goes further.

Suggestion: Japan's transport regulations could more comprehensively incorporate provisions making quality assurance programmes mandatory for the transport of radioactive material.

4. GENERAL CONCLUSIONS

4.1. The TranSAS appraisal team completed a comprehensive appraisal of the implementation of the Transport Regulations in Japan. The cooperation of the authorities in Japan, and of all those who participated in the discussions, was excellent and contributed to the success of the appraisal.

4.2. The comprehensive legal framework, with responsibilities identified in considerable detail and with clear lines of authority to minimize overlap of responsibilities, provides a sound basis for the implementation of the Transport Regulations.

4.3. Generally, the Transport Regulations are implemented in accordance with IAEA requirements. Some areas for possible improvement have been identified. These areas relate mainly to reduction of regulations, quality management systems, training, compliance assurance and lessening the administrative burden for incorporating amendments to the IMDG Code.

4.4. The findings include a considerable number of good practices, in particular in the area of maritime transport.

5. ACKNOWLEDGEMENTS

5.1. The Government of Japan provided valuable support to the TranSAS appraisal. The advance information considerably assisted the team members in preparing for the appraisal. Key staff of the facilities visited were most helpful throughout the team's tour by providing insight into facility operation and the implementation of transport safety measures.

5.2. The members of the TranSAS appraisal team wish to express their appreciation to the numerous officials of Japan's regulatory authorities who contributed to the success of the appraisal. The team was privileged to meet with many professionals who freely offered their expertise, and appreciates the time they spent patiently answering numerous questions.

5.3. All the personnel with whom the TranSAS appraisal team had contact with were extremely helpful. Their cooperation was instrumental in maintaining a professional and productive atmosphere throughout the course of the appraisal and contributed to its success. The exchange of information regarding transport safety practice was most beneficial to all parties.

Appendix I

SYNOPSIS OF FINDINGS

LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Good practice: The clear and comprehensive definitions of the terms 'vehicle shipment' and 'simple shipment' in the Regulations for Transport of Nuclear Fuel Material Outside Plants (Article 1 (i), (ii)) apply to any kind of transport. In accordance with the purpose of regulation in general — to protect the public, workers and the environment from the hazards of radiation — it is clear that any transport without exemption is under the jurisdiction and surveillance of the responsible regulatory body.

Good practice: The public is enabled to be informed directly, so that people and non-governmental institutions can play an active role in the process of submitting opinions relating to the establishment, amendment or abrogation of regulations.

Good practice: Any user of nuclear source material has to report to the responsible minister immediately if hazards arise when using nuclear source material or if the exposure of personnel engaged in radiation work has exceeded or is feared to exceed prescribed limits. Also, the operator of shipments of radioactive material (transport in general) is obliged to report to the competent minister not only in the event of specific incidents such as theft or unusual leakage but any event that is or is likely to be a hazard to people.

Suggestion: A smaller number of regulations could be useful for daily work in regulatory and operational practice, so it is suggested that the regulatory body could try to reduce or merge them to the extent possible.

ORGANIZATION OF THE REGULATORY BODY

Recommendation: Each regulatory body should review, and improve if necessary, its arrangements for implementing quality management in order to ensure that all regulatory activities related to radioactive material transport are covered.

Recommendation: All individual organizations that have not already done so should implement an appropriately defined training programme for those staff who are specifically engaged in transport safety activities.

ACTIVITIES OF THE REGULATORY BODY

Good practice: The packaging approval system established by METI and MEXT provides a comprehensive and updated register of serial numbers of approved package designs for all owners in Japan. It goes beyond the requirements of para. 819 of the Transport Regulations by providing more information. It confirms also that each manufactured packaging complies with the approved package design and documents any change to this packaging during its use so that the regulatory body is always informed about the actual status of the packaging.

Suggestion: METI, MEXT and the MLIT could review their certificates, including the English version, regarding the information to be included according to para. 833 of the Transport Regulations and revise them accordingly.

Suggestion: The MLIT could revise its certificate in such a way that a direct reference to the MEXT certificate for the same package design is included. Alternatively, it could investigate the option of issuing a single certificate valid for both modes of transport.

Good practice: The process used by Japan to ensure that all packages are in compliance with the most recent edition of the Transport Regulations in a timely fashion was found to be outstanding compared with those processes observed elsewhere.

Suggestion: The specifications for the thermal test according to para. 728 (a) of the Transport Regulations could be introduced into Japan's regulatory framework.

Good practice: The systematic controls on packaging, packages and transport methods lead to a high level of safety in the transport of uranium hexafluoride, fresh fuel, spent fuel, vitrified waste and high activity sources.

Suggestion: The regulatory body could review, and correct if necessary, its compliance programme for non-regulatory-body approved package designs to ensure that it also covers radiopharmaceuticals.

EMERGENCY PREPAREDNESS FOR TRANSPORT

Good practice: The comprehensive equipment and systems available at the Ibaraki Off-site Centre and at the NEAT Centre could be considered to be a role model for such facilities.

MARITIME TRANSPORT

Good practice: Japan has incorporated the provisions of IMO Resolution MSC.123(75) into the national legislation (Regulations for the Carriage and Storage of Dangerous Goods by Ships) and made them effective from 1 January 2005, prior to their formal entry under the provisions of the SOLAS Convention.

Suggestion: Although the efforts of Japan in producing the amendments to the IMDG Code in the Japanese language well in time are commendable, there could be benefit from a general updating provision in the national legislation whereby future amendments to the IMDG Code would enter into force without the need for a ministerial order being issued each time those amendments need to be implemented in Japan. Implementation of this suggestion would lessen the administrative burden on the relevant agencies.

Good practice: Japan requires mandatory education and training of all shoreside workers commensurate with their duties and responsibilities, including those associated with the handling of all dangerous goods.

Good practice: Japan requires all INF ships to fully comply with the relevant provisions of the SOLAS Convention and, in addition, to meet higher standards for structure and equipment than those provided in the INF Code.

Good practice: Japan requires the provisions of the ISM Code to be complied with by existing ships carrying INF cargo plying domestic routes.

Good practice: The state of the art vessel tracking system established by the NFT is commendable. It was installed on vessels engaged in domestic voyages prior to the required date of 1 July 2008.

AIR TRANSPORT

Good practice: The regulatory body for air transport (the MLIT) verifies that the exposure limit for workers is not more than 1 mSv in a year, which is the same as the dose limit to members of the public.

ROAD AND RAIL TRANSPORT

Good practice: In order to reduce the dose to members of the public, Japan's transport regulations limit the maximum dose rate to 0.1 mSv/h at 1 m from a vehicle, instead of 2 m as set out in the Transport Regulations.

Suggestion: Japan's transport regulations could explicitly incorporate provisions making stowage and segregation applicable not only to transport but also to transit operations for radioisotopes and radiopharmaceuticals.

Suggestion: Japan's transport regulations could more comprehensively incorporate provisions making quality assurance programmes mandatory for the transport of radioactive material.

Appendix II

ABBREVIATIONS

BSS	International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INF	irradiated nuclear fuel
ISM	International Safety Management
JAPC	Japan Atomic Power Company
JAEA	Japan Atomic Energy Agency
JNES	Japan Nuclear Energy Safety Organization
JRIA	Japanese Radioisotope Association
METI	Ministry of Economy, Trade and Industry
MEXT	Ministry of Education, Culture, Sports, Science and Technology
MHLW	Ministry of Health, Labour and Welfare
MIC	Ministry of Internal Affairs and Communications
MLIT	Ministry of Land, Infrastructure and Transport
MNF	Mitsubishi Nuclear Fuel Co. Ltd
NEAT Centre	Nuclear Emergency Assistance and Training Centre
NFT	Nuclear Fuel Transport Co.
NISA	Nuclear and Industrial Safety Agency
NK	Nippon Kaiji Kyokai
NKKK	Nippon Kaiji Kentei Kyokai
NUSTEC	Nuclear Safety Technology Centre
SK	Shin Nihon Kentei Kyokai

Appendix III

TRANSAS TEAM FOR JAPAN

FIG. 13. Japan TranSAS team. Front row (left to right): W. Huck, L. Grainger, I. Rahim, C. Young, M. Wangler, S. Cohen-Unger, N. Osgood. Back row (left to right): F. Chen, K. Dessent, J. Duffy, F. Nitsche, E. Jacob, R. Clark.

F. CHEN — team member

Mr. Chen serves as the technical authority of the Panama Canal Authority on the chemical and physical properties of dangerous cargo, especially radioactive cargo, on board transiting vessels and for contingency planning. He also serves as the lead inspector of vessels with dangerous cargo on board, including those with radioactive cargo. Mr. Chen is a marine safety specialist who works closely with the Canal Operations Captain in a number of marine safety areas, such as risk analysis and verification of vessel compliance with the applicable international maritime regulations. He holds a PhD degree in chemistry from the University of California at Santa Barbara.

Since 1987, as the senior expert in the maritime transport of radioactive material for the Panama Canal, he has lectured in Panama and in other countries and has participated in IMO and IAEA conferences dealing with the maritime transport of radioactive material. Mr. Chen was the alternative point of contact for the TranSAS appraisal for Panama and was a team member on the TranSAS appraisal for France.

R. CLARK — Team member

Mr. Clark is a radioactive material specialist with the Dangerous Goods Directorate of the Canadian Department of Transport, which is one of the two regulatory bodies in Canada for the transport of radioactive material. He holds a Bachelor's degree in public administration from Carleton University, Ottawa.

Mr. Clark has worked at the Department of Transport for over 17 years and has provided advice on regulations covering the conveyance of dangerous goods. Since 2001 he has been responsible for the development of departmental policy and regulations on the appraisal of radioactive material. He was a team member of the TranSAS appraisal for France and Chairman of an expert panel session at the 2003 IAEA International Conference on the Safety of Transport of Radioactive Material, attended by nearly 500 participants from 73 Member States. He is a member of the IAEA Transport Safety Standards Committee.

S. COHEN-UNGER — Technical writer

Ms. Cohen-Unger has been a consultant to the IAEA since 1993, working as a writer/editor on missions, at conferences and at the IAEA Headquarters on reports, guidelines and proceedings mainly for the Department of Safety and Security and the Department of Safeguards. Also, she teaches courses on organizational writing to IAEA staff. She holds a Bachelor of Arts degree and a diploma of education in English language and literature from the University of Sydney and a Master of Philosophy degree in applied linguistics from the University of Newcastle upon Tyne. Although this is her first TranSAS appraisal, it is her twelfth IAEA mission as team technical writer/editor.

K. DESSENT — Team member

Mr. Dessent holds a Bachelor of Science (physics) degree and a graduate diploma in occupational hygiene from Deakin University, Victoria, Australia. He has a certificate IV in government (statutory investigation and enforcement).

From 1983 to 1999 he worked with the Radiation Protection Unit of the Department of Human Services, Victoria. His work involved inspection of radiation apparatus, including transport containers, providing advice to stakeholders on radiation protection legislation and on transport requirements and lecturing on radiation effects, legislation and transport issues.

Since 1999 he has been working in the Standards Development and Committee Support Section of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). His work includes providing technical secretariat support to the Nuclear Safety Committee and to the National Uniformity Implementation Panel (Radiation Control) and preparing radiation codes of practice and standards, including the draft Code of Practice for the Safe Transport of Radioactive Material 2001 (which incorporates the 1996 edition of the Transport Regulations) and the Code of Practice on the Security of Radioactive Sources (to be published).

He has participated in various working groups, including the Transport Regulatory Bodies Working Group, the Transport Working Group (ARPANSA internal) and the Security of Sources Working Group.

J. DUFFY — Team member

Mr. Duffy is currently a senior scientific officer/inspector and manager of the Industrial Section within the Regulatory Services Division of the Radiological Protection Institute of Ireland. He joined the Institute in 1987 and has a Master of Applied Science degree (applied physics) from University College Dublin. He is a chartered scientist, a chartered physicist, a member of the Institute of Physics (UK/Irish Branch) and a member of the Society for Radiological Protection (UK).

Since 2001 Mr. Duffy has acted as a consultant to the IAEA in the preparation of training modules for radiation protection and has lectured to regulators and customs authorities on IAEA regional training courses in Turkey (2002) and Lebanon (2005). He participated in an IAEA Peer Review Mission in Cyprus (2003) to assess the existing infrastructure for radiation protection and the safety of radiation sources. He served as a team member on the TranSAS appraisal for France. He is currently the chair of the IAEA Transport Safety Standards Committee.

He has extensive experience in inspection, enforcement and incident investigation involving licensees using and transporting radioactive sources in industry, medicine and research.

L. GRAINGER — Maritime consultant

Mr. Grainger joined the United Kingdom Ministry of Transport in 1956. In 1979 he became Head of the Dangerous Goods Transport Policy Branch, also directly responsible for such transport by road and rail and in ports.

He led UK delegations to the United Nations Economic and Social Council Committee of Experts on the Transport of Dangerous Goods in Geneva from 1979 to 1996 and became Chairman of that committee in 1988. He then represented the committee in related discussions at the IAEA, International Labour Organization, United Nations Environment Programme, IMO, ICAO, Organisation for Economic Co-operation and Development and European Union (EU). He led UK delegations to the RID/ADR Joint Meeting of the United Nations Economic Commission for Europe (UNECE) in Geneva/ Intergovernmental Organisation for International Carriage by Rail in Bern, concerned with European road and rail transport over the same period, 1979–1996, and was Chairman of the UNECE's WP.15 Group of Experts from 1982 to 1987. From 1990, he led UK delegations in EU negotiations to agree on directives introducing the RID/ADR rules into UK domestic transport and establishing the Dangerous Goods Safety Adviser regime, and to define and contain a role for the European Commission in the subject.

He has been a member of the UK Maritime Administration's Standing Advisory Committee on the Carriage of Dangerous Goods in Ships and of the UK Civil Aviation Authority's Dangerous Goods By Air Advisory Group for over 25 years. He was promoted to Senior Principal Officer in the UK Department of Transport in 1991, appointed OBE in 1995 and took early retirement from government in 1996.

He became a transport consultant/specialist writer, as well as a cargo safety adviser to the Bahamas Maritime Authority. He represented the Bahamas in 1996–2003 at all levels within the committee process of the IMO, in particular at the DSC Subcommittee and in its expert E&T Group. He has also been a consultant with the IAEA. He has written many articles for the specialist trade press and has attended, spoken at and chaired numerous seminars and conferences. He has advised the Hazardous Material Advisory Council (now the DGAC) in Washington, DC, and the International Council of Intermediate

Bulk Container Associations in the UK. He has worked with both UPS Parcels and Coca Cola in Atlanta, GA, and with IATA, on the interface between the ICAO Technical Instructions and the UNECE road rules (ADR) in Europe. He has undertaken various commissions for Pira International in the UK. He continues to attend the regular meetings of the multimodal coordinating Working Party on the Transport of Dangerous Goods held by the UK Department for Transport (DfT), and to advise the DfT ad hoc.

Since 2001 he has advised the IMO, acting as a special envoy to Panama, lecturing at the Academy in Trieste, assisting in the preparation of successive official amendments to the mandatory IMDG Code, and taking part in technical cooperation training missions to Thailand, Indonesia, Eritrea, Egypt, Poland, Vietnam, Kenya and Malta. He was the IMO nominee during the IAEA's TranSAS appraisals for the UK, Panama and France.

W. HUCK — Legal consultant

Mr. Huck is professor for international business law, transport law and law in the field of technology at the University of Applied Sciences in Braunschweig/ Wolfenbüttel. After finishing his studies at the law faculty of the University of Bonn, he received his PhD in law with a thesis on the transport of radioactive material. Mr. Huck worked in 1990–1991 as an attorney and in 1991–1997 as Head of the Division for Law and Strategy in the Department of Nuclear Fuel Cycle, Transport and Storage of Radioactive Material in the Federal Office for Radiation Protection, responsible for the legal issues of this department.

Since 1997 Mr. Huck has been active in lecturing, research and also in the management of the university. He has been Dean of the Faculty of Law since 2000 and was also vice-president for Research and Technology from 2000 to 2004. Since 2001 he has been organizing — in cooperation with Tongji University, Shanghai, and Siemens Transportation Systems — annual law symposia in China and Germany for a better understanding of German–Chinese economic relationships, paying due regard to cultural aspects. Since 2002 Mr. Huck has worked for the IAEA as a legal consultant. He was a member of the TranSAS appraisals for Brazil, Panama and France.

Furthermore, Mr. Huck has been a member of the Board of the Chinese Centre in Hanover since 2003. In 2004 he founded the IBL Institute for International Business and Law (see www.law-and-business.com for information) and in 2005, with a university colleague, he founded the E-Government-Academy

(www.egovernment-academy.de) as a special branch of the Institute of E-Business in Wolfenbüttel.

E. JACOB — Team member

Mr. Jacob is the Coordinator of the Transport Unit at the Subdirectorate for Nuclear Fuel Cycle Installations, Sources and Transports (SD1) of the Direction générale de la sûreté nucléaire et de la radioprotection. His main tasks include issuing package design approvals, organizing the transport inspection programme, preparing national and international regulations for the transport of radioactive material, cooperating with the Ministry of Transport, training inspectors and helping users to interpret the regulations.

Mr. Jacob is a Member of the Interministerial Commission for the Transport of Dangerous Goods (CITMD). As Senior Transport Inspector he has performed 70 inspections in the field. At the Commissariat à l'énergie atomique in 1994–1998, he did research work involving numerical simulation of nuclear experiments and complete modelling of the electrothermal gun.

His international experience includes participation on the IAEA Review Panel for Transport in Bonn, November 2003, at the IAEA Technical Meeting to Develop Guidance in Support of the Application of the Revised Transport Regulations in Vienna, May 2002, and in the Seventh Symposium on Electromagnetic Launch Technology, San Diego, California, April 1994.

He holds postgraduate qualifications in engineering from the Grande Ecole Supélec (electric energy and information sciences) and a general certification of education (mathematics and technique).

F. NITSCHE — Team member

Mr. Nitsche is a physicist. Since 1998 he has been Head of the Transport Section of the Federal Office for Radiation Protection (BfS), the regulatory body for package design and shipment approvals in Germany.

Mr. Nitsche received his PhD degree in 1977 from the Technical University of Dresden. He has more than 25 years of professional experience in the area of the safe transport of radioactive material. He worked until 1983 for the National Board for Radiation Protection and Nuclear Safety, Berlin, on matters relating to the licensing of package designs and shipments of radioactive material and on safety related research. From 1984 to 1991 he

conducted research and development for the industry in the area of transport systems for fresh fuel and spent fuel, in radioactive waste and in safety assessments for final repositories. He has been with the BfS since 1991 and is responsible for the assessment and approval of package designs and shipments. Mr. Nitsche conducts regulatory work and research that stem from national and international transport regulations.

Mr. Nitsche has been involved in the development of the Transport Regulations since 1979 and has been a member of various advisory and working groups at the IAEA, IMO and ICAO.

N. OSGOOD — Team member

Ms. Osgood is Senior Project Manager for the Spent Fuel Project Office in the United States Nuclear Regulatory Commission (NRC). Ms. Osgood received a Bachelor of Science degree in biology and mathematics from the University of Richmond and studied nuclear engineering at the University of Maryland. She is certified in health physics by the American Board of Health Physics. She has over 30 years of experience in the field of radiation protection and has worked in the transport field since 1988. Her work at the NRC includes project management for the review of designs for regulatory body approved transport packages. She also serves as the NRC representative to the American National Standards Institute N14 Committee for Standards for the Packaging and Transportation of Radioactive Material. Ms. Osgood has participated in the development and review of the international radioactive material transport regulations over the past 15 years.

I. RAHIM — IMO representative

I. Rahim is a Senior Technical Officer in the Maritime Safety Division of the IMO. He started a sea-going career more than 30 years ago as a cadet and moved up to the rank of captain. He holds a Master Mariner's certificate of competency and an honours degree in transport technology. He has lectured at the Branch Campus of the World Maritime University in Malaysia on ports, shipping and maritime related matters, and developed new shipping courses before joining a major company that had its Asia and Pacific regional office in Kuala Lumpur, where he was involved in ports and shipping projects. At this company, he undertook numerous studies involving port privatizations, port management, and efficiency and productivity enhancements. He was Project Director when he resigned from the company. Before joining the IMO Secretariat in London, he undertook a number of consultancy assignments for

the IMO and the Economic and Social Commission for Asia and the Pacific (ESCAP) relating to the facilitation of maritime traffic and multimodal transport. At the IMO, in addition to being the Senior Technical Officer responsible for matters relating to the IMDG Code, he is secretary to the Editorial and Technical Group and to the Subcommittee on Dangerous Goods, Solid Cargoes and Containers. He represented the IMO as a team member on the TranSAS appraisals for the UK and Panama.

M. WANGLER — Appraisal coordinator

Mr. Wangler is Head of the IAEA's Safety of Transport of Radioactive Materials Unit in the Division of Radiation, Transport and Waste Safety. He is the Coordinator for the IAEA's Transport Safety Standards Committee. He has two degrees in physics: a Bachelor of Arts degree from the University of Dallas and a Master of Science degree from the University of Massachusetts. His professional career of 33 years spans various fields — health physics, radiological protection and engineering — including 25 years of work dealing with the safety of the transport of radioactive material.

Mr. Wangler has been active in the field of transport safety for the US Department of Transportation, the US Department of Energy and the US Nuclear Regulatory Commission. In addition, he has worked in the licensing and inspection of medical and radiation equipment, in developing standards for equipment that uses sources of ionizing radiation and in radiological assessments for environmental purposes. He has coauthored technical publications on transport safety and is on the editorial board of Packaging, Transport, Storage and Security of Radioactive Material. Mr. Wangler is a Member of the Health Physics Society in the USA.

C. YOUNG — Team leader

Mr. Young is an internationally recognized expert in safety standards for the transport of radioactive material. He has worked at the Department for Transport of the United Kingdom since 1978, and since 1996 has been Head of the Radioactive Material Transport Division and Transport Radiological Adviser to the Secretary of State for Transport. He served as Chairman of the Transport Safety Standards Committee of the IAEA from 1999 to 2004 and is currently Chairman of the Radioactive Material Working Group of the IMO and also chairs the Radioactive Material Transport Study Group. He previously held the position of research engineer in the field of heat transfer at the UK Atomic Energy Authority, Windscale. Mr. Young has a Bachelor of

Science degree in mechanical engineering from the University of Leeds (1968). He is a member of the Institution of Mechanical Engineers and is a chartered engineer.

Appendix IV

MISSION SCHEDULE AND TASKS PERFORMED

Sunday, 4 December 2005: Team briefing, Akasaka Prince Hotel.

Monday, 5 December 2005: Entrance meeting, Akasaka Prince Hotel. Reception hosted by the NSC.

Tuesday, 6 December 2005: Entrance meeting, Akasaka Prince Hotel. Interviews, start drafting of the report. Liaison meeting.

Wednesday, 7 December 2005: Interviews, drafting of the report, visit to MEXT. Courtesy call to the Senior Deputy Director General, Science and Technology Policy Bureau, K. Shimomura. Visit/interviews at the Ibaraki Nuclear Off-site Centre and the NEAT Centre, Tokai area.

Thursday, 8 December 2005: Visit/interviews at MNF. Visit/interview at the JAPC.

Friday, 9 December 2005: Drafting of the report/interviews at the MLIT. Courtesy call to the Deputy Director General for Engineering Affairs, Maritime Bureau, S. Ito. Liaison meeting.

Saturday, 10 December 2005: Drafting of the report.

Sunday, 11 December 2005: Free.

Monday, 12 December 2005: Drafting of the report/interviews at METI. Visit/interviews at Narita airport.

Tuesday, 13 December 2005: Interviews at METI. Courtesy call to the Director General of NISA, K. Hirose. Drafting of the report. Liaison meeting.

Wednesday, 14 December 2005: Drafting of the report/interviews at METI. Visit/interviews at the NFT. Liaison meeting. Dinner hosted by NISA.

Thursday, 15 December 2005: Drafting of the report/interviews. Complete the draft report and prepare the exit briefing. Liaison meeting.

Friday, 16 December 2005: Exit meeting, Akasaka Prince Hotel. End of appraisal.

Appendix V

PARTICIPANTS IN MEETINGS AND DISCUSSIONS

Japanese participants in the TranSAS meetings (5, 6 and 16 December 2005).

Affiliation	Position	Name
Secretariat of the Nuclear Safety Commission	Secretary General	S. Katayama
Nuclear Safety Commission, Radiation Protection and Accident Management Division	Director	H. Kuniyoshi
Nuclear Safety Commission, Radiation Protection and Accident Management Division	Deputy Director	Y. Shigeiri
Nuclear Safety Commission, Radiation Protection and Accident Management Division	Deputy Director	N. Takeda
Nuclear Safety Commission, Radiation Protection and Accident Management Division	Examiner	T. Oishi
Nuclear Safety Commission, Radiation Protection and Accident Management Division	Examiner	H. Morioka
Nuclear Safety Commission	Technical Counsellor	H. Umezawa
Nuclear Safety Commission	Technical Counsellor	S. Saigusa
National Police Agency, Consumer and Environmental Protection Division, Community Safety Bureau	Deputy Director	N. Kikuzawa
National Police Agency, Consumer and Environmental Protection Division, Community Safety Bureau	Unit Chief	T. Okada
MIC, Postal Policy Planning Division, Postal Services Policy Planning Bureau	Director	K. Sato
MIC, Postal Policy Planning Division, Postal Services Policy Planning Bureau	Deputy Director	A. Tokkou
MIC, Correspondence Delivery Business Division, Postal Services Policy Planning Bureau	Deputy Director	A. Ozu
MIC, Disaster Management Division, Fire and Disaster Management Agency	Deputy Director	M. Andou
MIC, Disaster Management Division, Fire and Disaster Management Agency	Unit Chief	K. Moriya

Affiliation	Position	Name
Ministry of Foreign Affairs, International Nuclear Energy Cooperation Division, Foreign Policy Bureau	Director	Y. Komizo
Ministry of Foreign Affairs, International Nuclear Energy Cooperation Division, Foreign Policy Bureau		D. Tanaka
MEXT, Nuclear Safety Division	Director	T. Ueki
MEXT, Nuclear Safety Division	Deputy Director	Y. Awatsuji
MEXT, Office of Nuclear Regulation, Nuclear Safety Division	Director	T. Aoki
MEXT, Office of Nuclear Regulation, Nuclear Safety Division	Director for Nuclear Facility Operations	S. Kuromura
MEXT, Office of Nuclear Regulation, Nuclear Safety Division	Deputy Director	T. Ikeda
MEXT, Office of Nuclear Regulation, Nuclear Safety Division	Unit Chief	T. Ikeda
MEXT, Office of Emergency Planning and Environmental Radioactivity, Nuclear Safety Division	Official	K. Tsutsui
MEXT, Office of Radiation Regulation, Nuclear Safety Division	Specialist	M. Endo
MEXT, Office of Radiation Regulation, Nuclear Safety Division	Unit Chief	T. Hidaka
MEXT, Office of Radiation Regulation, Nuclear Safety Division		H. Miyauchi
MEXT, Office of International Relations, Nuclear Safety Division	Director	H. Kawagoshi
MEXT, Office of International Relations, Nuclear Safety Division		M. Yamada
MHLW, Office of Compliance, Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau	Director	S. Onishi
MHLW, Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau	Deputy Director	T. Mitsuoka
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Affiliation	Position	Name
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7 December 2005, MNF

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Appendix VI

JAPAN'S LEGISLATION

National legislation relevant to the safe transport of radioactive material (excerpts).

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
A	Atomic Energy Basic Law	Article 3
B	Government Order for Definition of Nuclear Fuel Material, Nuclear Material Sources, Nuclear Power Reactors and Radiation	Articles 1–4
C-1	Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors	Articles 1 and 2, para. 1 of Article 3, Articles 6 (terminology only), 10 and 12, para. 1 of Article 13, Article 16 (terminology only), Articles 20 and 22, para. 1 of Article 23, Article 23-2 (terminology only), Articles 33–35 and 37, para. 1 of Article 43-4, Article 43-7 (terminology only), para. 1 of Article 44, Article 44-4 (terminology only), Article 46-7, para. 1 of Article 51-2, Article 51-5 (terminology), Article 51-14, para. 1 of Article 52, Article 55 (terminology only), Articles 56, 56-2, 56-3, 59-2, 61-2, 61-26, 61-27, 63, 64, 66 and 66-4, para. 1 of Article 67, para. 1 of Article 68, Article 70, paras 2, 12–14 of Article 79 and Article 80
C-2	Government Order for the Enforcement of the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors	Articles 17-4, 22, 15, 16-2, 18 and 19
C-3	Regulations for Processing Business of Nuclear Fuel Material	Article 7, Articles 7-2-2 to 7-2-8, 8 and 8-2

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
C-4	Regulations for Establishment and Operation of Commercial Power Reactors	Articles 7, 16 and 16-2
C-41	Regulations for Establishment and Operation of Test and Research Reactors	Article 6
C-5	Regulations for Use of Nuclear Fuel Material	Articles 2-11–2-13
C-6	Regulations for Use of Nuclear Source Material	Articles 2–4
C-7	Regulations for Transport of Nuclear Fuel Material Outside Plants	All provisions
C-8	Notice on the Details of Technical Standards for Transport of Nuclear Fuel Material Outside Plants in Accordance with the Provisions of Article 3 of the Regulations for Transport of Nuclear Fuel Material Outside Plants	All provisions
C-9	Regulations for Vehicle Transport of Nuclear Fuel Material, Etc.	Articles 1–23
C-10	Notice on the Details of the Regulations for Vehicle Transport of Nuclear Fuel Material, Etc.	Articles 1–18
C-11	Regulations for Actions in Emergencies Concerning Transport of Nuclear Fuel Material Outside Plants	Article 1
C-12	Cabinet Office Order for the Notification of Transportation of Nuclear Fuel Material, Etc.	Articles 2 and subpara. 9 of para. 1 of Article 4
C-14	Generic Letter on the Administrative Procedure for Confirmation of Transport of Nuclear Fuel Material Outside Plants (Generic Letter No. 2, 26 June 2001)	All provisions
C-15	Generic Letter on Confirmation, Etc., of Transport of Nuclear Fuel Material Outside Plants (Generic Letter No. 4, 7 June 2002)	All provisions
C-16	Generic Letter on Guidelines for Confirmation of Transport of Nuclear Fuel Material Outside Plants (Bylaw) (Generic Letter No. 6, 27 June 2002)	All provisions

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
C-17	Generic Letter on Procedures to Prepare the Explanatory Documents for the Application for Confirmation of the Vehicle Shipment and the Application for Approval of the Packaging, and the Application for Approval of the Nuclear Fuel Package Design (Generic Letter No. 2, 7 June 2002)	All provisions
C-18	Generic Letter on Guidelines for Quality Assurance for Manufacturing of Packagings (Generic Letter No. 5, 7 June 2002)	All provisions
C-19	Generic Letter on the Administrative Procedure for the Nuclear Fuel Package Related Application (Nuclear Regulation Office of the Nuclear Safety Division, Science and Technology and Academic Policy Bureau, Ministry of Education, Culture, Sports, Science and Technology)	All provisions
C-20	Notice on Design Approval Application, Design Change Approval Application, Design Approval Renewal Application, and Issue of the Design Approval Certificate: Notice from the Director of the Nuclear Safety Division (Notice No. 227/13 of the Science and Technology Policy Bureau (Ministry of Education, Culture, Sports, Science and Technology))	All provisions
C-21	Ministry Order for Implementation of the Inspection of the Incorporated Administrative Agency, Japan Nuclear Energy Safety Organization, in Accordance with the Provisions of the Law on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Order No. 112 of the Ministry of Economy, Trade and Industry)	Article 6

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
C-22	Ministry Order for Implementation of the Welding Inspection and Confirmation of Consignments by the Incorporated Administrative Agency, Japan Nuclear Energy Safety Organization, in Accordance with the Provisions of the Law on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Order No. 45 of the Ministry of Education, Culture, Sports, Science and Technology)	Article 4
C-23	Ministry Order for the Confirmation of Shipment Methods by the Incorporated Administrative Agency, Japan Nuclear Energy Safety Organization, in Accordance with the Provisions of the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Order No. 99 of the Ministry of Land, Infrastructure and Transport)	All provisions
D-1	Law Concerning Prevention of Radiation Hazards Due to Radioisotopes	Articles 1 and 6, paras 1–5 of Article 18, Articles 21, 25, 32, 33 and 41, para. 1 of Article 41-15, para. 1 of Article 41-19, Articles 41-21 and 41-22, para. 1 of Article 42, para. 1 of Article 43-2, Article 45, paras 5–7 of Article 54, Article 55
D-2	Government Order for the Enforcement of the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes	Articles 1 and 16
D-3	Regulations for the Enforcement of the Law Concerning Prevention of Radiation Hazards Due to Radioisotopes, Etc.	Articles 18-14–18-16, 21, 24 and 29
D-4	Notice on the Details of Technical Standards for Transport of Radioisotopes or Material Contaminated with Radioisotopes Outside Plants	All provisions

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
D-5	Regulations for Vehicle Transport of Radioisotopes	Articles 1–22
D-6	Notice on the Details of the Regulations for Vehicle Transport of Radioisotopes	Articles 1–16
D-7	Regulations for Actions in Emergencies Concerning Transport of Radioisotopes Outside Plants	Articles 1–3
D-8	Cabinet Office Order for the Notification of Transportation of Radioisotopes	Article 2, subpara. 10 of para. 1 of Article 3
D-10	Ministry Order for the Registered Shipment Method Confirmation Agency Concerning Radioisotopes	Articles 1–18
D-11	Law for Technical Standards for Prevention of Radiation Hazard	Articles 1 and 6
D-12	Generic Letter on Handling Procedure Related to the Regulations on Shipment of Radioisotopes by Vehicle and Handling Procedure Related to the Regulations on Shipment of Nuclear Fuel Material by Vehicle	All provisions
D-13	Notice on Approval by the Minister for Education, Culture, Sports, Science and Technology Concerning Shipment of Radioisotopes (Notice No. 256/13 of the Science and Technology Policy Bureau, 12 July 2001)	All provisions
E-1	Ship Safety Law	Articles 1, 2, 4, 5, 11, 12, 25-46, 25-47 and 28
E-2	Regulations for the Enforcement of the Ship Safety Law	Paragraph 14 of Article 1, Articles 50-2 and 60-5
E-3	Regulations for the Carriage and Storage of Dangerous Goods by Ships	Articles 1, 2, 5-8, 5-10, 7, 17, 45, 74–82, 85, 86–88, 90, 91, 94, 96–99, 101–107, 111, 112, 391, 392 and 394–399, separate table 4
E-4	Ministry Order Concerning Certification Under the International Convention for the Safety of Life at Sea	Paragraph 1 of Article 2, para. 2 of Article 2, para. 7 of Article 2, para. 1 of Article 4, para. 3 of Article 4 and para. 4 of Article 4

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
E-5	Notice on the Details of Standards Concerning the Carriage of Radioactive Material by Ships	All provisions
E-6	Notice on the Carriage of Dangerous Goods by Ships	Paragraph 2 of Article 14-3, Article 16-9 and Annex 3
E-7	Regulations for Issuance of a Ship Management Certificate	Articles 1–3
E-8	Generic Letter on Handling of Ships Carrying Irradiated Nuclear Fuel (KAISA No. 300-3, 18 June 1998)	All provisions
E-9	Load Line Regulations	Articles 36, 66–69
E-10	Regulations for Life-saving Appliances of Ships	Paragraph 4 of Article 1-2 and Article 69
E-11	Regulations for Fire-fighting Appliances of Ships	Articles 36–41, 47, 53–56 and 63-2–64
E-12	Regulations for the Installations of Ships	Articles 146-12, 146-16, 146-23, 183-2 and 300, para. 1 of Article 299
E-13	Regulations for Construction of Ships for Fire Protection	Paragraphs 14, 16, 17, 19 and 22 of Article 2
E-14	Notice Concerning Fire-fighting Appliances of Ships	Articles 2, 5–7, 10, 14, 15, 34 and 35
E-15	Generic Letter on Confirmation of Consignment in Accordance with the Regulations for the Carriage and Storage of Dangerous Goods by Ships (KAISA No. 592, 27 December 1990)	All provisions
E-16	Generic Letter on Paperwork Concerning Safety Confirmation of Packages and Safety Confirmation of Package Carriage Pursuant to the Regulations for the Carriage and Storage of Dangerous Goods by Ships (KAISA No. 64, 2 March 1987)	All provisions
E-17	Generic Letter on Establishment of Paperwork Procedures for the Safety Confirmation of Radioactive Material Packages and the Package Carriage Plan (KAISA No. 379, 28 August 1987)	All provisions

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
E-18	Generic Letter on Amendments to the Generic Letter on Paperwork of Shipment Vessel for Irradiated Nuclear Fuel (KAISA No. 520, 19 September 1995)	All provisions
E-19	Generic Letter on Establishment of Safety Confirmation Manual for Radioactive Material Packages (KAIKEN No. 96, 28 August 1987)	All provisions
E-20	Generic Letter on Expiration Date of Safety Confirmation Document for Package Carriage Plan (dated 21 November 1994)	All provisions
E-21	Generic Letter on Paperwork for Inspection and Measurement of Ships with the Enforcement of Administrative Procedures Act (KAISA No. 547, 26 September 1994, KAISA No. 162, 1 April 1999, partially amended)	All provisions
E-22	Regulations for Document Management of the Ministry of Land, Infrastructure and Transport	Articles 1, 2, 4, 16, 17, 19, 28, 30, 34 and 35
E-23	Generic Letter on Procedures for Establishment of a Technical Adviser System for the Transport of Radioactive Material by Ships (23 January 1981)	All provisions
E-24	List of Penalties in Accordance with the Regulations for the Carriage and Storage of Dangerous Goods by Ships	All provisions
F-1	Port Regulations Law	Articles 21–23
F-2	Regulations for the Enforcement of the Port Regulations Law	Articles 12–14
F-3	Notice to Define the Kinds of Dangerous Goods Under the Regulations for the Enforcement of the Port Regulations Law	Annexed table 2 (9)

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
G-1	Civil Aeronautics Law	Article 1, Articles 73–75, para. 1 of Article 86, Article 86-2, Article 112, para. 2 of Article 134, subpara. 13 of para. 1 of Article 145, para. 6 of Article 150, subpara. 1 of para. 1 of Article 157, Articles 158 and 159
G-2	Regulations for the Enforcement of Civil Aeronautics	Subparagraph 7 of para. 1 of Article 194, subitems 2–5 of subpara. 2 of para. 2 of Article 194 and paras 4 and 5 of Article 194
G-3	Notice on Standards for Transport of Radioactive Material by Air (Notice No. 1094 of 26 June 2001 of the Ministry of Land, Infrastructure and Transport)	All provisions
G-4	Generic Letter on Regulations for Transport of Radioactive Material (Generic Letter No. 542 of the Director-General of the Civil Aviation Bureau of the Ministry of Land, Infrastructure and Transport)	All provisions
G-5	Generic Letter on Contents of Safety Analysis Document to be Attached to Application for Confirmation of Radioactive Material Package (Generic Letter No. 544 of the Manager of the Flight Standards Division of the Engineering Department of the Civil Aviation Bureau of the Ministry of Land, Infrastructure and Transport)	All provisions
G-6	Generic Letter on Education and Training Relating to Transport of Dangerous Goods (Generic Letter No. 546 of the Manager of the Flight Standards Division of the Engineering Department, Civil Aviation Bureau)	All provisions
G-7	Generic Letter on Contents of Transportation Plan to be Attached to the Confirmation Application of Radioactive Packages	All provisions

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
H-1	Postal Law	Article 1, Article 13, para. 1 of Article 14, Article 40, Article 42 and Article 81
H-2	Notice No. 384 of the Ministry of Communications, 1947, to Define Explosive, Inflammable or Other Dangerous Substances Pursuant to the Provisions of the Postal Law, Article 14, Subpara. 1	Paragraph 9 of Article 1
H-3	Law Concerning Correspondence Delivery Provided by Private-sector Operators	Article 1, Article 27, paras 2–4 of Article 36, Article 42, Article 47 and subpara. 1 of para. 1 of Article 47
H-4	Notice No. 203 of 2003 to Define Explosive, Inflammable or Other Dangerous Substances Pursuant to the Provisions of the Law Concerning Correspondence Delivery Provided by Private-sector Operators, Article 47, Para. 1, Subpara. 1	All provisions
H-5	Regulations for the Enforcement of the Law Concerning Correspondence Delivery Provided by Private-sector Operators	Article 47
H-6	Japan Post Law	Paragraph 1 of Article 58 and para. 1 of Article 61
H-7	Universal Postal Convention	Paragraph 2 of Article 25 and Article 26
H-8	Letter Post Regulations (Ministry of Post and Communications Notice No. 823 of 2000)	Articles 414 and 501
H-9	Parcel Post Regulations (Ministry of Post and Communications Notice No. 824 of 2000)	Articles 301 and 302
I-1	Pharmaceutical Affairs Law	Article 1, para. 2 of Article 18, para. 1 of Article 69, para. 1 of Article 72-3, subpara. 15 of para. 1 of Article 86 and para. 9 of Article 87
I-2	Regulations for Manufacturing and Handling of Radiopharmaceuticals	Paragraphs 6 and 7 of Article 2, Articles 13, 14 and 15
I-3	Notice on Standards for Transport of Radioactive Material	All provisions

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
J-1	National Government Organization Law	Articles 1–4 and 8
J-2	Law for the Ministry of Economy, Trade and Industry	Article 3, Article 19, paras 57–59, 62 and 64 of Article 4, paras 1 and 3 of Article 20
J-3	Government Order for Organization of the Ministry of Economy, Trade and Industry	Paragraphs 1–3 of Article 132
J-4	Law for the Ministry of Education, Culture, Sports, Science and Technology	Article 3, paras 72 and 74 of Article 4
J-5	Government Order for Organization of the Ministry of Education, Culture, Sports, Science and Technology	Paragraphs 2 and 4 of Article 58
J-6	Law for the Ministry of Land, Infrastructure and Transport	Articles 3 and 4
J-7	Government Order for Organization of the Ministry of Land, Infrastructure and Transport	Article 12, Article 13, subpara. 3 of para. 1 of Article 15 and para. 4 of Article 15
J-8	Regulations for Organization of the Ministry of Land, Infrastructure and Transport	Article 103
J-9	Law for the Ministry of Internal Affairs and Communications	Article 3, paras 79 and 80 of Article 4
J-10	Government Order for Organization of the Ministry of Internal Affairs and Communications	Paragraphs 1–4 of Article 12, Article 99 and Article 102
J-11	Law for the Ministry of Health, Labour and Welfare	Article 3 and para. 31 of Article 4
J-12	Government Order for Organization of the Ministry of Health, Labour and Welfare	Article 6
J-13	Law for the Incorporated Administrative Agency, Japan Nuclear Energy Safety Organization	Articles 11 and 13
J-14	Law for the Cabinet Office	Article 3
J-15	Law for the Atomic Energy Commission and the Nuclear Safety Commission	Articles 1, 13 and 25
J-16	Planning of Nuclear Safety Research	Summary
J-17	Law for Technical Standards for Prevention of Radiation Hazards	Articles 1 and 6

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
K-1	Basic Law for Emergency Preparedness	Article 1
K-2	Emergency Preparedness Planning — Section 10, Emergency Preparedness for a Nuclear Disaster	Introductory part only
K-3	Operational Plan for Disaster Prevention	Section 24 of Chapter 1
K-4	Special Law for Emergency Preparedness for a Nuclear Disaster	Articles 3, 4, 6, 10 and 13 and para. 2 of Article 15
K-5	Administrative Appeal Law	Article 1
K-51	Law for Administrative Procedure	Article 8
K-6	National Civil Servant Law	Article 100
K-7	Information Disclosure Law for Information Possessed by Administrative Bodies	Articles 1 and 3
K-8	Government Order for the Enforcement of the Information Disclosure Law for Information Possessed by Administrative Bodies	Table 2
K-9	Generic Letter on Procedure for Submitting Opinions Relating to Establishment, Amendment or Abrogation of Regulations (Cabinet decision, 23 March 1999)	All provisions
K-10	Outline of the Interagency Coordination Meeting for the Safe Transport of Radioactive Material	All provisions
K-11	Provisions for Safety Measures Against a Transport Accident of Radioactive Material (Agreement by the Interagency Coordination Meeting for the Safe Transport of Radioactive Material)	All provisions
K-12	Dispatch of Expert for Transport Accident of Radioactive Material (Agreement by the Interagency Coordination Meeting for the Safe Transport of Radioactive Material)	All provisions
K-13	Guidelines for Manual for Safe Transport of Nuclear Fuel Material	All provisions
L-1	Articles of Association of Nippon Kaiji Kentei Kyokai (Japan Marine Surveyors and Sworn Measurers Association)	Article 3

	Name of legislation (laws, government orders, regulations, generic letters)	Relevant provisions
L-2	Regulations for Inspection Work of Dangerous Goods	Articles 1, 5, 19 and 21, Article 21 of Annex 1

Note: C-13 and D-9 have been removed from the list. They are not relevant or have been superseded.

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APPRAISAL FOR BRAZIL OF THE SAFETY OF THE TRANSPORT OF RADIOACTIVE MATERIAL
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STI/PUB/1166 (78 pp.; 2003)
ISBN 92–0–108903–1 Price: €15.00

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IAEA Safety Standards Applications — TranSAS-6
STI/PUB/1208 (120 pp.; 2004)
ISBN 92–0–111204–1 Price: €23.00

The IAEA has the specific statutory function within the United Nations system of establishing standards of safety for the protection of health against exposure to ionizing radiation. As part of this mandate, the IAEA has issued Regulations for the Safe Transport of Radioactive Material, and has also established the Transport Safety Appraisal Service (TranSAS) to carry out, at the request of States, appraisals of the implementation of these regulations. The IAEA carried out such an appraisal in Japan in December 2005. The appraisal addressed all relevant transport activities in Japan, both national and international, for all modes of transport, with special emphasis on the land and maritime transport of radioactive material. This report summarizes the findings of the twelve independent experts who participated in the appraisal.

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA
ISBN 92–0–109506–6
ISSN 1684–7520