

IAEA Safety Standards

for protecting people and the environment

Compliance Assurance for the Safe Transport of Radioactive Material

Safety Guide

No. TS-G-1.5



IAEA

International Atomic Energy Agency

COMPLIANCE ASSURANCE
FOR THE SAFE TRANSPORT OF
RADIOACTIVE MATERIAL

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA SAFETY STANDARDS SERIES No. TS-G-1.5

COMPLIANCE ASSURANCE
FOR THE SAFE TRANSPORT OF
RADIOACTIVE MATERIAL

SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2009

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FOREWORD

**by Mohamed ElBaradei
Director General**

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the contracting parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection

of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures¹ have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. The safety requirements use 'shall' statements together with statements of

¹ See also publications issued in the IAEA Nuclear Security Series.

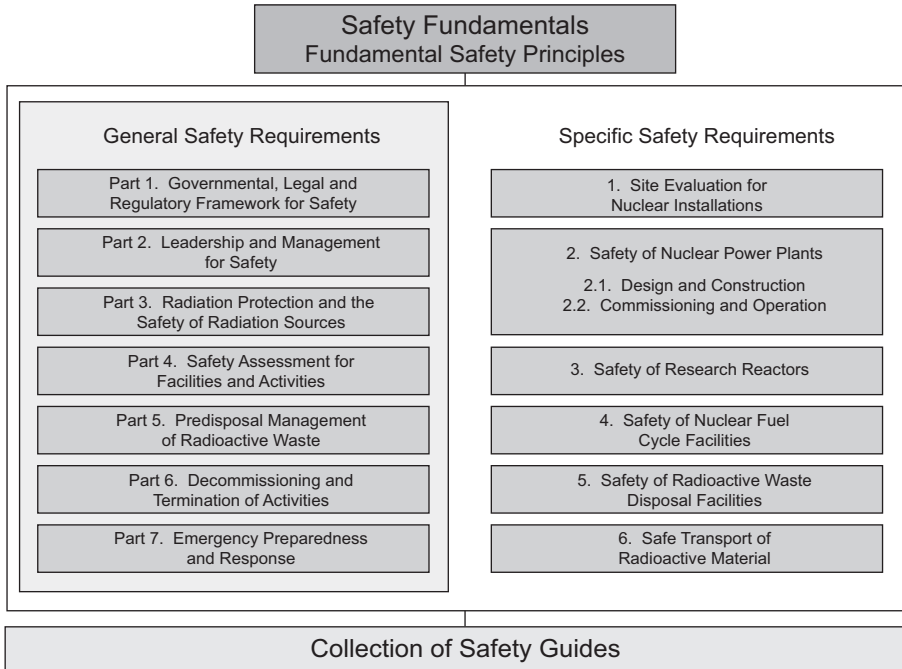


FIG. 1. The long term structure of the IAEA Safety Standards Series.

associated conditions to be met. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as ‘should’ statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety

standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and four safety standards committees, for nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on

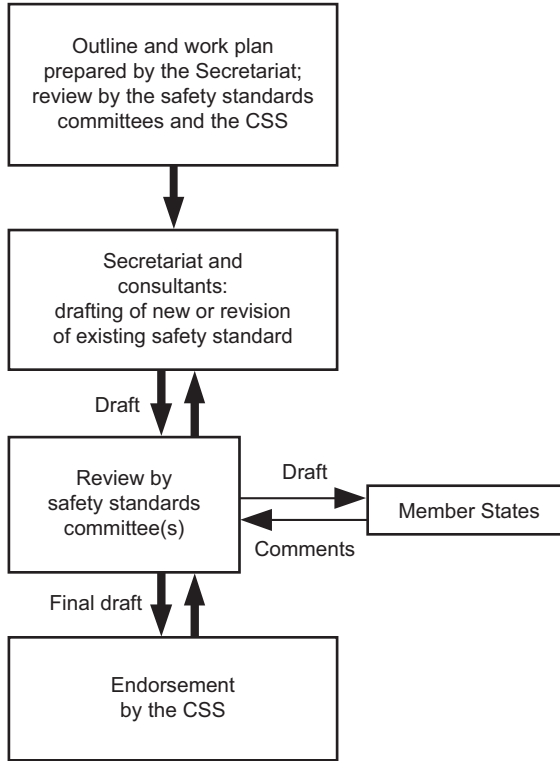


FIG. 2. The process for developing a new safety standard or revising an existing standard.

Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see <http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

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1. INTRODUCTION

BACKGROUND

1.1. The transport of radioactive material involves potential radiological hazards. To ensure the protection and safety of people, property and the environment, appropriate regulations, both at the national level and at the international level, are necessary. Government authorities regulate the transport of radioactive material by means of national regulations, in which the relevant international regulations and recommendations are taken into account. This Safety Guide provides recommendations for ensuring that the transport of radioactive material, both domestic and international, is carried out in compliance with the IAEA Regulations for the Safe Transport of Radioactive Material (the Transport Regulations) [1].

1.2. This Safety Guide is intended to be used by competent authorities that are establishing or further developing programmes to ensure compliance with the Transport Regulations. The recommendations provided will also be useful to competent authorities with established programmes that are seeking greater harmony internationally in the implementation of the Transport Regulations. Additionally, the Safety Guide will assist users of the Transport Regulations in their interactions with competent authorities. As this Safety Guide relates to the 2005 Edition of the Transport Regulations, future changes to the Transport Regulations may compromise some specific advice provided in this Safety Guide. Competent authorities should therefore be alert to any future changes in the Transport Regulations and should take into account such changes in following the recommendations provided in this Safety Guide in their own compliance assurance programmes¹.

1.3. The Safety Requirements publication on The Management System for Facilities and Activities [2] establishes requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements to ensure that safety is properly taken into account in all the activities of an organization. This Safety Guide also uses the concept of a ‘management

¹ Compliance assurance is a systematic programme of measures applied by a competent authority that is aimed at ensuring that the provisions of the Transport Regulations [1] are met in practice.

system', which reflects and includes the initial concept of 'quality control' (controlling the quality of products) and its evolution through 'quality assurance' (the system for ensuring the quality of products) and 'quality management' (the system for managing quality). The terms 'quality assurance programme' and 'management system' have often been used, with cultural and national variations, to mean the same thing.

1.4. It is expected that competent authorities will need to utilize relevant parts of the management systems of users² when implementing the compliance assurance programme. Indeed, auditing by the competent authority of the management system established by the user to fulfil a regulatory requirement is one of the most effective methods available for monitoring the compliance of the user with the Transport Regulations.

OBJECTIVE

1.5. The objectives of this Safety Guide are to assist competent authorities in the development and maintenance of compliance assurance programmes in connection with the transport of radioactive material, and to assist applicants, licensees and organizations in their interactions with competent authorities. In order to increase cooperation between competent authorities and to promote the uniform application of international regulations and recommendations, it is desirable to adopt a common approach to regulatory activities. This Safety Guide is intended to assist in accomplishing such a uniform application by recommending most of the actions for which competent authorities need to provide in their programmes for ensuring compliance with the Transport Regulations.

SCOPE

1.6. This Safety Guide addresses radiation safety aspects of the transport of radioactive material; that is, the subjects that are covered by the Transport Regulations. Radioactive material may have other dangerous properties, however, such as explosiveness, flammability, pyrophoricity, chemical toxicity

² In the context of this Safety Guide, a 'user' is a person who or an organization that designs, tests, assesses, manufactures, services, maintains, consigns, carries or otherwise uses a package in connection with the transport of radioactive material.

and corrosiveness; these properties are required to be taken into account in the regulatory control of the design and transport of packages (see, e.g., paras 109, 305 and 507 of the Transport Regulations [1]).

1.7. Physical protection and systems for accounting for and control of nuclear material are also discussed in this Safety Guide (see paras 2.3, 2.14, 2.15, 3.12 and 3.13). These subjects are not within the scope of the Transport Regulations, but information on them is included here because they must be taken into account in the overall regulatory control of transport, especially when the regulatory framework is being established.

STRUCTURE

1.8. Section 2 provides recommendations on the responsibilities and functions of the competent authority. Section 3 provides information on the various national and international regulations and guides for the transport of radioactive material. Section 4 provides recommendations on carrying out compliance assurance, and Section 5 provides recommendations on approvals and approval certificates. Section 6 provides recommendations on cooperation between competent authorities at the international level. The annexes provide examples of procedures and checklists for use by a competent authority in its compliance assurance programme.

2. RESPONSIBILITIES AND FUNCTIONS OF THE COMPETENT AUTHORITY

REGULATORY BASIS

2.1. According to para. 307 of the Transport Regulations [1], “The *competent authority* is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of *packaging, special form radioactive material and low dispersible radioactive material*, and the preparation, documentation, handling and stowage of *packages* by *consignors* and *carriers*, to provide evidence that the provisions of these Regulations are being met in practice.”

2.2. While competent authorities are responsible for ensuring compliance with the Transport Regulations (which includes the oversight and enforcement of all regulations), the prime responsibility for ensuring safety in transport rests with consignors and carriers, which are required to take account of all relevant safety regulations. Thus, consignors, carriers and any other users of the Transport Regulations are required to comply with the actual regulations, and the competent authority is required to ensure compliance with these regulations. The competent authority itself is required to comply with the Transport Regulations, for example, in such matters as the issuing of approvals and the allocation of identification marks.

2.3. A State whose industry for the transport of radioactive material is not yet fully established may develop its compliance assurance programme in stages, depending on the size of the transport industry. For example, initially the competent authority may need to deal only with the movement of packages that were originally assessed and approved by the authorities of other Member States. Later, that competent authority may have to monitor the quality of packages (approved or not) that are designed, built and used within its own jurisdiction. The compliance assurance programme of the competent authority can then be developed accordingly. In an effective programme for compliance assurance, all users of the Transport Regulations should be taken into account; that is, persons who or organizations that, at one time or another, may be subject to the requirements of the Transport Regulations, such as:

- (a) Consignors;
- (b) Carriers;
- (c) Suppliers and/or manufacturers of packagings;
- (d) Regulatory bodies (which may share responsibilities).

2.4. A compliance assurance programme should include two major elements: First, the competent authority should review certain activities for approval before these activities are conducted. Second, the competent authority should ensure, through a programme of inspection and enforcement, that all the regulatory requirements are correctly fulfilled in practice. The competent authority should be provided with adequate resources to perform these activities for review, inspection and enforcement. Compliance assurance should also cover activities relating to emergency response.

2.5. Through the compliance assurance programme, the competent authority should obtain assurance that all transport requirements are being met in practice by the users of the Transport Regulations. Monitoring of the effectiveness of

compliance is generally performed by routine, periodic inspections (announced or unannounced) of the user's activities. For consignors, such inspections are generally examinations of the procedures before, during or after the transport. For carriers, such inspections are generally performed during or after the transport. The frequency of inspection should be established by taking into account the scope and potential importance to safety of the user's activities.

LEGAL BASIS

2.6. The responsibilities and duties of the competent authority (regulatory body) are required to be defined within the national legal framework of a State, in accordance with the requirements established in Ref. [3]. The responsibilities of the competent authority include:

- (a) The establishment, promotion or adoption of regulations for the transport of radioactive material upon which its regulatory actions are based;
- (b) Activities in connection with discharging these responsibilities for the safe transport of radioactive material, such as:
 - (i) Providing guidance for applicants;
 - (ii) Conducting safety reviews and safety assessments;
 - (iii) Issuing approvals;
 - (iv) Carrying out regulatory inspections and taking any necessary enforcement actions;
 - (v) Providing for the reporting of incidents, including accidents;
 - (vi) Making provisions for emergency response;
 - (vii) Coordinating research and development activities;
- (c) The promotion of information exchange by means of activities such as training courses and seminars on the safe transport of radioactive material.

INTERLINKED RESPONSIBILITIES

2.7. More than one organization may be responsible for the regulatory control of the transport of radioactive material in a State, depending on:

- (a) The existing regulations;
- (b) The mode of transport (e.g. for the design of packages that are subject to restrictions on the mode of transport);
- (c) The type of radioactive material (e.g. 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, they should cooperate closely and there should be legal or formal agreements between them covering the responsibilities of each authority. Each competent authority is required to communicate with and provide information to other governmental and non-governmental organizations that have related responsibilities (Ref. [3], para. 3.3). The competent authority of a State may also be responsible for security, physical protection and the system for accounting for and control of radioactive material. However, these functions may also be carried out by other authorities, depending on the legal framework of the particular State.

ORGANIZATION AND RESPONSIBILITIES OF THE COMPETENT AUTHORITY

2.8. There is no ideal or universal organizational model for the competent authority. Its organization will depend mainly on its areas of responsibility and on the general organizational approach in the State concerned. However, to avoid conflicts of interest, the competent authority is required to be independent of the activities it regulates. In order to discharge its responsibilities in an efficient and equitable manner, and to perform its many varied regulatory functions, the competent authority is required to establish, implement, assess and continually improve its own management system [2]. Further recommendations on meeting the requirements for the management system are provided in Ref. [4].

INFORMATION, GUIDANCE AND TRAINING

2.9. The competent authority is required to provide information and guidance on the safe transport of radioactive material (Ref. [3], para. 3.3). Specifically, the competent authority should provide the general public and users with adequate information concerning the authority's safety and regulatory approach, organization, procedures and decisions. In particular, specific guidance for users regarding the presentation of applications for approval may be necessary (see paras 5.4–5.7 and Annex II for further information). To achieve the goal of full compliance with the Transport Regulations, provisions should be put in place for the appropriate training of all personnel. The competent authority may need to ensure that adequate training information and programmes are available so that the staff of users can acquire appropriate

levels of knowledge of the regulatory requirements. The competent authority should also promote seminars and conferences for all parties involved in the transport of radioactive material. Further recommendations and information on training are provided in paras 4.103–4.107.

INDEPENDENT ASSESSMENT

2.10. The competent authority should be able to independently assess and verify the technical and test data submitted by an applicant. Such independent assessment may cover nuclear criticality control, heat transfer, radiation protection, structural analysis and risk studies, and all related measures of the management system of the applicant.

2.11. The competent authority need not be entirely self-sufficient in all technical areas of assessment. It may delegate some of its specific activities to organizations having the necessary technical abilities. The competent authority may also engage consultants, as necessary. Such organizations and consultants are required to be independent of the organizations whose work they are to evaluate (Ref. [3], para. 4.3). However, the responsibility for such activities is required to remain with the competent authority (Ref. [3], para. 4.4), which should evaluate the results of any work that is delegated. Suitable subjects for consultancy are, for example, inspections and materials testing, and analysis of safety reports for the purposes of verification.

RESOURCES

2.12. The competent authority is required to be provided with adequate resources for carrying out the activities outlined in para. 2.6 (see Ref. [3], paras 2.1, 2.4). To carry out these activities, the competent authority will need to have access to expertise in many different fields. The resources and the number of staff needed will depend on the nature and extent of the transport operations. Depending on the types of package that exist or that are expected to be developed within a State, the areas of expertise of the competent authority should include some or all of the following:

- (a) Criticality safety;
- (b) Radiation safety;
- (c) Thermal analysis;
- (d) Structural analysis;

- (e) Materials science and mechanical engineering;
- (f) The management system;
- (g) Emergency preparedness;
- (h) Transport operations;
- (i) Inspection and enforcement.

TRAINING OF EMPLOYEES

2.13. The competent authority should establish and maintain a programme for training its own employees. The training provided should be sufficient to ensure consistency in the application of the Transport Regulations. Training should be carried out at an early stage in the development of the industry for the transport of radioactive material. International seminars and conferences are also important for the education and training of employees of the competent authority. Further recommendations and information on training are provided in paras 4.103–4.107.

EMERGENCY RESPONSE

2.14. The competent authority should be provided with adequate resources to respond to transport accidents. This means that the competent authority will need to be provided with sufficient resources to enable it to provide overall direction for response to a transport emergency or, alternatively, will need to act as a coordinator for or to advise other agencies involved in the response to an emergency. Requirements on preparedness for and response to a nuclear or radiological emergency are established in Ref. [5], and recommendations on emergency response to transport accidents are provided in Ref. [6].

LIST OF NATIONAL COMPETENT AUTHORITIES

2.15. A list of National Competent Authorities Responsible for Approvals and Authorizations in Respect of the Transport of Radioactive Material [7] is published annually by the IAEA. Competent authorities should ensure that the information provided in this list is checked annually to verify that it is correct.

LIAISON BY THE COMPETENT AUTHORITY WITH OTHER GOVERNMENT AGENCIES

Liaison concerning the Transport Regulations

2.16. As noted in para. 2.7, more than one organization may be responsible for the regulatory control of transport in a State. For example, the following persons and agencies may be linked directly with the competent authority for the purpose of the safe transport of radioactive material:

- (a) Agencies with responsibilities for transport;
- (b) Agencies with responsibilities for dangerous goods;
- (c) Agencies with responsibilities for health and safety;
- (d) Agencies with responsibilities for radiation protection;
- (e) Legal authorities;
- (f) Police;
- (g) Customs officials;
- (h) Post offices;
- (i) National research institutes and institutes for materials testing;
- (j) Institutions that provide training and education.

2.17. The competent authority should arrange regular meetings for all parties within this complex network of agencies and persons in order to ensure:

- (a) An exchange of information regarding existing regulations for the transport of radioactive material;
- (b) An exchange of information on changes to national laws and regulations as well as changes to the Transport Regulations;
- (c) A complete programme of training for personnel at all levels;
- (d) Consistent application of inspection and enforcement relating to compliance assurance;
- (e) A regular review of all measures for emergency response, including the responsibilities of the competent authority, the industry for the transport of radioactive material and other relevant agencies;
- (f) A suitable forum for the discussion and resolution of issues relating to the Transport Regulations and compliance assurance.

Liaison concerning other regulations

2.18. The competent authority should put in place formal agreements with agencies responsible for national regulations that are only indirectly linked with the Transport Regulations. Examples of such agencies are:

- (a) Other technical regulatory bodies;
- (b) National agencies involved in accounting for and control and physical protection of nuclear material;
- (c) Customs agencies;
- (d) Environmental agencies;
- (e) Agencies with responsibilities for toxic waste;
- (f) Agencies with responsibilities for emergency planning.

2.19. In the case of agencies responsible for security, accounting for and control of nuclear material, and physical protection, the requirements in some States necessitate that the competent authority maintains total control over all transit, import, export and inland shipments relating to nuclear material and other radioactive material. In such cases, some applications in connection with the transfer of such material are required to be checked by the competent authority prior to shipment, to confirm that all proposed shipments and packages are in compliance with the Transport Regulations. Such checks are often required by national regulations irrespective of whether the proposed shipment or package requires approval in accordance with the Transport Regulations. In such cases the liaison between the supervising authorities should be extremely close.

2.20. Liaison between competent authorities and customs agencies can usually be restricted to occasional meetings at which each party is informed of current developments. Particular consideration should be given to the exchange of information when new versions of regulations, including the Transport Regulations, come into force. The competent authority should also be prepared to provide consultation by telephone for customs officers confronted with the complex collection of papers that accompanies shipments of radioactive material at national customs points.

2.21. The liaison with environmental agencies should normally be arranged on demand. The competent authority should keep such agencies generally informed to be able to provide adequate information to the general public, as described in para. 2.9. In practice, the competent authority is most likely to come into contact with environmental agencies when it has to provide written

answers to questions relating to specific shipments or incidents, or when it develops emergency plans.

2.22. The competent authority should liaise very closely with agencies involved in emergency planning. In practice, the plans of such agencies usually concern the response to accidents involving dangerous goods in general or the response to emergencies involving nuclear reactors, or both. The competent authority should agree to an adaptation of the emergency procedures of such agencies to the particular case of accidents in the transport of radioactive material. Although the solution to such problems may be relatively simple, the competent authority should agree to the procedures for emergency response and should initiate a system of periodic review of any such procedures. Further recommendations on planning and preparing for response to an emergency involving radioactive material in transport are provided in Ref. [6].

3. REGULATIONS AND GUIDES

GENERAL

3.1. Regulations for ensuring the protection and safety of people, property and the environment are formulated primarily according to the national legal framework of a State. However, the transport of radioactive material is often international. National regulations as well as international modal regulations, which are based on the Transport Regulations, apply to such transport.

NATIONAL REGULATIONS AND GUIDES

3.2. To meet the requirements of Ref. [3], an authority responsible for promulgating regulations for the transport of radioactive material should be established.

3.3. National documents for regulating the transport of radioactive material can in principle be grouped into three main categories, namely:

- (a) Documents that set out legislation and national regulations;
- (b) Approval certificates issued by the competent authority and other mandatory documents;
- (c) Guides and other advisory documents.

3.4. National regulations drawn up by the government of a State or by a competent authority on behalf of the government are based on the appropriate legislation. Requirements that are not directly covered by the legislation should be set out in the regulations. The regulations should define the procedures for applying for and granting approval, and should establish the mandatory safety requirements.

3.5. National regulations for the transport of radioactive material should be clear in their intent, purpose and prescription, so that they are readily understandable and applicable, and should be sufficiently comprehensive for the size and type of transport industry to which they apply. Their existence, implementation and enforcement should be widely publicized, so that all persons and organizations concerned are aware of them and of the need to comply with the requirements contained therein.

3.6. Guides may be circulated by the competent authority in order to provide specific and detailed information on the acceptable technical and administrative approaches to satisfying the safety requirements. Such guides should be considered non-mandatory documents, except when the competent authority decides to make them mandatory or to make certain aspects of them obligatory.

3.7. In the preparation of national regulations and guides for the transport of radioactive material, all relevant international agreements, regulations and recommendations should be taken into account. The language used in the preparation of such documents should be appropriate to ensure correct and unambiguous understanding by the users of the regulations. If international regulations and/or modal conventions are adopted or used as national regulations, they should be translated into the official national language(s), and the accuracy of the translations should be verified.

INTERNATIONAL REGULATIONS AND GUIDANCE

3.8. The provisions of the IAEA Transport Regulations govern the worldwide transport of radioactive material. Many supporting publications have been

issued by the IAEA. In 2000, the IAEA changed its regulatory review process and moved to a two year review cycle so as to be consistent with the international modal organizations that produce revisions to their regulations on a biennial basis.

3.9. International bodies have issued many general and modal regulations and recommendations on the safe transport of dangerous goods. As far as the transport of radioactive material is concerned, these documents are based on the Transport Regulations [1]. International regulations and recommendations have been issued, for example, by the International Civil Aviation Organization [8], the International Maritime Organization [9] and the Universal Postal Union [10]. These regulations and recommendations are updated periodically.

3.10. There are also regional agreements, conventions and regulations concerning the safe transport of radioactive material, for example:

- (a) The European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) [11];
- (b) The Convention Concerning International Carriage by Rail (COTIF) [12];
- (c) The Regulations for the Transport of Dangerous Goods on the Rhine (ADNR) [13];
- (d) The MERCOSUR/MERCOSUL Agreement of Partial Reach to Facilitate the Transport of Dangerous Goods, signed by the Governments of Argentina, Brazil, Paraguay and Uruguay in 1994 [14].

The foregoing agreements and conventions are consistent with the Transport Regulations.

3.11. All international transport operations are required to be conducted in accordance with the same regulations. It follows, therefore, that individual States are required to follow and fully implement the provisions of the Transport Regulations, in the interests of international harmonization and safety. However, a State may need to deviate from, or add to, the provisions of the Transport Regulations or of other international regulations and guidelines. In such cases, the competent authority should communicate such differences to the transport industry for the transport of radioactive material, to other competent authorities as appropriate, to the international modal organizations and to the IAEA. Such communications should be used to assist in the efficient

movement of radioactive material between countries and to minimize any delays or misunderstandings.

3.12. The peaceful use of nuclear material is normally ensured by the application of a system for accounting for and control of nuclear material. An introduction to the IAEA safeguards system, which is based on several international agreements, is provided in Ref. [15].

3.13. The Convention on the Physical Protection of Nuclear Material [16] provides for the protection of nuclear material in transport against sabotage and theft. The convention concerns specifically the international transport of nuclear material and is in conformity with the provisions of Ref. [15].

3.14. Security provisions for the transport of radioactive material are provided for in the modal regulations and the IAEA Nuclear Security Series.

3.15. International cooperation may be required when States are affected by transport accidents. Transport incidents, including accidents, that occur in international waters or air space will normally attract international interest and debate, but incidents, including accidents, that occur within a national boundary may also have implications for a neighbouring State or States, and close cooperation between States and authorities is invaluable in such circumstances. Certain transport accidents are covered by the Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency [17].

4. COMPLIANCE ASSURANCE

GENERAL

4.1. The following recommendations will be of assistance specifically to competent authorities that are in the process of developing a compliance assurance programme; however, competent authorities that have established a compliance assurance programme may also benefit from these recommendations. The recommendations will also assist in the uniform application and interpretation of international regulations and guidance on the safe transport of radioactive material.

4.2. The competent authority should put in place a programme for compliance assurance for examining and reviewing all aspects of the transport of radioactive material within its jurisdiction or area of influence with regard to safety and the provisions of the Transport Regulations. In determining the national programme for compliance assurance, the competent authority should take into account not only the quantities and types of packages being transported, but also the size and complexity of the industry for which it has responsibility, as well as its own resources. In all circumstances, compliance assurance should include, as a minimum, the following three fundamental activities:

- (a) Activities relating to review and assessment, including the issuing of approval certificates;
- (b) Activities relating to inspection and enforcement;
- (c) Activities relating to emergency response.

PROVIDING FOR COMPLIANCE ASSURANCE

4.3. Before a compliance assurance programme can be considered to operate and, consequently, reasonable assurance (and evidence) of compliance can be provided, there are a number of actions that need to be taken. In order for a competent authority to obtain assurance of compliance with the Transport Regulations, it should:

- (a) Create and maintain a legal environment in which the competent authority can function effectively;
- (b) Organize itself so as to be independent;
- (c) Be of an appropriate size and have access to the appropriate expertise for the activities relating to the transport of radioactive material for which it is responsible;
- (d) Issue and/or revise regulations and guidelines appropriate to the activities for which it is responsible, with account taken of international regulations and conventions and any changes to these.

4.4. Even after a compliance assurance programme has been developed and introduced, it should not be considered to be complete. Rather, the compliance assurance programme should be reviewed periodically by the competent authority in the light of regulatory changes and with account taken of the experience with its performance of users of the Transport Regulations since the establishment of the compliance assurance programme. The compliance

assurance programme should be updated in a timely fashion when there is any specific change to the Transport Regulations, and should also be reviewed periodically to ensure that it continues to achieve the goals that it was designed to achieve. In some cases such reviews may be performed by external groups.

4.5. As discussed in Section 2, the competent authority should have adequate resources to carry out its functions, which include the operation of its own compliance assurance programme.

4.6. Compliance assurance programmes may be relatively simple and straightforward or may be complex and wide ranging, depending on the size and variety of the industry for which the competent authority has responsibility. For a simple compliance assurance programme, for example, for a State whose industry for the transport of radioactive material is involved only in activities relating to the transport of medical isotopes, account should be taken of, as a minimum:

- (a) Material classification;
- (b) Import and export operations;
- (c) All relevant modes of transport;
- (d) All package types and associated certificates;
- (e) The low volume of transport movements;
- (f) End disposal of packaging.

4.7. A more complex compliance assurance programme will be needed for a State whose industry for the transport of radioactive material is involved in all types of movement of radioactive material. For such a programme, account should additionally be taken of:

- (a) Package design, manufacture and maintenance;
- (b) The high volume of transport movements.

4.8. Irrespective of the size or complexity of the competent authority or its industry, the three fundamental activities stated in para. 4.2 should be addressed in the compliance assurance programme, in a manner that is graded according to the complexity and variety of the particular responsibilities of the competent authority.

METHODS OF ASSURANCE AND INSPECTION

4.9. Assurance of compliance with the Transport Regulations and the associated inspections can be obtained in various ways. Examples of activities that may be carried out in obtaining assurance of compliance are:

- (a) Issuing of approvals by the competent authority;
- (b) Assessment of designs;
- (c) Assessment and approval of the management systems of users of the Transport Regulations;
- (d) Witnessing or inspection of test arrangements;
- (e) Inspection or observation of manufacturing;
- (f) Inspection or observation of maintenance and servicing arrangements;
- (g) Inspection or observation of transport operations;
- (h) Inspection or observation of emergency preparedness arrangements;
- (i) Distribution of information (communication with the industry for the transport of radioactive material);
- (j) Application of enforcement measures, such as:
 - (i) Written notices;
 - (ii) Suspensions;
 - (iii) Prosecutions;
- (k) Interdepartmental liaison and cooperation;
- (l) Review of national and international regulations;
- (m) Review of the compliance assurance programme of the competent authority.

An example of how a complete compliance assurance programme can be organized is provided in Annex I.

ISSUING OF APPROVALS BY THE COMPETENT AUTHORITY

4.10. The Transport Regulations distinguish between cases in which radioactive material can be transported without approval by the competent authority and cases in which some kind of approval is required. In all cases, the Transport Regulations place the primary responsibility for compliance on the consignor. In cases requiring some kind of approval, an independent assessment by the competent authority is required, as appropriate, in respect of the following (Ref. [1], para. 802):

- (a) Designs for:
 - (i) Special form radioactive material;
 - (ii) Low dispersible radioactive material;
 - (iii) Packages containing 0.1 kg or more of uranium hexafluoride;
 - (iv) Packages containing fissile material;
 - (v) Type B(U) packages and Type B(M) packages;
 - (vi) Type C packages;
- (b) Special arrangements;
- (c) Certain shipments;
- (d) Radiation protection programmes for special use vessels;
- (e) The calculation of radionuclide values that are not listed in Table 1 of the Transport Regulations.

As described in Section VIII of the Transport Regulations, some of the items listed above may be subject to the approval of several competent authorities.

4.11. Within the provisions of the national legislation or regulations, approval for the transport of radioactive material should be sought directly from the competent authority in the cases referred to in para. 4.10.

4.12. The respective responsibilities of and the relationship between the competent authority and the applicant or licensee should be clearly understood by all parties. It is the responsibility of the applicant or licensee to demonstrate compliance with the Transport Regulations, and it is the responsibility of the competent authority to review and assess compliance. This should not discourage or prohibit the competent authority from giving informal advice, without commitment, on what is likely to be an acceptable way of demonstrating compliance.

4.13. Upon receipt of an application for approval, the competent authority should evaluate whether or not all relevant regulatory requirements are fulfilled. A competent authority may also be interested in the safety of a shipment within or through the State, for which its approval is not required by the Transport Regulations. If this is the case, all necessary documents should be made available to the competent authority of the State concerned.

4.14. When an approval by the competent authority is required for a design or a shipment, approval should be considered on the basis of the assessment that was made of the application that was sent to the competent authority. A list of items that may be submitted to the competent authority is provided in Annex II.

4.15. For each application for approval, the competent authority should evaluate compliance with the Transport Regulations. The application should be accepted or rejected on the basis of the results of this evaluation. If the application is successful, the competent authority should provide the applicant with an approval certificate (see Section VIII of the Transport Regulations and Annex III of this Safety Guide).

4.16. To meet the requirements of the Transport Regulations and of Ref. [2], an integrated management system is required for all transport related activities. The competent authority should verify that the management system of the applicant provides for compliance with the Transport Regulations and that it is consistent with the number, complexity and radiological significance of the transport movements that are carried out.

4.17. The competent authority should verify that the applicant and subsequently consignors and carriers have in place adequate provisions for preparedness for and response to an emergency in the transport of radioactive material.

4.18. When considering applications for approval of shipments under special arrangement, the competent authority should assess the demonstration by the applicant that the overall level of safety provided by the design of the package and the supplementary operational controls during transport is at least equivalent to that which would be achieved if all applicable regulatory requirements were met. Possible additional operational controls that may be employed are discussed in Ref. [18] (para. 825.1), for example.

4.19. The different types of approval certificate are discussed in greater detail in Section 5 of this Safety Guide, and details of specific information that may be included in applications for approval are provided in Annex II. The competent authority is required to comply with the Transport Regulations when it considers applications for approval, and to issue the appropriate certificates of approval containing all the required information. Appropriate records should be maintained by the competent authority to demonstrate that proper and due consideration was given to each application before the necessary approval was issued.

4.20. Consistent with the national practice and with due regard for any legitimate commercial considerations, the competent authority should be prepared to supply copies of its approvals to other users of the Transport Regulations (other than the original applicant) in order to facilitate their compliance with any specific requirements or conditions.

SPECIAL FORM RADIOACTIVE MATERIAL AND LOW DISPERSIBLE RADIOACTIVE MATERIAL

4.21. The Transport Regulations require unilateral approval for the design for special form radioactive material and multilateral approval for the design for low dispersible radioactive material to be issued prior to transport.

4.22. The competent authority should satisfy itself that the arrangements of the management system for the design for and testing and manufacture of special form radioactive material or low dispersible radioactive material are appropriate and adequate, with due regard for the nature of the material and the amounts that are likely to be produced.

4.23. Before the commencement of tests by the applicant, the competent authority should inspect the test facilities and arrangements, especially the specimens, the target for drop tests, and the measuring and recording systems. The competent authority may also witness the tests. The applicant should inform the competent authority of any deviation from the test plan and should present the results of testing — for example, evidence of leakage, distortion or other damage — to the competent authority.

4.24. The final application for approval of the design for special form radioactive material or low dispersible radioactive material should be sent to the competent authority. The application should include, among other information as described in Annex II, the final test programme and the test results, which need to be evaluated by the applicant. The application should specify the requirements for the individual special form radioactive material or low dispersible radioactive material and should demonstrate that the regulatory requirements have been met.

4.25. The competent authority should give consideration to the design life, the operating lifetime and the necessary identification of special form radioactive material or low dispersible radioactive material, as well as to the in-service inspections and safety checks to be made in order to ensure the continued integrity of the special form radioactive material or low dispersible radioactive material.

4.26. When the competent authority has verified that the design for special form radioactive material or low dispersible radioactive material meets all the valid regulations, it should issue an approval certificate. Examples of templates for approval certificates are given in Annex III.

4.27. During the manufacture of special form radioactive material or low dispersible radioactive material, the competent authority should carry out random inspections and/or reviews of the management system of the manufacturer to ensure that all the requirements have been correctly implemented.

PACKAGES REQUIRING COMPETENT AUTHORITY APPROVAL AND PACKAGE DESIGN ASSESSMENT

4.28. The competent authority may discuss the development and the proposed tests of a package with the applicant on the basis of the preliminary information provided. The preliminary information may cover the topics described in Annex II. Specifically, it may include the test plan for the package, with a clear statement of the scale of the model, the requirements and specifications of the model, the number of tests proposed, the drop attitudes for packages, the essential measuring and recording equipment to be used, and the nature of the target for drop tests. The preliminary information may also cover the requirements of the management system for design and testing.

4.29. The competent authority should give particular consideration to special features of the package design, as well as to the test plan. If it is proposed by the applicant to use a scale model specimen, it should be ensured that all relevant features of the original are adequately scaled and represented, including materials, contents and internal structures. The adequacy of the means proposed to establish compliance with the Transport Regulations should be reviewed. Account should be taken of instrumentation to be used for the measurement of physical quantities such as local accelerations, strains and internal pressure transients.

4.30. The competent authority should verify that the manufacture of models or prototypes is carried out in a controlled manner that complies with the management system of the manufacturer so that the models or prototypes are representative of the proposed package design. Particular consideration should be given to materials, welding and inspections, as well as to the results of quality control tests. Any deviations from the requirements and specifications should be declared, justified and recorded by the applicant, and presented to the competent authority for agreement.

4.31. Before the commencement of tests by the applicant, the competent authority should inspect the test arrangements, especially the specimen, the

target for drop tests, and the measuring and recording systems. The competent authority may also witness the tests. The applicant should inform the competent authority of any deviations from the test plan and should present the results of testing — for example, evidence of leakage, distortion or damage — to the competent authority.

4.32. The final application for approval of the package design should be sent to the competent authority. The final application for approval should include, among other information as described in Annex II, the final test programme, the results of testing and the evaluation report. The application should describe the management system of the applicant and should state in particular the requirements for the series production of packagings and their proper maintenance and use. Specifically, the applicant should demonstrate that the requirements for the package type in question have been met. The following aspects should be included, if appropriate, and should be verified by analyses (for routine, normal and accident conditions of transport):

- (a) Criticality safety;
- (b) Heat transfer;
- (c) Radiation safety (including shielding);
- (d) Structural integrity.

According to the Transport Regulations, compliance with the specific test requirements may also be demonstrated by means of analyses if suitable criteria or established comparative data are available.

4.33. When assessing safety, the competent authority should, as appropriate, make independent assessments to verify the results presented in the application for approval of the package design. In making such assessments, the competent authority should ensure that proper computer codes and models have been used, that they have been validated and that all input data have been correctly and, if appropriate, conservatively defined. Depending on the package type, expertise in different areas will be needed by the competent authority. The evaluation by the competent authority should also specifically cover the provisions made by the applicant or designer for the manufacture, servicing, maintenance and use of the package.

4.34. When assessing applications for approval of package design, the competent authority should ensure that full and proper provision has been made for the application, legibility and durability of identification marks and serial numbers, as well as for the proper notification to the competent authority

of the serial numbers of packages. This is particularly important in cases where multiple or interchangeable packaging components are used.

4.35. In the case of applications for full approval in respect of the current edition of the Transport Regulations [1] concerning designs previously approved under the 1973, 1973 (As Amended), 1985 or 1985 (As Amended 1990) editions of the Transport Regulations, the competent authority should evaluate the design fully against all appropriate aspects of the current Transport Regulations. This may involve an in-depth ‘design review’ of the materials and manufacturing methods, as well as of the testing and the programme of quality assurance applied to the original design of packagings. Similarly, when changes are made in the design of the packaging or in the nature or quantity of the authorized radioactive contents that would significantly affect safety, as described in paras 816 and 817 of the Transport Regulations, the competent authority should ensure that all appropriate aspects of the design and of the manufactured packaging are evaluated against the requirements of the current edition of the Transport Regulations [1].

4.36. The design of the package in question should be accepted or rejected on the basis of the evaluation results. In the case of acceptance, an approval certificate should be issued by the competent authority. More detailed recommendations on approval certificates are provided in Section 5, and an example of a template for approval certificates is provided in Annex III.

APPROVAL OF SHIPMENTS UNDER SPECIAL ARRANGEMENT

4.37. The Transport Regulations permit a consignment that is known beforehand not to satisfy the applicable requirements to be transported under special arrangement. Upon approval of such a shipment under special arrangement, the competent authority issues an approval certificate, as required in para. 826 of the Transport Regulations. Moreover, for international shipments of this type, multilateral approval is required.

4.38. For a shipment under special arrangement, the applicant is required to demonstrate to the competent authority that the overall level of safety is at least equivalent to that which would be provided if the applicable requirements of the Transport Regulations had been met. The competent authority should give consideration to the reasons why the shipment cannot be made in full accordance with applicable requirements.

4.39. The competent authority should carefully evaluate the provisions for control of design and operation submitted to it by the applicant for approval. To maintain its objectivity, the competent authority should not take part in activities relating to the control of design and operation.

4.40. The information submitted by the applicant for approval of a shipment under special arrangement is required to include, as appropriate:

- (a) The necessary information relating to the particular package design;
- (b) The applicable requirements of the Transport Regulations with which the shipment is not in compliance;
- (c) The design, operational, administrative or special provisions that will be employed during transport and storage in transit to compensate for the inability to meet the applicable requirements of the Transport Regulations.

PACKAGES NOT REQUIRING APPROVAL BY THE COMPETENT AUTHORITY

4.41. The compliance assurance programme of the competent authority should also cover the design, manufacture and use of packages and the maintenance of packagings that do not require approval by the competent authority.

4.42. Experience with the certification and use of package designs that do not require approval by the competent authority has shown that particular consideration should be given by the competent authority to ensuring that there is full compliance with the applicable requirements (paras 306 and 801 of the Transport Regulations). In particular, the following subjects for inspection by the competent authority should be addressed:

- (a) The management system within which the package is designed, manufactured and transported;
- (b) The design process and the internal process for granting approvals;
- (c) Control of manufacturing;
- (d) The programme for maintenance of packagings (in the case of reusable packagings).

IDENTIFICATION OF PACKAGES AND SERIAL NUMBERS OF PACKAGINGS

4.43. For the safe transport of radioactive material, once packagings have been correctly designed, assessed and manufactured, it is required that they be correctly identified throughout their lifetime. The Transport Regulations specify the identification marks assigned by the competent authority, the serial numbers of packagings and the markings of the package types that are required to be present during transport; Ref. [18] provides further recommendations on the legibility, durability and positioning of such markings. In its activities relating to compliance assurance, the competent authority should take every opportunity to verify that all required markings, serial numbers and identification marks are correctly, durably and appropriately applied to packages.

4.44. The scheduled inspection and maintenance programme of the user should include provisions for inspecting and, if necessary, correcting all permanent markings and for repairing any damage or defects. Such inspections by the user will show whether markings are indeed durable.

4.45. The competent authority should control the allocation of the required identification marks and should advise applicants of the allocation process. Identification marks can be assigned readily by the competent authority during the preliminary design assessment or evaluation phase. The arrangements for the allocation of the required identification marks should be such as to prevent two or more different designs of packages entering service with the same identification marks. The competent authority should also communicate to the transport industry recommendations on the self-allocation or determination of identification and design numbers for package designs that are not subject to approval by the competent authority, to avoid confusion in transport and in the event of an emergency.

4.46. The serial number on the packaging is required to uniquely identify each packaging manufactured. For packagings manufactured to an approved Type B(U), Type B(M) or Type C package design, and for packagings designed to contain fissile material, it is required that the appropriate competent authority be informed of the serial number (Ref. [1], para. 819). In this case, the term 'appropriate' has a broad interpretation and could pertain to any or all of the following:

- (a) The competent authority of the State in which the design of the packaging originated;

- (b) The competent authority of the State in which the packaging was manufactured;
- (c) The competent authority of the State or States in which the packaging is used.

In the case of packagings approved for continued use under paras 816 and 817 of the Transport Regulations, all competent authorities involved in the multilateral approval process should be provided with and should retain information on the serial numbers of the packagings.

4.47. An approved package design may be such that different internal components are used with a single outermost component, or that the internal components of a packaging are interchangeable between more than one outermost component. In such cases, each outermost component of the packaging with a unique serial number will identify the packaging as an assembly of components; this will satisfy the requirements of para. 539(b) of the Transport Regulations, provided that the assembly of components is in accordance with the design approved by the competent authorities. In such cases, the correct identification and use of the components should be ensured through the management system established by the consignor.

RADIATION PROTECTION

4.48. Paragraphs 301–303 of the Transport Regulations establish the general requirements for radiation protection and the requirements for radiation protection programmes in the transport of radioactive material. Through its compliance assurance programme, the competent authority should ensure that the requirements have been met, for example, by requesting information on and inspecting the radiation protection programmes in use in the industry. Specific recommendations on Radiation Protection Programmes for the Safe Transport of Radioactive Material are provided in Ref. [19].

4.49. Appropriate radiation monitoring equipment should be used, as well as appropriate equipment and containers for samples of radioactive material to be analysed. The equipment should be calibrated and maintained, and the staff using it should be adequately trained and qualified. Where necessary, the competent authority should require the inclusion of information on radiation protection programmes in applications for approval. Further, the places where radioactive material is handled and stored are required to be segregated sufficiently from places occupied by transport workers and members of the

public (see paras 563 and 569 of the Transport Regulations). The competent authority should ensure that the parameters for calculating the segregation distances have been properly determined. The competent authority should ensure through inspections that the requirements for all modes of transport have been met in practice.

4.50. The Transport Regulations require that radiation exposures from the handling, storage and transport of radioactive material be kept as low as reasonably achievable, with economic and social factors being taken into account (i.e. optimization of radiation protection). The competent authority should ensure through its compliance assurance programme that this requirement has been met.

4.51. The competent authority is required to arrange for periodic assessments to evaluate the radiation doses to workers and to members of the public due to the transport of radioactive material (para. 308 of the Transport Regulations). Data from consignors and carriers that need to assess the doses arising from their transport operations may be used in such assessments of radiation doses by the competent authority. However, the competent authority should independently verify the data received from consignors and carriers. Questionnaires, analyses, site visits and measurements may be used to assess doses.

RADIOACTIVE MATERIAL HAVING OTHER HAZARDOUS PROPERTIES

4.52. In addition to posing radiological hazards, radioactive material may have other hazardous properties that may pose additional hazards, for example, chemical toxicity and corrosiveness. Such properties are known as ‘subsidiary hazards’ in international regulations and recommendations on the transport of dangerous goods.

4.53. The Transport Regulations stipulate provisions against radiological and criticality hazards of radioactive material; in addition, they require that national regulations and international requirements for the transport of dangerous goods also be complied with in the transport of radioactive material having other hazardous properties. The competent authority should ensure that national regulations for the transport of dangerous goods are followed in practice in the transport of radioactive material posing subsidiary hazards. This may involve liaison and cooperation between the competent authority and any other governmental bodies that are responsible in such matters, to ensure that

all primary and subsidiary hazards are properly recognized and that protection against them is provided for, and that a true perspective of the relative importance of the hazard is maintained in the various inspections carried out by different bodies or inspectors.

THE MANAGEMENT SYSTEM IN SUPPORT OF COMPLIANCE ASSURANCE

4.54. It is expected that competent authorities will need to make increasing use of the management system of the user in ensuring compliance with the Transport Regulations (see, e.g., Annex IV of this publication). The Transport Regulations (para. 306) require the establishment and implementation of quality assurance programmes for all packages and all aspects of transport. When issuing competent authority approvals, the competent authority is required to consider the appropriate quality assurance programme(s) within the management system for transport. Therefore, in a compliance assurance programme the competent authority should pay particular attention to assessing the user's application of the management system for the design, procurement, manufacture, testing, inspection, use and maintenance of packagings.

4.55. It is recognized that the management system plays an important part in the efforts of the competent authority to obtain full assurance of compliance with the Transport Regulations because:

- (a) For all aspects of the transport of radioactive material, an appropriate management system is necessary.
- (b) The management system uses quality assurance as a management tool.
- (c) The management system can be used to demonstrate compliance.
- (d) The management system can assist in self-correction or self-improvement.
- (e) Techniques of the management system can be used by the competent authority in assessing compliance.
- (f) The application and use of a management system can promote public confidence in the transport of radioactive material.

4.56. The competent authority should use the management system employed by the transport industry in support of its own programme for compliance assurance. When applications for approval are received by the competent authority, the management system of the applicant should be examined and

verified. The management system may be relatively straightforward, or it may involve more complex interacting programmes if design, testing, manufacture, use, servicing and maintenance are carried out by different organizations, each with its own, separate management system. Matters may be further complicated if, for example, the management system of a particular organization applies to the design, testing and manufacture of a range of packages, but separate quality plans are applicable for each individual package design or type. The competent authority may confirm the adequacy of the applicant's management system not only by examining the actual written programmes and plans but also by auditing the arrangements to verify their correct functioning. When the competent authority has confirmed the existence of a satisfactory management system, it may issue an approval certificate for the management system.

4.57. The interest in the management system does not end with the issuing of a certificate; further action should be taken to ensure that the packages concerned continue to comply with the approved specification. The original design and its approval should not be compromised in subsequent use. The competent authority should therefore further examine or audit the management system applied to all transport operations that take place after manufacturing, such as servicing, maintenance, modification and use.

4.58. The competent authority should put in place an auditing programme to verify that the user's management system is implemented and followed correctly. The management systems used by designers and manufacturers, and by users of special form radioactive material, low dispersible radioactive material, Type B(U) packages, Type B(M) packages, Type C packages and packages containing fissile material, will be of particular interest to the competent authority. However, the competent authority should also ensure by means of an ongoing audit or inspection programme that suitable management systems are implemented in the transport of packages of other types. In determining the auditing programme, the continuity of the activity in question should also be taken into account; that is, the auditing programme for the manufacture of a single package may be different from that for the manufacture of packages in a continuous manner.

4.59. The auditing programme may cover all aspects identified in Ref. [20]. An example of a checklist for auditing a management system is provided in Annex V of this Safety Guide. The competent authority should give particular consideration to the activities in the management system before the manufacture of packagings begins.

4.60. Irrespective of the size of the organization concerned or the scale of its activities, the competent authority should verify through audits that, consistent with the recommendations provided in Ref. [20], the management system of the applicant, the designer, the manufacturer and/or the user is based on the following:

- (a) An organizational structure and competent personnel for administering and conducting activities in the management system;
- (b) The capability to develop, as needed, all procedures and instructions required to guide, control and verify the conduct and evolution of activities in the management system;
- (c) Means to develop, maintain and make accessible to the competent authority all necessary records and documents of the management system;
- (d) Activities carried out to comply with the Transport Regulations and any additional national requirements.

4.61. The extent of the management system will depend on the type of transport activities being considered, ranging from minor requirements for infrequent transport of packages excepted from approval by the competent authority to extensive detailed requirements for the regular transport of packages subject to such approval. Annex I of Ref. [20] provides information on how to address the various elements of the management system; this is presented in the form of a table. The management system of each user should be made available for review and audit by the respective competent authority or by another relevant authority.

4.62. In verifying the effectiveness of the arrangements within the management system of a user, the competent authority should inspect procedures, records and facilities, especially facilities in which designers and manufacturers perform their operations. The competent authority should verify that:

- (a) The design of a package is accurately described by engineering drawings, material specifications and records of the methods of construction. (Note: For package designs requiring approval by the competent authority, this information is a required part of the application for the approval certificate. For package designs that do not require approval by the competent authority, the information should be provided to the competent authority by the user upon request.)
- (b) The packagings are manufactured in complete accordance with the design. (Note: For package designs that require approval by the

competent authority, changes or modifications in the construction methods for the packaging, the materials of construction, etc., are subject to the approval of the competent authority. Such changes or modifications are required to be approved by the competent authority before the change or modification can be put into effect. For package designs that do not require approval by the competent authority, such changes should be documented and made available to the competent authority upon request. This applies equally to new package designs and to packagings in service.)

- (c) Equipment used for inspection, measurement, testing and manufacturing is suitable for its purposes, and is properly controlled, calibrated, used and maintained in accordance with procedures and schedules, and all results from inspections, measurements and testing and all products of manufacturing are fully documented.
- (d) The packages are correctly prepared, packed and transported. This includes all necessary servicing, maintenance and other administrative procedures, as well as appropriate measures for radiation protection.
- (e) All non-conformance is correctly documented and reviewed, and accepted or rejected, and notified to the competent authority as appropriate.

TRANSPORT INSPECTIONS

4.63. A major feature of the compliance assurance programme of a competent authority will be the performance of inspections of transport operations, since such 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. Such inspections may be carried out during any phase of the transport or during storage in transit and may be announced or unannounced. They should, however, be planned (as far as possible), and their frequency should be determined in accordance with the scope and activities of the organization being inspected, as well as with the complexity and radiological significance of the activities. Examples of checklists that could be used for such inspections are provided in Annexes VI and VII.

4.64. Inspections of transport operations should be carried out by the competent authority or by an agent nominated by it. In some States 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. In such cases, the

competent authority acts as an adviser to the agents nominated to carry out inspections and as the coordinator of the inspections. All types and aspects of transport should be periodically inspected, in accordance with the size of the industry for the transport of radioactive material in the State.

4.65. In inspections of a user's activities, the competent authority or its agent should give specific consideration to verifying the following:

- (a) The user's management should provide the necessary personnel and resources to carry out an effective programme for compliance with the Transport Regulations. This programme may be a part of the management system of the user. The persons who are responsible for fulfilling the various specific requirements and who are capable of doing so should be clearly identified. The management should clearly delegate authority to those responsible persons.
- (b) The user's management should provide proper training for those persons who are responsible for carrying out the programme for compliance with the Transport Regulations, and should document the training.
- (c) The consignor should use the proper packaging for the specific contents of packages. The packages being prepared for shipment should be examined by the competent authority, where practicable.
- (d) The user should have in its possession all the required documentation, including the relevant approval certificates of the competent authority and any associated instructions for handling, loading, stowage and use of packages, and for the maintenance of packagings. These instructions are usually in the form of an instruction manual.
- (e) The user should follow established procedures for the preparation and use of the packages, in accordance with the approval certificate, the instruction manual and related documents.
- (f) Procedures should be established and followed to properly mark and label packages in accordance with the Transport Regulations. This should include the proper determination and application of the correct transport index. When practicable, the competent authority should observe these actions by the user.
- (g) Procedures should be established and followed, and appropriate and properly calibrated instruments should be provided, to monitor both the levels of radiation and the contamination of packages.
- (h) Procedures should be established and followed for the correct preparation and control of all relevant shipping documents, as well as for the correct placarding of the carrier's vehicles and the provision of the required documentation for carriers and of any required notification of

the competent authorities of each State into which or through which the consignment is to be transported.

- (i) In transport, carriers should be performing the required actions relating to the placarding, stowage and separation of packages, etc., and in particular any administrative controls relating to exclusive use shipments or supplementary operational controls as specified in the approval certificate of the competent authority.
- (j) Procedures should be established to respond to cases of non-compliance and to meet the requirements of para. 309 of the Transport Regulations.

4.66. Upon completion of the inspection by the competent authority, the user's management should be provided with a summary of the results of the inspection, including any non-compliance noted; this makes it possible for the management to react to these findings. Such a summary may be followed by a letter from the competent authority to summarize the findings and request a written response, if necessary.

4.67. As part of its compliance assurance programme and the associated inspections of transport operations, the competent authority should also consider the occasionally different requirements that apply to freight containers and tanks. Other international conventions and standards concerning these types of package should also be taken into account (see, e.g., Refs [8–10]). The recommendations provided in this Safety Guide apply equally to transport operations involving freight containers and tanks.

4.68. The specific requirements for notification of the competent authority are established in paras 558–561 of the Transport Regulations. The competent authority may request additional notification before a package is shipped or after it has been received, so that plans can be made for certain inspections. The need for further notification should be determined in accordance with the package types and the number of shipments made and received.

4.69. The competent authority should analyse the reports of all relevant inspections as well as their findings. Such analysis will help the competent authority to decide whether the performance of the user and the user's compliance with the Transport Regulations are satisfactory. It will also assist in detecting unsatisfactory performance or trends and enable the competent authority to take whatever action it considers appropriate to restore a satisfactory situation, thereby continuing to ensure compliance with the Transport Regulations. All inspection reports should be retained by the competent authority for an appropriate time, because they constitute part of

the evidence of compliance as required in para. 307 of the Transport Regulations.

4.70. If, as a result of transport inspection or of any other actions, an unsatisfactory situation or a case of non-compliance comes to the attention of the competent authority or its agent, the matter should be followed up to determine the real cause of the problem and to initiate suitable action to prevent its recurrence. Certain enforcement actions (discussed in paras 4.115–4.120) may be necessary if non-compliance is discovered. In some cases a more informal approach by the competent authority involving education or training may be more appropriate.

RESPONSIBILITIES AND ACTIONS OF CONSIGNORS

4.71. Regulations for the transport of dangerous goods require the consignor to dispatch a package safely and in a manner that complies with the regulations. The consignor may be the owner or manufacturer of the package, or the user or operator of a package owned by a third party. The consignor is required to comply with the Transport Regulations both at the point of dispatch and during the subsequent transport of the package. The consignor may delegate some of the actions needed to achieve this compliance but is required to retain overall responsibility for these actions and for their completion. The declaration on the transport documents signed by the consignor attests to this responsibility.

4.72. The competent authority should be provided with the legal means that enable it to determine that the consignor's responsibilities, as defined in paras 549–562 of the Transport Regulations, are clearly understood and followed by all consignors of radioactive material. The competent authority should verify the following:

- (a) The consignor should have an appropriate and functioning management system to cover all aspects of its responsibilities and activities in the transport of radioactive material. (For example, if a consignor consigns only one type of package infrequently, the consignor may control and carry out all activities directly. Another consignor that produces or reuses a large number of different package types may use different contractors for different parts of the work, but the activities of such contractors should be provided for and controlled by means of the consignor's management system.)

- (b) The consignor should have an appropriate and clear understanding of the nature, form and levels of activity of the radioactive material to be consigned. For all radioactive materials, preparation, loading and filling are required to be done under carefully controlled appropriate conditions in accordance with detailed procedures to ensure compliance with the Transport Regulations [1].
- (c) The consignor should fill or load the material into the packaging for transport in a correct way. (For example, this could involve verifying that the contents of the package have been positioned correctly within the packaging to maximize the shielding protection afforded by the packaging; it could also involve verifying that other specified parameters are correct.)
- (d) The consignor should correctly identify and use a suitable packaging for which there is an appropriate valid approval certificate. (For example, package design approvals should be valid for the duration of the complete journey and should not expire in the course of long international transport. Also, the approval certificate or series of certificates is required to cover the entire radioactive contents permitted to be carried; the consignor is required to have available the correct certificate for the contents being transported.)
- (e) The consignor should have the relevant packing instructions for the package; copies of these instructions are required to be available at the location where the package is prepared for transport. The packing instructions provide detailed information and instructions on the loading configuration of the contents, the closure methods, the tightening torques of fasteners, etc. Such packing instructions should be complied with so that transport safety is preserved.
- (f) The consignor should have procedures in operation to ensure that the packaging used for transport conforms to the specifications indicated on the approval certificate and is in an acceptable condition. (For example, for new packagings, the consignor should have evidence, such as certificates of conformity or inspection reports, that the packagings conform to the specifications quoted on the approval certificate. In the case of reusable packagings, the consignor should have evidence, in the form of inspection reports, release notes, certificates of conformity, etc., that all necessary and specified servicing and maintenance work has been carried out and that the packaging is suitable for the next complete transport operation or programme of movements. The consignor's procedures should be such as to prevent the use of a package that does not comply with the approved specifications or that has not been subjected to the required and specified servicing and maintenance.)

- (g) The consignor should be able to determine, complete and apply the correct labels for packages and should also understand what other markings are required to be featured on the package when it is presented for transport. (For example, the consignor should be able to demonstrate to the competent authority the appropriate ways to determine the transport index and should have correctly functioning and calibrated monitoring instruments for measuring the radiation levels of the package, the overpack, the freight container, etc. The consignor should also know what other kinds of markings, such as competent authority identification marks, are required to appear on the package, how they are determined and how durable they should be.)
- (h) The consignor should have appropriate knowledge and instruments to carry out the necessary relevant measurements and the necessary checks for contamination associated with the transport of radioactive material. (For example, the consignor or the person or organization contracted by the consignor to carry out measurements and checks under the consignor's control should be able to satisfy the competent authority that it is capable of carrying out valid, calibrated measurements of the levels of radiation and contamination, to ensure radiation protection and transport safety.)
- (i) The consignor should have the necessary licences or other permissions, granted by the competent authority or by other federal or governmental bodies, to function as a consignor of radioactive material. Also, the competent authority should be satisfied that the consignor is cognizant of the applicable current approvals required for the transport of radioactive material. (For example, in some States the consignor must obtain appropriate permissions or licences from the responsible organization(s) to be able legally to consign or transport radioactive material; this is particularly important for the movement of radioactive material in cases where considerations of security and physical protection and considerations for the accounting and control of nuclear material apply. The consignor should also be in possession of the relevant approval certificate for the package design and of other approvals of the competent authority for inspection by another competent authority, if necessary.)
- (j) The consignor should be able to obtain and complete the necessary transport documents, giving the appropriate information as required in paras 550–554 of the Transport Regulations. The consignor should also provide the necessary transport documents to enable any subsequent carrier(s) to meet any other applicable national or international modal regulations; the consignor should maintain records of consignments for a time period as agreed with the competent authority. (For example, during

inspections by the competent authority it should be verified that pertinent and accurate information is given in the transport documents, which are sometimes called shipper's certificates or consignment notes. These documents are provided by the consignor, which should have either suitable evidence or a management system to substantiate the declared details. In the transport documents, account should also be taken of any variations imposed by national or international modal regulations, and the consignor should be able to demonstrate to the competent authority an understanding of such regulations. It should also be verified that the transport documents cover the entire journey of the package(s) and are not restricted to a particular airport or port of entry or exit.)

- (k) The consignor should provide sufficient information and documents to the carrier(s) to enable the package(s) to be carried safely and in compliance with the Transport Regulations. (For example, the provision of essential information and documents to the carrier(s) can be verified by the competent authority in its inspections of both the consignor and the carrier(s). The carrier(s) should have a clear understanding of all applicable transport or in-transit operational requirements, all restrictions on the mode of transport or conveyance and all necessary routing restrictions, and of the appropriate arrangements in the event of an emergency or mishap, which they should be able to put into effect without misunderstanding.)
- (l) The consignor should be able to determine when it is necessary to notify the competent authorities of transport movements and should understand the importance of such notifications. (For example, through its inspections of consignors and its liaison with other competent authorities, the responsible competent authority should verify that the required notifications are being made.)
- (m) The consignor should have dispatched or should be capable of dispatching a package or consignment in compliance with the Transport Regulations. (For example, the competent authority should verify that the consignor's management system provides evidence that all necessary pre-dispatch activities have been specified and completed, and that the declaration and signature of the final consignor is valid and meaningful.)
- (n) The consignor should have appropriate procedures in place to detect cases of non-compliance and to respond in accordance with the requirements of para. 309 of the Transport Regulations.
- (o) The consignor should establish an appropriate radiation protection programme that meets the requirements of para. 302 of the Transport Regulations (additional information on radiation protection programmes is provided in Ref. [19]).

ACTIONS AND OPERATIONS OF CARRIERS

4.73. According to the Transport Regulations, the consignor has the primary responsibility for transport safety; the consignor is required to ensure safety through the selection of packagings and the procedures for preparation of packages. Each carrier (there may be several carriers for a single international transport operation) should ensure that its contribution to transport safety is complementary to the efforts of the consignor and that overall transport safety is not compromised as a result of the carriage operations.

4.74. Although the Transport Regulations do not identify specific responsibilities for carriers, the competent authority should ensure — for example, by contract or direct inspection — the following:

- (a) The carrier should have an appropriate and functioning management system that covers all relevant aspects of the carrier's responsibilities and activities in the transport of radioactive material. (For example, a carrier that carries only one type of package only occasionally, using one mode of transport within national boundaries, may have a relatively simple management system, whereas a national or international carrier that carries large numbers of packages frequently and operates a multimodal carriage and distribution service will need a more comprehensive management system to control its activities and to provide the necessary assurances.)
- (b) The carrier should have sufficient knowledge of national and international regulations to be aware of the information and documents that it should receive from the consignor. (For example, the carrier should be able to demonstrate its knowledge and understanding of the applicable requirements of the Transport Regulations and its procedure for checking the validity and accuracy of the transport documents.)
- (c) The carrier should have the ability and the resources to respond to any additional specified requirements concerning loading, stowage, transport, handling and unloading of packages, as well as the ability to recognize and comply with any restrictions on routeing, means of conveyance or mode of transport. (For example, the carrier should be able to demonstrate that the means of conveyance used, such as trucks or railway wagons, have the necessary facilities or equipment for achieving secure tie-down arrangements and that any additional speed limits that are specified are complied with. Also, if escort vehicles and personnel are required for the transport operation to be approved or to comply with

other regulations, the carrier should satisfy the competent authority that it can provide them.)

- (d) The carrier should be able to recognize damaged or poorly prepared packages; should be familiar with all appropriate placards, package labels and markings, and should understand their meaning and purpose; and should be able to relate the information displayed to the details given in the transport documents. (For example, the carrier should have the appropriate procedures and the necessary understanding to ensure that any damaged, poorly prepared or incorrectly labelled packages will be rejected or quarantined, that packages will be correctly stowed within the vehicle and that basic checks of the transport documents against the package labels will be conducted.)
- (e) The carrier should operate vehicles or other means of conveyance that can be used to carry the radioactive material or packages safely, without overloading, without infringing the required segregation distances and without exceeding the limitations on the transport index and the criticality safety index, etc.; also, the carrier should ensure that, when required, the number, type and size of placards on the conveyance meet the regulatory requirements.
- (f) The carrier should have in place appropriate arrangements for an emergency involving the types of radioactive material being carried and the type of conveyance being used. (For example, the carrier may have its own emergency arrangements; alternatively, the carrier may participate in or use the consignor's emergency arrangements or other national emergency schemes or arrangements. Irrespective of the emergency arrangements that apply, the carrier should be able to demonstrate suitable familiarity with and understanding of such matters, and all personnel involved should receive the necessary training in the emergency arrangements.)
- (g) The carrier should have provided for appropriate control of operations in connection with storage in transit, in particular with regard to the safety of workers and the public, and should also have provided for the control of radiation exposure and for the necessary segregation of the radioactive material from other dangerous goods. (For example, the carrier should not allow radioactive material to be stored during transit in places occupied by workers or other persons, or in places where photographic film is stored. The carrier should be able to demonstrate that it is cognizant of and controls the number of category II-YELLOW and category III-YELLOW packages, for example, that may be stored in certain areas.)

- (h) The carrier should have appropriate procedures in place to recognize cases of non-compliance and to respond in accordance with the requirements of para. 309 of the Transport Regulations.
- (i) The carrier should have established an appropriate radiation protection programme that meets the requirements of para. 302 of the Transport Regulations (additional guidance on radiation protection programmes is provided in Ref. [20]).

ADDITIONAL RESPONSIBILITIES

4.75. The examples given in paras 4.72 and 4.74 should not be considered to be exhaustive; other examples may be added in the light of knowledge and experience.

DESIGN ASSESSMENTS

4.76. Design is defined in the Transport Regulations (para. 220) as “the description of *special form radioactive material, low dispersible radioactive material, package, or packaging* which enables such an item to be fully identified. The description may include specifications, engineering drawings, reports demonstrating compliance with regulatory requirements, and other relevant documentation.” Thus, ‘design’ should be considered to include much more than the drawings and specifications that enable the packaging to be manufactured. The design to be assessed includes the supporting reports and documents that substantiate or verify statements or assumptions made by the designer. It also includes all relevant arrangements for package preparation, instructions or provisions for maintenance and servicing, and any approved procedures for repair or modification.

4.77. Section VI of the Transport Regulations establishes requirements for all packagings, packages, low dispersible radioactive material, special form radioactive material and low specific activity material; the designs of such radioactive material, packagings and packages can be assessed in respect of their compliance with the regulatory requirements. In the case of the designs specified in para. 802 of the Transport Regulations, approval by the competent authority is required, and hence the design is required to be assessed by the competent authority or its agent.

4.78. It is the responsibility of the competent authority to ensure that the designs of packages are assessed against all the relevant parts of the Transport Regulations. Therefore, the competent authority or its agent should not only conduct assessments of designs in respect of para. 802(a) of the Transport Regulations, but should also ensure that similar assessments of package designs that do not require approval by the competent authority (such as Type A packages or industrial packages) are carried out by the appropriate organizations and that the necessary evidence of such assessments is made available to the competent authority, if requested.

4.79. Irrespective of which organization carries out the design assessment, the assessor should be aware of the basic purpose of the Transport Regulations and should give very careful consideration to any aspect of the design, however obscure, that could adversely affect:

- (a) The effective containment of the radioactive material;
- (b) The effective control of any radiation emitted from the package;
- (c) Maintenance of a subcritical condition for any fissile material;
- (d) The adequate dissipation of heat generated within the package.

4.80. The applicant seeking approval should provide the assessor with all necessary information, including the documents to demonstrate that the design meets all regulatory requirements. The assessor should be clearly independent of the applicant and should not be expected to 'make the case' for the applicant. However, the assessor should encourage early contact with the applicant, even in the preliminary design feasibility stages (i.e. before formal application for approval is made). The assessor and the applicant should discuss the application for approval and the implementation of any novel and other relevant design features or principles, thereby avoiding unnecessary or wasted efforts by both parties involved.

4.81. Reviews and assessments by competent authorities of applications for approval are usually demanding with regard to the necessary resources, skills and expertise. The following aspects should be considered:

- (a) The assessor should have a thorough knowledge of the Transport Regulations pertinent to the design under assessment.
- (b) The assessor should examine in detail the shielding features and radiation safety aspects of the design; the assessor should satisfy himself or herself that, with regard to the maximum proposed radioactive contents, the design of the finished package will provide sufficient radiological

shielding in all directions to comply with the relevant Transport Regulations and the principle of optimization of protection. The assessor should confirm that computer codes or other methods of calculation used by the applicant are appropriate, valid and quality assured. The assessor should satisfy himself or herself that the material used for shielding is physically and chemically stable and is not likely to move or to deteriorate during transport, since this would decrease the degree of shielding provided by the packaging. Particular care should be taken to verify the absence of any 'shine paths' through package closures and ports used for package testing. The need to decontaminate the packagings in use should also be considered, and the creation of contamination traps or the use of materials that are difficult to decontaminate should be avoided by design.

- (c) The assessor should thoroughly examine the thermal aspects of the package design; the assessor should consider both dissipation and absorption of heat in normal and accident conditions of transport. Thermal stresses should be analysed to ensure that leaktightness or mechanical properties of the package are not unduly compromised in normal conditions of transport or in thermal test conditions. Any computer codes or other methods of calculation used by the applicant should be verified by the assessor and should be confirmed to be appropriate, valid and quality assured.
- (d) The assessor should thoroughly examine all aspects of containment provided by the package. The assessor should also consider the features of the design that provide for containment and should investigate how they might be adversely affected by normal transport operations, by the prescribed servicing and maintenance periods and instructions, and by the effects of accident conditions of transport and related testing.
- (e) The assessor should thoroughly examine the design and supporting documents to ensure that all factors pertinent to radiation safety in respect of the design have been identified and addressed, and that the design will yield a package that is safe under routine, normal and accident conditions of transport.
- (f) The assessor should examine all physical and mechanical aspects of the package design in order to confirm that the package will be physically able to safely carry the specified radioactive material under both normal and accident conditions of transport (this includes tie-down points, trunnions, etc.). The assessor should analyse the structural attributes of the package and should verify that any impact or other damage that the package may sustain in routine, normal or accident conditions of

transport will not compromise its ability to meet the applicable requirements of the Transport Regulations.

- (g) The assessor should examine all materials intended for use in manufacturing the package with regard to their correct specification and condition, their ability to perform satisfactorily under all expected and specified environmental conditions (temperature, pressure, irradiation, humidity, etc.) and their compatibility with other materials used.
- (h) The assessor should examine the in-service handling, inspection, maintenance and servicing instructions in sufficient depth, to verify that all such instructions and specifications are accurate and adequate, and that they will allow the designer's original intentions for the package to be upheld and not to be compromised. The assessor should verify that such in-service instructions and specifications provide for authorized repairs and modifications of the packaging. The procedures for repair and modification should be agreed to or approved by the assessor. (The assessor should also bear in mind that such package instructions may have to be followed by persons who, and organizations that, as consignees, may be unfamiliar with the package and its design principles.)
- (i) When scale modelling is used in testing to support an application for approval, the assessor should confirm that all scaling factors have been taken into account, with all pertinent features of the package design being accurately represented.
- (j) Before commencing the design assessment, the assessor should be satisfied that a management system at an appropriate level has been applied throughout the design process; appropriate evidence of this should be made available to the assessor.

4.82. Where a number of very similar package designs exist, the assessor may make comparisons relating to the final acceptability of the designs; however, this should be done only after the detailed differences between the package designs have been identified and accepted as being of minor or known significance.

TESTING

4.83. It is often necessary to test packages and scale models or representative examples of package features and materials (including special form radioactive material) to prove compliance of the design with the regulatory requirements. Testing may be carried out by the designer, the applicant, a third party testing organization, or the competent authority or its nominated independent agent.

Irrespective of the organization that actually performs the testing, testing should be carried out to the satisfaction of the competent authority and in a quality assured manner. The following points should be considered when seeking to determine compliance with the regulatory requirements for testing:

- (a) There should be an appropriate management system for the test to be performed in support of the demonstration that the finished package will meet the regulatory requirements. The management system should address all aspects of the testing. It should cover not only the manufacture of the specimens to be tested but also all the relevant activities relating to management, preparation, measuring, testing, recording, analysing and reporting associated with the particular test or series of tests to be carried out.
- (b) The actual test programmes should satisfy the approving body (the competent authority or other appropriate organization), and the number of tests and specimens, the drop sequences, the drop attitudes, the measurement techniques and the methods of analysis should be clearly established. The outcome of test work is inevitably uncertain; therefore, some variation in the programme may be necessary in the course of testing, and allowance should be made for this fact when preparing test specimens, scheduling tests and using test facilities. The competent authority (or other approving body) should reserve the right to vary the test programmes in the course of testing in the light of the experience gained.
- (c) The objectives and parameters of the test(s) should be clearly established; that is, it should be made clear whether the sole objective of the test(s) is a straightforward verification that the package meets all of the regulatory requirements or only a part of them, whether the designer wants different or more stringent test criteria to be applied, or whether additional information is sought from the test(s) to improve the designer's knowledge of the design principles, safety margins, performance, etc.
- (d) It should be clearly established that the test facilities comply with the regulatory requirements, particularly in the case of the targets used for drop and penetration tests, where the weight of the test specimen should not exceed the capacity of the test facility.
- (e) All measuring and monitoring equipment used before, during and after the test(s) to confirm and record the state of the test specimen and any forces imposed upon it as a result of the test(s) should be operated within the accepted limits for the particular pieces of equipment. It should be verified that this equipment works accurately, within accepted or declared limits. This is usually achieved by using properly calibrated

measuring or test equipment, such as pressure and leak test equipment, accelerometers, strain gauges and thermal measuring apparatuses.

- (f) Adequate methods of recording the information obtained during the test programme should be prescribed, and appropriate actual records should be made available to the competent authority (or other approving body) so that compliance with the regulatory requirements can be confirmed.
- (g) All analyses of the test results, including measurement and assessment of any instances of damage, should be compared with the final package design, and compliance with the regulatory requirements should be verified by the competent authority (or other approving body).

4.84. Test programmes are important for demonstrating that the performance of packages complies with the applicable regulations; the competent authority should therefore consider the need to witness the actual tests periodically.

4.85. Designers will sometimes want to make changes (significant or otherwise) to a design after testing. When carrying out the final design assessment, the assessor should give particular consideration to relating all packages tested, tests witnessed and test results submitted by the applicant or designer to the final design.

CONTROL OF MANUFACTURE

4.86. Packagings should be manufactured in a controlled manner and in accordance with the design specifications and the management system. In order to confirm this, the competent authority may request sufficient information to carry out such inspections of the manufacturing as it deems necessary to obtain assurance of compliance with the Transport Regulations. An example checklist for inspections of the manufacture of packagings is provided in Annex VIII.

4.87. Manufacturing facilities and subcontractors may be subject to inspections by the competent authority. The frequency and extent of such inspections should be determined by the level of confidence that the competent authority has in the manufacturing arrangements and by the importance to safety of the package features concerned.

4.88. The manufacturing arrangements and the management system may be audited by the competent authority before the commencement of manufacturing of a packaging. The purpose of such audits is to ensure that the manufacturer's

management system is suitable to achieve and demonstrate compliance with the approved specifications and that qualified methods are used. In the case of continuous manufacture of packagings, additional audits of the management system may be carried out periodically. However, significant changes to the manufacturing arrangements and the management system should be agreed to by the competent authority before they are put into effect.

4.89. During manufacture, the competent authority may perform random inspections of the manufacturing activities and of the activities in the management system. This may include taking samples for independent non-destructive or destructive testing. The purpose of such inspections is to verify that the packaging is manufactured in compliance with the Transport Regulations and in accordance with the approved design. The manufacturer should be required to record all deviations from the specifications and to provide the reasons for accepting or rejecting such deviations. If a safety related deviation is planned to be corrected by repair, the plan for the repair work may be subject to the agreement of the competent authority or of another approving body. Reports of the accepted deviations and repairs should be made available to the competent authority for inspection. The competent authority or another approving body should review in particular all reports of safety related deviations and should be given the power to accept or reject any deviations from the approved manufacturing specifications.

4.90. All results of inspections carried out by the competent authority or by another approving body should be recorded and communicated to the manufacturer for information and for possible action.

4.91. The competent authority should ensure that, before the first shipment of a packaging, the manufacturer has fulfilled the requirements of para. 501 of the Transport Regulations. On the basis of the results of quality control tests, reports on deviations and other measures within the management system, the manufacturer should be required to verify that the packaging has been manufactured in compliance with the Transport Regulations. The competent authority may confirm the manufacturer's verification of compliance by means of direct inspections.

4.92. Following the manufacturer's verification of compliance, the responsible organization should legibly and durably mark the packaging in accordance with the requirements of paras 535–540 of the Transport Regulations and in accordance with any other requirements for identification by the competent authority. For packages approved by the competent authority, the competent

authority is required to be informed of the serial number of each accepted packaging, in accordance with para. 819 of the Transport Regulations.

MAINTENANCE AND SERVICING ARRANGEMENTS

4.93. The competent authority needs to be assured that the user has verified, before each use of a packaging, that the requirements of para. 502 of the Transport Regulations have been met. Inspections and maintenance as required by the original designer or the competent authority should have been systematically carried out. An example checklist for inspections of maintenance and servicing operations is provided in Annex IX.

4.94. The person or organization carrying out the maintenance and servicing operations is required to have an appropriate management system and to adhere to it. The current relevant instructions covering maintenance and servicing of packagings should be made available for the necessary maintenance and servicing tasks. (This can present certain difficulties when a packaging has to be maintained or serviced in a place or State away from that of the owner or user of the packaging or the competent authority that originally granted approval.)

4.95. Any proposed modifications to a packaging during maintenance and servicing operations should be carried out only when the necessary modification specifications are available to the person or organization carrying out the modification. The accepted modifications are required to be carried out by means of approved or agreed techniques, processes and materials. Any departure from such agreed modifications, techniques, processes and materials may render the packaging unusable and may compromise the original design intent and transport safety.

4.96. It should be indicated on the packagings when the last maintenance or servicing operation was done or, preferably, when the next maintenance or servicing operation is due. This, in conjunction with appropriate records of all such maintenance and servicing operations, can demonstrate that the package fully complies with the conditions of approval. Consignors should plan to complete any transport operations within the specified maintenance or servicing period; they should not permit the use of a packaging whose maintenance or servicing will become due during the actual transport.

4.97. The competent authority should witness the maintenance and servicing operations carried out by the user (this should be planned but perhaps not announced). During the lifetime of the packaging, the user should maintain sufficient records of the management system to demonstrate that the requirements of para. 502 of the Transport Regulations have been met. The user is required to make available such records to the competent authority, and to permit it to inspect the records, the packaging and the facility. Appropriate use should be made of records and logbooks (as described in the Ref. [20]) when servicing and maintenance operations are carried out at different locations.

4.98. For packages approved by the competent authority, the user should be required to record all safety related deviations from and modifications to the specifications, as well as any significant damage noted during the use of the packages. The competent authority should be informed of these deviations before the packages are returned to service, within a certain time period (e.g. 30 days), in accordance with the requirements of the competent authority. Corrective measures or modification proposals, including any plans for repairs, should be subject to the agreement of the competent authority. Any packages undergoing such repairs, modifications or changes should not be returned to use until the competent authority has agreed to or approved the change.

ACCIDENTS AND EMERGENCY RESPONSE

4.99. The competent authority should periodically assess the risk of an accident involving the transport of radioactive material and its potential consequences. Emergency planning by the competent authority and other responsible authorities, usually organizations with responsibility for public health and safety, should be based on these and other relevant assessments.

4.100. Detailed recommendations on emergency planning and preparedness are provided in Ref. [6].

4.101. International cooperation may be needed in the case of a transport accident, as discussed in paras 3.15 and 6.10.

DISTRIBUTION OF INFORMATION

4.102. Preparation and issuing of information and guidance by the competent authority are needed for the implementation and functioning of a compliance

assurance programme. Such information may be in the form of bulletins on important safety related matters. It may also be in the form of information notices and guides that are intended to assist users in the application and interpretation of the Transport Regulations. Finally, it may involve the development and sponsoring of seminars, conferences or training courses for personnel of regulatory bodies, consignors, carriers and other groups, to explain the correct application of the Transport Regulations.

TRAINING AND JOB RELATED SKILLS

4.103. Only appropriately trained persons are permitted to be engaged in the transport of radioactive material, as described in paras 311–314 of the Transport Regulations. The jobs and the associated duties and responsibilities of personnel should be clearly indicated in the descriptions of the organizations of the consignor, the carrier and the consignee. The duties and responsibilities of other personnel, such as employees of the competent authority, independent inspectors and emergency personnel, should also be specified so that the necessary training can be determined and provided.

4.104. In addition to providing for the training of its own personnel, the competent authority should, as appropriate, specify and participate in the training of other persons involved in the transport of radioactive material. Furthermore, the competent authority should ensure through its compliance assurance programme and its monitoring of management systems that all the training needs of the organizations involved in transport are recognized and implemented. The training programme for an individual may be varied slightly or considerably, depending on the relevant experience of the person.

4.105. In some States, the incumbents of certain posts within the competent authority and the organizations of the consignor, the carrier and/or the consignee have to be authorized or certified before they are allowed to perform their duties. In such cases, means of authorization and training should be planned and organized.

4.106. Each organization should maintain adequate records of its training plans, the performance of individual trainees and the authorizations issued. Also, records should be maintained in accordance with the applicable requirements for the management system, and these should be examined or inspected periodically by the competent authority. The main purposes of such records are:

- (a) To provide the competent authority with evidence of the appropriate qualifications of all persons whose duties have a bearing on safety, and with evidence of the required authorizations;
- (b) To provide evidence of the basis for these authorizations;
- (c) To provide documentation that can be used in reviews of the training programme to enable any necessary corrective actions to be taken.

4.107. Further information on the training of all personnel involved in the transport of radioactive material is given in Ref. [21].

MAINTENANCE OF REGULATIONS AND FEEDBACK TO THE COMPETENT AUTHORITY

4.108. National and international regulations and conventions are discussed in Section 3. The maintenance and further development of the existing national regulations are considered to be important aspects of compliance assurance. National regulations should be regularly reviewed and revised to take account of developments in all areas of the industry for the transport of radioactive material as well as developments in comparable activities and industries.

4.109. The IAEA recognizes the value of a continuous review of its Transport Regulations and has implemented a two-year review and revision process. It is only by means of such a review and revision process that specific and more general needs and developments in the safe transport of radioactive material can be recognized and provided for in a timely manner.

4.110. Also, the competent authority should periodically review the national and international regulations for the transport of radioactive material and should make any necessary changes to the national regulations. This can be difficult or time consuming in States in which the competent authority must obtain formal permission from the government to make changes to regulations or where it must refer to the legislative process. Consideration should be given by the competent authority to developments in international organizations, such as the International Maritime Organization, and in conventions, and to any associated mandatory timescales for changes to be introduced.

4.111. Evidence of compliance and non-compliance with the regulations, which may consist of reports on inspections and enforcement actions, audit reports, communications by and with the industry, etc., should be used by the

competent authority to assist it in determining the degree of effectiveness and adequacy of the national regulations for the transport of radioactive material.

4.112. The competent authority should carefully evaluate all reported and perceived problems and developments, as well as proposals for regulatory changes; it should then consider all aspects and implications of any proposed changes, and should consult with the relevant users of the national regulations and acknowledged experts.

4.113. The competent authority should exercise great care when it considers changes to national regulations, so as to prevent disharmony or conflict with the requirements of accepted international regulations and conventions or the requirements of other applicable national regulations.

4.114. Any change to the national regulations should be carefully monitored by the competent authority after its implementation, to verify that the change has been effective and that the objective or the desired result has been achieved without compromising safety and without adversely affecting other parts of the industry for the transport of radioactive material.

ENFORCEMENT ACTIONS AND INVESTIGATIONS OF INCIDENTS

4.115. Every system for compliance assurance should include provisions for enforcement. In this context, enforcement means any formal actions by the competent authority against the user of the regulations when cases of violation or non-compliance by that user have been observed. Such observations are most often made in the course of routine inspections by the competent authority. A range of enforcement actions may be applied, depending on the safety significance of the violation or non-compliance. Enforcement sanctions should be applied in an appropriate manner and within the legal framework of the individual State. These sanctions may include, for example, the following measures:

- (a) *Written notice:* A written notice may be sent from the competent authority to the user setting out the non-compliance that has been observed or reported. The user would be required to provide a written reply explaining the causes of the non-compliance and the corrective actions taken to prevent a recurrence.
- (b) *Suspension:* This may involve a written notice of non-compliance accompanied by a statement of intent to suspend or revoke or modify a

user's authorization unless or until the user provides an acceptable reason why the suspension should not be applied. The user would be obliged to demonstrate that the non-compliance has ceased or that steps to prevent recurrence have been taken. In applying this type of sanction, the competent authority should take into account the safety significance of the non-compliance, the prior enforcement history of the user, and the financial and social impact of the suspension on the user and on other affected parties.

- (c) *Prosecution*: In circumstances in which non-compliance has occurred and the foregoing measures are considered inappropriate or have failed to prevent the user from continuing with the non-compliance, the competent authority may wish to initiate legal action against the user; this would be considered a higher form of sanction. In some States, prosecution may include a monetary and/or criminal penalty. Prosecution may be appropriate in cases in which one or more of the following apply:
- (i) The user has refused to rectify a case of non-compliance;
 - (ii) The user has failed to discontinue an unsafe practice;
 - (iii) There is evidence of deliberate negligence;
 - (iv) There is evidence of criminal action.

4.116. Suitable guidelines for the use of such sanctions should be provided by the appropriate authorities in individual States to ensure fair and uniform application of the sanctions.

4.117. The inspection and enforcement programmes of the competent authority should be applied to all activities that are important to safety (design, testing, manufacture and maintenance of packagings, preparation for and carrying out of transport, and use of the management system), irrespective of whether an approval certificate from the competent authority is required.

4.118. A system for the reporting of all significant incidents, including accidents, or of deviations from the Transport Regulations, should be developed, and the competent authority or its authorized representatives should investigate any reported occurrences. Such investigations may reveal where:

- (a) Clear breaches of regulations have occurred;
- (b) Individual or collective procedures are in need of improvement;
- (c) Individual or collective work practices are in need of improvement;
- (d) Closer supervision of personnel is necessary;
- (e) Improved training is necessary;

- (f) A misunderstanding of regulatory requirements has occurred;
- (g) Unwelcome trends in transport operations are developing;
- (h) Apparent inadequacies exist in the regulations.

On the other hand, the investigations may confirm that transport operations are being carried out safely, or may indicate only minor problems and a limited occurrence of radiation exposure.

4.119. Section 2 of this Safety Guide covers interdepartmental and interagency liaison in general and recommends that the competent authority arrange periodic meetings of all governmental bodies involved in the transport of radioactive material. One of the aims of such meetings is to ensure the consistent application of inspection and enforcement measures relating to compliance assurance. It may often be the case that the control of the safe transport of radioactive material — for example, inspection of aviation safety — is only a small part of the work of the department or agency carrying out the inspection. The regulations and inspection criteria for the transport of radioactive material should be understood and applied by inspectors of such agencies in a manner similar to that in which other regulations and inspection criteria are applied, such as those relating to maritime safety or road traffic.

4.120. The competent authority should also liaise with other groups concerning enforcement to obtain a clear understanding of the respective responsibilities and operating methods of each of the departments or agencies involved. When the competent authority has such an understanding, it can consider the completeness of the inspection and enforcement arrangements and identify any areas of overlap between the arrangements of different agencies, or, more importantly, it can identify where there are gaps between the operations of one agency and those of another agency. At meetings for liaison purposes, enforcement levels and criteria can be discussed, compared and subsequently standardized, wherever possible, and it can be ensured that the interfaces between the liaising departments or agencies are well defined and are functioning correctly.

5. APPROVALS AND APPROVAL CERTIFICATES

APPLICATIONS FOR APPROVALS

5.1. One of the responsibilities of the competent authority is to issue approvals. The decision to grant an approval is based upon the competent authority's evaluation of the applicant's demonstration of compliance with the relevant requirements of the Transport Regulations. Depending on the type of approval, the corresponding application should contain at least the information as described in Section VIII of the Transport Regulations (paras 803, 805(c), 807, 810, 813, 822 and 825). As described in Section 4 of this Safety Guide, the competent authority should complete and record the results of such safety evaluations, which provide the basis for the issuing of approvals.

5.2. The first contact of applicants with the competent authority is often when they apply for an approval, but the applicants should also be encouraged to contact the competent authority during the preliminary design stages to discuss the implementation of the relevant design principles and to establish both the approval procedure and the actions incumbent on the applicant.

5.3. Experience has shown that many applicants make their first submission to the competent authority for a specific need, which can be rather narrow in scope, and later make several requests for amendments to the approval certificate, trying to expand its scope in order to be able to use the packaging for other types of material and/or shipment. Whenever possible, applicants should be encouraged to first submit an application for a general approval certificate that anticipates and covers their future needs. This will make the approval system operate more efficiently and will result in much lower costs to the applicant. Additionally, in some cases it is advantageous for both the prospective applicant and the competent authority to discuss an outline of the proposed application before it is formally submitted in detailed form.

PROVISION OF GUIDANCE FOR APPLICANTS

5.4. In some States it has been found to be advantageous to provide a guide to assist applicants in submitting the necessary information in a convenient form for approvals of: (i) special form radioactive material, (ii) low dispersible radioactive material, (iii) packages, (iv) shipments under special arrangement and (v) shipments. Such a guide is also of value to the competent authority in

evaluating the completeness and accuracy of submissions. An example of the contents of such a guide is shown in Annex II. The guide is not intended to be a substitute for the Transport Regulations. It is not necessary to print the text of a regulatory provision in the guide; rather, the applicant should be referred to the Transport Regulations by means of the relevant paragraph numbers; for example:

Show what the maximum normal operating pressure will be within each successive enclosure of the containment system:

- Before shipment (para. 502(d));
- During normal transport (paras 228, 661);
- During and subsequent to tests for demonstrating the ability to withstand accident conditions in transport (paras 660, 719–724 and 726–729).

5.5. For simple designs the guide may be used as a questionnaire, whereas for more sophisticated designs — for example, packages of irradiated fuel — the submission needs to be in the form of a more comprehensive report on safety. In the latter case, however, the various sections and paragraphs will need to refer to the questions in the guide to which they relate.

TYPES OF APPROVAL

5.6. In accordance with para. 802 of the Transport Regulations, competent authority approval is required for the following:

- (a) Special form radioactive material;
- (b) Low dispersible radioactive material;
- (c) Packages containing 0.1 kg or more of uranium hexafluoride;
- (d) All packages containing fissile material unless excepted by para. 672 of the Transport Regulations;
- (e) Type B(U) and Type B(M) packages;
- (f) Type C packages;
- (g) Special arrangements;
- (h) The radiation protection programme for special use vessels;
- (i) The calculation of radionuclide values that are not listed in Table 1 of the Transport Regulations.

5.7. According to paras 803, 805(b) and 806 of the Transport Regulations, unilateral approval by the competent authority is specifically required for:

- (a) The design of special form radioactive material;
- (b) The design of packages containing 0.1 kg or more of uranium hexafluoride that meet the requirements of paras 629–631 of the Transport Regulations (in this case, unilateral approval by the competent authority of the country of origin of the design is required);
- (c) Type B(U) and Type C package designs, except package designs for fissile material.

5.8. According to paras 803, 805(a), 806(a), 806(b), 809, 812, 816, 817, 820 and 824 of the Transport Regulations, multilateral approval by the competent authority is specifically required for:

- (a) The design of low dispersible radioactive material;
- (b) The design of packages containing 0.1 kg or more of uranium hexafluoride that meet the requirements of para. 632 of the Transport Regulations;
- (c) The design of packages for fissile material;
- (d) The design of Type B(U) packages for low dispersible radioactive material;
- (e) The design of Type B(M) packages;
- (f) Package designs approved by the competent authority under the provisions of the 1973 Edition and the 1973 Edition (As Amended) of the Transport Regulations;
- (g) Package designs approved by the competent authority under the provisions of the 1985 Edition and the 1985 Edition (As Amended 1990) of the Transport Regulations;
- (h) The shipment of Type B(M) packages not conforming with the requirements of para. 637 of the Transport Regulations or designed to allow controlled intermittent venting;
- (i) The shipment of Type B(M) packages containing radioactive material with an activity greater than $3000A_1$ or $3000A_2$ as appropriate, or 1000 TBq, whichever is lower;
- (j) The shipment of packages containing fissile material, if the sum of the criticality safety indexes of the packages in a single freight container or in a single conveyance exceeds 50;
- (k) Radiation protection programmes for shipments by special use vessels according to para. 576(a) of the Transport Regulations;
- (l) Consignments transported under special arrangement.

5.9. Whenever possible, standard formats should be utilized for each type of certificate. Minimum requirements for the contents of approval certificates are specified in Section VIII (paras 830–833) of the Transport Regulations. Examples of templates for approval certificates for use by the competent authority are provided in Annex III of this Safety Guide.

5.10. Certificates for international carriage of certain packages, provided to the IAEA by national competent authorities, are listed in Ref. [22], which is updated periodically.

MULTILATERAL APPROVAL

5.11. Under the Transport Regulations, multilateral approval of a design or shipment may be effected by either of the following:

- (a) Independent certification as part of a chain of multilateral competent authority approvals;
- (b) Validation of the approval certificate issued by the original competent authority.

5.12. The essential difference between an independent certificate and a validation is that the latter is not (and should not be) self-contained; that is, some reference to the original approval certificate is made, for example, for the description of packaging or contents or for shipment provisions. For reasons of convenience to local users, the validation may, however, contain parts or summaries of parts of the original approval certificate, in translation if necessary.

5.13. A validation generally reduces, but does not necessarily exclude, the possibility of differences between provisions of certificates issued by different competent authorities that cover the same case. Such differences may arise because of supplementary or divergent local regulations or different practices of the competent authorities.

5.14. An endorsement is a special kind of validation that simply states that all provisions of the original certificate are endorsed. An endorsement may contain supplementary provisions or information, provided that they do not conflict with the provisions of the original certificate and do not modify the design. An endorsement should not bear a separate identification mark but should use the identification mark of the original certificate.

5.15. Independent certification provides more flexibility in determining the extent of the multilateral approval. This is useful if modification of any of the essential detailed provisions of the certificate of the original competent authority is deemed necessary, or if new provisions are to be added to the approval. In such cases, independent assessment of the application should be carried out by the relevant competent authority.

5.16. Both an independent certificate and a validation may cover either all parts of the original certificate requiring multilateral approval (full multilateral approval) or only the parts deemed appropriate by the applicant or the competent authority (partial multilateral approval).

5.17. The competent authority should communicate to the applicants its policy on how multilateral approval is performed (i.e. guidelines on which type of approval — independent certification or validation — will be issued for which type of design or shipment). The competent authority's policy may be based on criteria such as the risk associated with the use of the package on its territory.

5.18. When a vessel is used for transport, the competent authority of the flag State of the vessel can take part in any chain of multilateral approvals by competent authorities, even if the ship is not destined to enter a port on the territory of that competent authority. The competent authorities of the States from which the vessel departs and at which it arrives may also be involved in the multilateral approval process.

5.19. When a competent authority is requested to give its approval as part of a chain of multilateral approvals, parallel assessment of the application may be considered at the discretion of the competent authority. However, such multilateral approvals should not be issued before the approval certificate is issued by the competent authority of the State of origin of the design or shipment.

6. INTERNATIONAL COOPERATION BETWEEN COMPETENT AUTHORITIES CONCERNING PACKAGES AND SHIPMENTS ON FOREIGN TERRITORY

INTERNATIONAL COOPERATION RELATING TO COMPLIANCE ASSURANCE

6.1. National competent authorities meet regularly under the auspices of the IAEA in order to further develop the Transport Regulations and their associated advisory and explanatory Safety Guides for the safe transport of radioactive material. The common aim of such meetings is related to the uniformity of the application of the Transport Regulations in all Member States. International cooperation in the field of compliance assurance is clearly a powerful tool that can help to achieve that aim.

6.2. The national competent authority has a clear responsibility regarding compliance assurance for all activities relating to the transport of radioactive material within its national jurisdiction. However, a large number of movements involve packages of foreign origin. Such movements will often occur without the knowledge of the national competent authority; nevertheless, each such instance of transport should be in compliance with the regulatory requirements.

6.3. To confirm compliance with the Transport Regulations in the case of the transport of radioactive material of foreign origin transiting its area of jurisdiction, the competent authority should inspect such packages or shipments. Cooperation with other competent authorities should also be considered. Packages and shipments of foreign origin coming within the jurisdiction of a national competent authority belong to two categories:

- (a) Packages and shipments that are subject to multilateral approval;
- (b) Packages and shipments that do not require notification of competent authorities.

PACKAGES AND SHIPMENTS OF FOREIGN ORIGIN THAT ARE SUBJECT TO MULTILATERAL APPROVAL

6.4. Operations associated with foreign packages and shipments (see para. 5.10) may also require multilateral approval by and/or notification of the

competent authority of each country through or into which the consignment is to be transported, as stated in paras 558–561 of the Transport Regulations. For such cases, the competent authority that is requested to issue a validation of the original approval certificate can justifiably require that it be informed of the details relating to the management system before it issues a certificate of validation. Through cooperation between the validating competent authority and the competent authority that issued the original approval certificate, the necessary compliance guarantees can be provided.

6.5. In cases where there is doubt about a specific management system, the validating competent authority should contact the competent authority of the State of origin of the package or shipment and should request the relevant details of inspections and audits. Where important shipments or large scale operations are concerned, this international cooperation may justify visits between competent authorities and joint visits of the respective organizations for detailed discussion of the management system. The purpose of such visits is to gain confidence in the standards used in different States and to reach agreement on the approach concerning differences in standards.

6.6. Where multilateral approval is effected by the issuing of independent certificates by successive countries, a further useful measure is to require that the user be responsible for ensuring that the validating mark, as required in para. 829(b) of the Transport Regulations, is indelibly printed on the packaging. In the case of multiple use packagings, the date of the next maintenance inspection should also be noted on each packaging; this measure can help to avoid the accidental use of a packaging after the date on which the maintenance is due.

PACKAGES AND SHIPMENTS OF FOREIGN ORIGIN THAT DO NOT REQUIRE NOTIFICATION OF THE COMPETENT AUTHORITY

6.7. Transport of radioactive material that does not require competent authorities to be notified, particularly packages and shipments of foreign origin, may nevertheless be subject to inspections by the competent authority in the framework of its compliance assurance programme. International cooperation between competent authorities can be used to inform interested parties, but competent authorities may also identify such packages and shipments in the same way as the transport of other dangerous goods.

6.8. The competent authority will receive only the notifications required under paras 558 and 559 of the Transport Regulations. Nevertheless, the carrier will be in possession of the transport documents supplied by the consignor, which will contain the information required in paras 550–554 and 556 of the Transport Regulations. The competent authority may check this information as part of its compliance assurance programme.

6.9. In some States, information arising from legal requirements associated with, for example, the shipment of certain radioactive materials across national borders may also be used to augment any information obtained from consignors or carriers, or through international protocols and/or codes of conduct established to facilitate cooperation between competent authorities.

6.10. The competent authorities in the States of origin and destination of the package or shipment, by means of their compliance assurance programmes, should ensure compliance with Transport Regulations and therefore safety in States not required to be notified under the Transport Regulations. Nevertheless, para. 309 of the Transport Regulations requires that consignors and carriers notify the relevant competent authorities in the event of non-compliance in respect of radiation levels or contamination. Reference [6] recommends that the carrier notifies relevant authorities in the event of an accident (para. 3.15). This will ensure that, in the event of an accident involving the transport of radioactive material, relevant competent authorities will be informed, irrespective of the requirements within the Transport Regulations for the notification of competent authorities.

6.11. The IAEA operates and maintains databases containing information on incidents, including accidents; this information may be used and updated by Member States.

REFERENCES

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NOTE ON THE ANNEXES

The annexes present sample documents and forms; they show how the procedures for organizing and implementing a compliance assurance programme for the safe transport of radioactive material may be documented and controlled. Most of the sample documents have been provided by one competent authority. The compliance assurance programme implemented by any other competent authority will need to reflect its own working practices and methods that have been developed to meet the requirements of para. 307 of the Transport Regulations.

The views expressed in the annexes are not necessarily those of the IAEA or its Member States.

Annex I

EXAMPLE OF THE ORGANIZATION OF A COMPLIANCE ASSURANCE PROGRAMME

This annex illustrates the steps in the development of a compliance assurance programme and the 'compliance assurance circle' (Fig. I-1).

STEPS

- (1) Determination or confirmation of the size and state of the existing industry for the transport of radioactive material;
- (2) Determination or confirmation of the existing legal powers and other resources available to the competent authority;
- (3) Establishment of liaison with government departments or organizations having a legitimate interest in or an interface with aspects of the transport of radioactive material;
- (4) Provision of a sound legal framework to enable the effective functioning of the competent authority;
- (5) Formal confirmation of the working relationships between other governmental bodies and other organizations in respect of the transport of radioactive material;
- (6) Gathering of further detailed information on the size of the industry for the transport of radioactive material, including information on package types and numbers of movements;
- (7) Formal specification of the size, structure and resources of the competent authority, and development of a management system for the competent authority;
- (8) Initial training of personnel of the competent authority and other personnel involved in the enforcement of regulations;
- (9) Creation or adoption of national regulations for the transport of radioactive material (with provision for all package types, transport operations and modes of transport);
- (10) Development of an initial compliance assurance programme (including existing activities of the competent authority, such as inspections and assessments);
- (11) Distribution of information to all parts of the industry regarding the competent authority's policies, regulations and plans for the transport of radioactive material;

- (12) Implementation of the initial compliance assurance programme;
- (13) Collection of initial evidence of compliance with the Transport Regulations by means of the activities shown in Fig. I-1;
- (14) Accumulation and review of evidence of compliance on a continual basis;
- (15) Conduct of periodic reviews of all aspects of the compliance assurance programme; adjustment of the input or effort deployed by the competent authority in addressing the various segments of the compliance assurance circle shown in Fig. I-1.

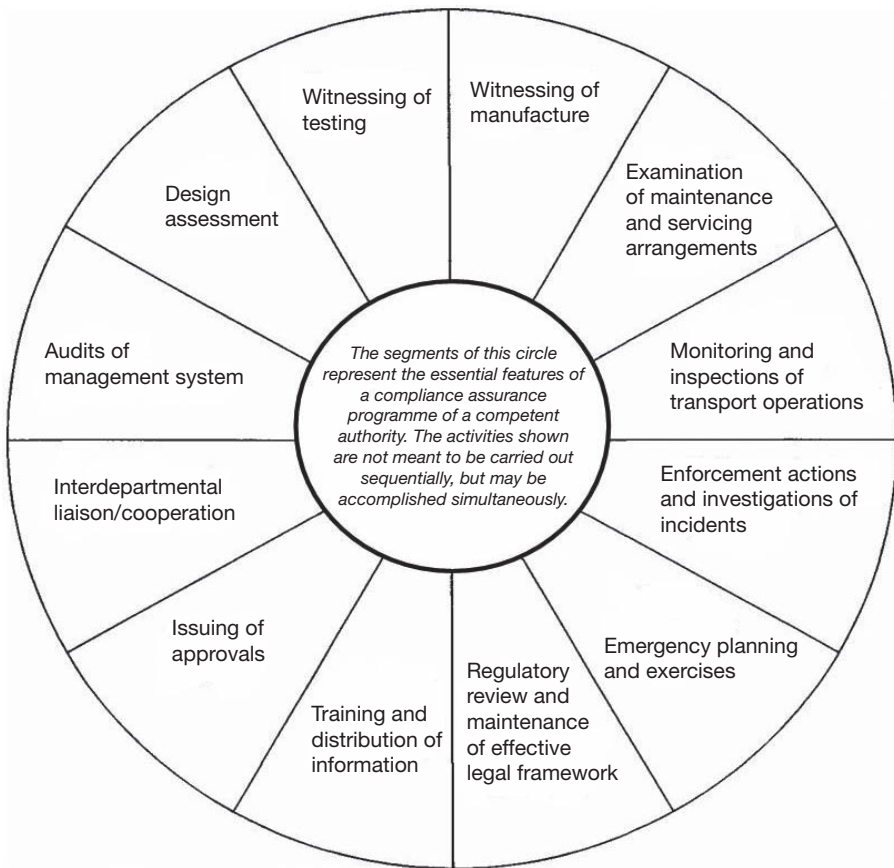


FIG. I-1. The compliance assurance circle.

Annex II

INFORMATION TO BE INCLUDED IN THE GUIDE FOR APPLICATIONS FOR APPROVALS

This annex provides details of the information that may be included in the guide for applications for approvals.

PARTS

- I: General information;
- II: Administrative information;
- III: Specification of the radioactive contents;
- IV: Specification of packaging and instructions for use;
- V: Package analyses and tests;
- VI: Shipment;
- VII: Transport operations under special arrangement;
- VIII: Special form radioactive material and low dispersible radioactive material;
- IX: The management system;
- X: Modifications.

PART I: GENERAL INFORMATION

General information, including a list of applicable national and international regulations and specifying the edition of the Transport Regulations under which competent authority approval is sought.

PART II: ADMINISTRATIVE INFORMATION

- Name, address and telephone number of the applicant;
- Name, address and telephone number of the designer;
- Name, address and telephone number of the manufacturer;
- Type of approval required, for example, special form radioactive material, low dispersible radioactive material, Type B(U) packages, Type B(M) packages, Type C packages, packages containing fissile material, shipments, special arrangements;

- Anticipated modes of transport;
- Identification mark of the competent authority, if previously allocated;
- General arrangement drawing number;
- Date of application;
- Date by which approval is desired.

PART III: SPECIFICATION OF THE RADIOACTIVE CONTENTS

- General nature;
- Radionuclide(s) present;
- Physical and chemical states;
- Quantity, in mass units; for packages containing fissile material, quantity of fissile isotopes, in mass units and levels of enrichment;
- Total activity and specific activity;
- Calculation of A_1/A_2 values other than those listed in the Transport Regulations;
- Nature of the emitted radiation;
- Information on irradiated fuel, for example, rating, irradiation, initial enrichment and cooling time;
- Heat output;
- Other dangerous properties, as applicable.

PART IV: SPECIFICATION OF PACKAGING AND INSTRUCTIONS FOR USE

- Drawings (arrangement, assemblies, subassemblies and details);
- Specifications of material;
- Types of closure;
- Overall dimensions and mass;
- Handling system;
- Tie-down system;
- Radiation shielding;
- Neutron absorbers;
- Containment system;
- Confinement system;
- Special features (e.g. devices for protection from contamination, canopy, transport frame, load securing devices);
- Provisions for maintenance;
- Actions before shipment;

- Actions during shipment;
- Restrictions (including modal restrictions);
- Instructions for handling and stowage;
- Instructions for emergency situations.

PART V: PACKAGE ANALYSES AND TESTS

- Behaviour of the radioactive material;
- Effects of radiolysis;
- Structural evaluation;
- Evaluation of the containment system;
- Evaluation of the radiation shielding;
- Thermal evaluation;
- Criticality evaluation;
- Model tests;
- Prototype tests;
- Tests with specimens.

PART VI: SHIPMENT

- Mode of transport;
- Consignor;
- Carrier, if available;
- Consignee;
- Consignment details;
- Proposed route;
- Type of conveyance;
- Provisions for exclusive use;
- Operational controls during shipment;
- Storage in transit;
- Stowing, handling and lifting;
- Radiation protection programme for special use vessels;
- Transport instructions;
- Emergency instructions.

PART VII: TRANSPORT OPERATIONS UNDER SPECIAL ARRANGEMENT

- Mode of transport;
- Consignor;
- Consignee;
- Consignment details;
- Reason for the special arrangement;
- Proposed compensatory measures.

PART VIII: SPECIAL FORM RADIOACTIVE MATERIAL AND LOW DISPERSIBLE RADIOACTIVE MATERIAL

- Drawings;
- Specifications of materials and closures, where applicable;
- Overall dimensions and mass;
- Radionuclides present;
- Physical and chemical states;
- Nature of the emitted radiation;
- Heat output;
- Demonstration of compliance with test and design requirements;
- Results of leakage and/or leaching tests.

PART IX: THE MANAGEMENT SYSTEM

- Description of the organizations involved in transport;
- Duties and responsibilities of different organizations;
- Management systems of the organizations involved in transport.

PART X : MODIFICATIONS

- Administrative information;
- Details of modifications and associated justifications;
- Categorization of modifications;
- Concessions;
- Analyses of the impact on safety of the modifications or concessions.

Annex III

EXAMPLES OF TEMPLATES FOR APPROVAL CERTIFICATES FOR USE BY THE COMPETENT AUTHORITY

This annex provides examples of templates for approval certificates for:

- (1) Design of special form radioactive material and low dispersible radioactive material;
- (2) Package design;
- (3) Shipments;
- (4) Shipments under special arrangement.

These templates for approval certificates may be used by the competent authority.

**III-1. APPROVAL CERTIFICATE FOR DESIGN
OF SPECIAL FORM RADIOACTIVE MATERIAL
OR LOW DISPERSIBLE RADIOACTIVE MATERIAL**

1. Expiry date of certificate	2. Competent authority identification mark
3. This certificate is issued on the basis of the application by	
[Name and address of the applicant]	[Reference to the application]
4. Identification of the special form radioactive material or low dispersible radioactive material (model name/number)	
5. Radioactive material (radionuclide(s), chemical and physical form)	6. Maximum activity
7. Design specifications	8. Reference to the management system
9. Specific actions to be taken prior to shipment	
10. This is to certify that the design of the special form radioactive material (or low dispersible radioactive material) described above meets the applicable requirements in the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1, and in the regulations listed in the following.	
Date	
[Signature of authorized official(s)]	
Address, telephone number and email address of the competent authority	
11. Applicable regulations concerning the transport of radioactive material	
<ul style="list-style-type: none"> (a) Road: (b) Rail: (c) Sea: (d) Inland waterways: (e) Air: (f) International: (g) Other: 	
12. Table summarizing past and current revisions of the approval certificate	

III-2. APPROVAL CERTIFICATE FOR DESIGN OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Expiry date of certificate	2. Competent authority identification mark
3. This certificate is issued on the basis of the application by	
[Name and address of the applicant]	[Reference to the application]
<p>4. This is to certify that the design of the package described in the following meets the applicable requirements for [Type B(U), B(M), Type C package] [Type ... package containing fissile material] in the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1, and in the regulations listed in the following.</p> <p>This certificate does not relieve the consignor of compliance with any requirement of the government of any State through or into which the package will be transported.</p>	
Date	
[Signature of the authorized official(s)]	
Address, telephone number and email address of the competent authority	
<p>5. Package identification</p> <ul style="list-style-type: none"> (a) Reproducible illustration not larger than 21 cm × 30 cm showing the make-up of the package (b) Packaging <ul style="list-style-type: none"> (i) Model name or number (ii) Description (use, dimensions, materials, closures, penetrations, gross mass, etc.) (iii) Reference to drawings and specifications (iv) Description of the containment system (c) Radioactive contents (non-fissile): <ul style="list-style-type: none"> (i) Radioisotopes (ii) Chemical and physical form (including special form radioactive material or low dispersible radioactive material, if applicable) (iii) Maximum activity per package (including activities of the various isotopes) 	

<p>(d) Packages containing fissile material:</p> <ul style="list-style-type: none"> (i) Type and form of fissile material (ii) Maximum activity and quantity per package (iii) Description of the confinement system (iv) Reference to the documentation that demonstrates the criticality safety of the contents (v) Criticality safety index (vi) Special features (on the basis of which the absence of water from certain void spaces has been assumed in the criticality assessment) (vii) Irradiated fissile material (any allowance for a change in neutron multiplication assumed in the criticality assessment as a result of actual irradiation experience) (viii) The ambient temperature for which the package design has been approved
6. References to certificates for alternative radioactive contents, other competent authority validation, or additional technical data or information
7. Restrictions on the modes of transport
8. Shipment approval requirements, if deemed appropriate
9. Specification of the management system(s) of the organizations involved in transport
10. Operational controls for the preparation, loading, carriage, unloading and handling of the consignment, and stowage provisions for safe dissipation of heat, as well as use of the packaging and specific actions to be taken prior to shipment
11. (Ambient conditions if they are not in accordance with paras 654, 655 and 664, as applicable, of the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1)
12. (For Type B(M) packages, the prescriptions of paras 637, 653–655 and 658–664 of the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1, with which the package design does not conform, as well as amplifying information that may be useful to other competent authorities)

13. (For packages containing more than 0.1 kg of uranium hexafluoride, a statement specifying those prescriptions of para. 632 of the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1, that apply, if any, and amplifying information that may be useful to other competent authorities)
14. Emergency arrangements
15. Applicable regulations concerning the transport of radioactive material <ul style="list-style-type: none"> (a) Road: (b) Rail: (c) Sea: (d) Inland waterways: (e) Air: (f) International: (g) Other:
16. Table summarizing past and current revisions of the approval certificate

III-3. APPROVAL CERTIFICATE FOR SHIPMENTS

1. Expiry date of certificate	2. Competent authority identification mark
3. This certificate is issued on the basis of the application by	
[Name and address of the applicant]	[Reference to the application]
<p>4. This is to certify that the shipment of the radioactive material described in the following is designed to meet the applicable requirements for the shipment of the radioactive material in the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1, and in the regulations listed in the following.</p> <p>This certificate does not relieve the consignor of compliance with any requirement of the government of any State through or into which the package will be transported.</p>	
<p>Date</p> <p>[Signature of the authorized official(s)]</p> <p>Address, telephone number and email address of the competent authority</p>	
5. Identification of the package design approval certificate(s)	
<p>6. Specification of actual radioactive contents, including:</p> <ul style="list-style-type: none"> (a) Radioisotopes (including fissile material) (b) Physical and chemical form (special form radioactive material or low dispersible radioactive material) (c) Total activity per package and per conveyance (including activities of the various isotopes) (d) Total amount in grams of fissile material per package and per conveyance (e) Other applicable contents restrictions 	
7. Restrictions on the modes of transport, type of conveyance and/or freight container, and routeing instructions	
8. Specification of the management system(s) of the organizations involved in transport	

<p>9. Operational controls for the preparation, loading, carriage, stowage, unloading and handling of the consignment, and storage provisions for safe dissipation of heat or maintenance of criticality safety, as well as specific actions to be taken prior to shipment</p>
<p>10. Emergency arrangements</p>
<p>11. Applicable regulations concerning the transport of radioactive material</p> <ul style="list-style-type: none"> (a) Road: (b) Rail: (c) Sea: (d) Inland waterways: (e) Air: (f) International: (g) Other:
<p>12. Table summarizing past and current revisions of the approval certificate</p>

**III-4. APPROVAL CERTIFICATE FOR SHIPMENTS
UNDER SPECIAL ARRANGEMENT**

1. Expiry date of certificate	2. Competent authority identification mark
3. This certificate is issued on the basis of the application by	
[Name and address of the applicant]	[Reference to the application]
<p>4. This is to certify that the shipment of the radioactive material described in the following is designed to meet the applicable requirements for the shipment of the radioactive material under special arrangement, in the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1, and in the regulations listed in the following.</p> <p>This certificate does not relieve the consignor of compliance with any requirement of the government of any State through or into which the package will be transported.</p>	
<p>Date</p> <p>[Signature of the authorized official(s)]</p> <p>Address, telephone number and email address of the competent authority</p>	
<p>5. Package identification</p> <ul style="list-style-type: none"> (a) Reproducible illustration not larger than 21 cm × 30 cm showing the make-up of the package (b) Packaging: <ul style="list-style-type: none"> (i) Model name or number (ii) Descriptions (use, dimensions, materials, closures, penetrations, gross mass, etc.) (iii) Reference to drawings and specifications (iv) Description of the containment system (c) Radioactive contents (non-fissile): <ul style="list-style-type: none"> (i) Radioisotopes (ii) Chemical and physical form (including special form radioactive material or low dispersible radioactive material, if applicable) (iii) Maximum activity per package (including activities of the various isotopes) 	

<p>(d) Packages containing fissile material:</p> <ul style="list-style-type: none"> (i) Type and form of fissile material (ii) Maximum activity and quantity per package (iii) Description of the confinement system (iv) Reference to the documentation that demonstrates the criticality safety of the contents (v) Criticality safety index (vi) Special features (on the basis of which the absence of water from certain void spaces has been assumed in the criticality assessment) (vii) Irradiated fissile material (any allowance for a change in neutron multiplication assumed in the criticality assessment as a result of actual irradiation experience) (viii) The ambient temperature for which the package design has been approved
6. References to certificates for alternative radioactive contents, other competent authority validation, or additional technical data or information
7. Mode(s) of transport and identification of carrier(s)
8. Restrictions on the modes of transport, type of conveyance and/or freight container, and routeing instructions
9. Specification of the management system(s) of the organizations involved in transport
10. Operational controls for the preparation, loading, carriage, stowage, unloading and handling of the consignment, and stowage provisions for safe dissipation of heat, as well as use of the packaging and specific actions to be taken prior to shipment
11. Reasons for the special arrangement
12. Compensatory measures as a result of the shipment under special arrangement
13. (Ambient conditions if they are not in accordance with paras 654, 655 and 664, as applicable, of the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1)
14. Emergency arrangements

15. Applicable regulations concerning the transport of radioactive material

- (a) Road:
- (b) Rail:
- (c) Sea:
- (d) Inland waterways:
- (e) Air:
- (f) International:
- (g) Other:

16. Table summarizing past and current revisions of the approval certificate

Annex IV

MODEL OF COMPETENT AUTHORITY PROCEDURES FOR AUDITING A MANAGEMENT SYSTEM

AUDITS AND INSPECTIONS¹ BY THE COMPETENT AUTHORITY

The following is a list of general items to which the competent authority may direct its attention during audits and/or inspections to ensure the following:

- (a) The management of the organization has provided the necessary personnel and resources to carry out an effective programme for compliance with the Transport Regulations. This programme needs to identify clearly the persons who are responsible for fulfilling the various specific requirements. There needs to be a clear delegation of authority by management to those responsible persons.
- (b) The management has provided proper training to the persons who are responsible for carrying out the programme for compliance with the Transport Regulations. Documentation of the training that has been provided must be submitted to the competent authority upon request.
- (c) Established procedures are followed for the design and fabrication or for the selection and procurement of packagings.
- (d) The consignor is using the proper packaging for the specific contents of packages. The competent authority may carry out direct examination of packages being prepared for shipment.
- (e) The organization has in its possession all the required documentation, including the relevant competent authority certificates and any associated instructions for handling, loading, storage, use and maintenance of the packaging (often given in the form of an instruction manual for the packaging).
- (f) Established procedures are followed for the preparation and use of the package, in accordance with the approval certificate, the instruction manual and related documents.
- (g) Established procedures are followed for the proper marking and labelling of packages, in accordance with the Transport Regulations. This includes the proper determination and application of the correct transport index. When practicable, the competent authority may directly observe such actions.

¹ Inspections may also include measurements carried out by the competent authority.

- (h) Established procedures are followed, and appropriate and properly calibrated instruments are provided, to monitor packages for both radiation and contamination.
- (i) Established procedures are followed for the correct preparation and control of all relevant shipping documents, for providing correct placarding of the carrier's vehicles, for providing all the required documentation to carriers, and for providing any required notification to the competent authorities of each State into which or through which the consignment is transported.
- (j) During transport, carriers perform any required actions relating to placarding, stowage and segregation of packages, etc., particularly any administrative controls relating to exclusive use shipments, or supplementary operational controls as specified in the competent authority certificate.
- (k) The organization has established an appropriate radiation protection programme for its activities concerning the transport of radioactive material, and the programme is maintained, reviewed and complied with.
- (l) Procedures have been developed and implemented to respond to cases of non-compliance, appropriate investigative and corrective action is carried out, and the necessary reporting and communicative action is achieved.
- (m) The organization has developed and continues to maintain appropriate emergency response provisions, and such provisions are exercised periodically.

Examples of checklists that may be used by competent authorities for their audit and inspection activities are given in Annexes V–IX. These checklists are not comprehensive and may be used as a starting point for a competent authority to develop its own checklists in accordance with the size and complexity of the industry and operations being inspected.

EXAMPLE OF A PROCEDURE FOR AUDITING OF THE MANAGEMENT SYSTEM

AUDITING OF THE MANAGEMENT SYSTEM	Procedure No.
	Revision No.
	Page No.
	Originator
	Date

CONTENTS

1. Purpose
2. Scope
3. Definitions
4. Responsibilities
5. Procedure
6. Records
7. Declaration

Rev. No.	Approval date	Authorized by	Position	Approved by	Position

1. PURPOSE

1.1. To define the method used by the competent authority to perform compliance audits of the management system (in support of the compliance assurance programme developed by the competent authority in compliance with the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material, 2005 Edition, TS-R-1).

2. SCOPE

2.1. The procedure covers the auditing activities of the competent authority and its agents in connection with a programme specified by a nominated person

(denoted in this annex as the ‘head of compliance’) and agreed to by management. In addition to the planned programme of auditing, extra auditing activities may be arranged if this is requested by other sections.

Auditing activities include, but are not limited to:

- (a) Establishing whether the elements within the management system are properly documented;
- (b) Verifying through reviews and evaluation of documentary evidence that the management system is being implemented;
- (c) Evaluating the adequacy, effectiveness and efficiency of the management system;
- (d) Identifying non-compliance, requesting and verifying corrective actions.

3. DEFINITIONS

3.1. Audit checklist

A listing of the enquiries to be raised by the audit team.

3.2. Audit matrix

A chart of activities audited and the standard(s) for management systems against which the activities have been audited.

3.3. Audit plan

A timetable of auditing activities.

3.4. Auditee

The department or organization that is the subject of the audit.

3.5. Auditor(s)

The person(s) responsible for undertaking the audit.

3.6. Compliance audit

An audit of the prescribed arrangements and their provisions against the requirements of international or national regulations.

3.7. Corrective actions

Measures or actions taken to rectify non-compliance or to prevent any recurrence.

3.8. Non-compliance

An identified deviation or departure from the provisions of the specified standard for the management system or the arrangements prescribed under the management system.

3.9. Observation

A reportable deviation from good working practice that may give rise to a problem with quality.

3.10. Audit of the management system

A systematic and independent examination to determine whether the activities in the management system and the related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving the objectives of the organization.

4. RESPONSIBILITIES

4.1. The head of compliance is responsible for the management of all audits of the management system and for compliance auditing by the competent authority. The head of compliance is responsible for appointing the audit team leader.

4.2. The team leader is responsible for the planning, preparation, documentation and reporting of all quality audit activities. In undertaking audits of the management system, the following are developed:

- (a) The audit plan;
- (b) Checklists;

- (c) The audit matrix;
- (d) The audit report;
- (e) A statement of completion of the audit.

4.3. Auditees are responsible for implementing the corrective actions noted on documented requests for corrective action.

4.4. The team leader is responsible for verifying that requests for corrective action have been implemented.

5. PROCEDURE

5.1. Audit preparation

5.1.1. The head of compliance, or the designate, prepares and issues to management an overall audit programme. The programme is reviewed and updated periodically.

5.1.2. The head of compliance selects the audit team and nominates a team leader. The team leader may delegate preparatory and follow-up activities to team members. Team members other than observers should have received formal training in appropriate auditing techniques.

5.1.3. The team leader opens an audit file (all commercial information being confidential), allocates a sequential reference number and arranges initial contact with the auditee. If other government departments have an interest in the audit, they may be informed in accordance with any extant interdepartmental agreements.

5.1.4. The general arrangements and plans for the audit are prepared by correspondence and, if necessary, by means of a pre-audit meeting of the team leader and the auditee.

5.1.5. The team leader records the proposed audit activities in an audit plan. A questionnaire (audit checklist) is used, which covers the scope of the audit to be undertaken.

5.1.6. An audit matrix is drawn up, reflecting the criteria of the codes or standards against which the auditee will be audited.

5.1.7. The agreed date(s) for the audit is (are) confirmed by means of correspondence with the auditee; other interested parties are also notified. In all instances the notification includes the following points:

- (a) The date and time of the planned audit;
- (b) Details of the audit plan;
- (c) The name(s) of the auditor(s);
- (d) The agenda for the opening meeting.

5.1.8. Prior to the audit, an auditors meeting is convened at which the audit plan, the audit checklist and the audit matrix are discussed. Any other relevant information, such as the results of previous audits or reviews, is included.

5.2. Performance of the audit

5.2.1. The audit is opened by a meeting between the audit team and the representatives of the auditee. The topics covered at the meeting include:

- (a) Introduction;
- (b) The purpose of the audit;
- (c) The audit plan and the scope of the audit;
- (d) The interests of other government departments;
- (e) The closing meeting and attendance.

5.2.2. The audit is conducted objectively so as to establish whether the areas under examination have a satisfactory management system and whether the auditee is adhering to it.

5.2.3. An audit matrix is completed by each auditor, indicating the criteria that have been audited. In the final audit review, the team leader checks all the audited criteria against the criteria of the respective codes and standards. Areas not audited are then highlighted, and the team leader can decide what actions have to be taken. The completed audit matrix is then included in the audit record, which can be used when future audits are planned, for example, for criteria not audited or areas considered weak.

5.2.4. Evidence and details of non-compliance regarding the standards or procedures on which the audit is based are recorded. The record of non-compliance should indicate whether the necessary corrective action should be taken immediately or within a given time. This record is signed by a representative of the auditee to confirm that it is factual and correct. However,

if the representative of the auditee does not countersign the non-compliance record, it may still be considered to be admissible if the team leader so decides.

5.2.5. The auditor regularly reviews the progress of the audit, discussing non-compliance, changes of the audit plan (if necessary) and other topics. In a final review before the closing meeting, the non-compliance, observations and conclusions to be presented at the closing meeting are agreed upon. Also, the audit matrix is completed, recording the areas and topics covered during the audit. (This completed audit matrix is considered to constitute evidence of compliance with the Transport Regulations.)

5.3. Closing meeting

5.3.1. A closing meeting (as decided upon at the opening meeting) is convened with the management of the auditee and the audit team. The team leader presents a balanced summary of the audit undertaken, referring to the positive aspects emerging from the audit, as well as to the points of non-compliance and the observations indicating where the management system has been found to be inadequate. Copies of the reports on non-compliance and observations are presented to the auditee.

5.3.2. The representatives of the auditee are invited to comment on the findings; any disagreement or clarification concerning corrective actions is discussed and resolved. The auditee is advised by the team leader that a written report of the audit will be sent by the competent authority in due course.

5.4. Audit report

5.4.1. The auditor(s) prepare(s) an audit report, which includes the findings of the audit and the corrective actions to be undertaken. Further consultation with other government departments is held at this stage, if necessary. When considered appropriate by the head of compliance, an interim audit report, covering only the findings, may be prepared and sent to the auditee for prompt information.

5.4.2. The audit report is sent to the auditee, together with a covering letter referring to follow-up and verification of corrective actions. Auditees are requested to respond formally to these requirements, stating the timescale for the completion of such actions.

5.4.3. The progress of corrective actions is monitored by the team leader, using a statement of audit completion. If problems are encountered in connection with these required actions, the head of compliance and management may also be involved in this process. Where required, follow-up reports are issued to inform the appropriate senior management of the auditee that a potential problem remains. When the audit is complete, the team leader confirms this in a letter to the auditee. The team leader also checks that all required documentation and records are filed and indexed. Completion of the audit is certified by a written statement of audit completion, which is signed by the team leader.

6. RECORDS

6.1. The following audit records are retained by the competent authority:

- (a) Audit programmes;
- (b) Individual audit files, containing audit plans, audit matrices, audit reports, follow-up letters, correspondence and statements of completion of the audit;
- (c) Index of completed audits.

7. DECLARATION

This procedure does not preclude the competent authority from any enforcement action deemed necessary in accordance with its management framework for enforcement.

Annex V

EXAMPLE/MODEL OF A CHECKLIST FOR AUDITING A MANAGEMENT SYSTEM

MANAGEMENT SYSTEM AND STRATEGIC PLANNING

1. Is there an established and appropriately documented management system?
2. Is the organization's policy and statement of authority with respect to the management system documented?
3. Does the management system fully identify those processes and activities covered by the management system and provide for their effective control?
4. Is involvement in and commitment to the management system and its objectives evident on the part of senior management?
5. Does the management system fully cover the activities carried out by the organization (these activities may include the design, manufacture, maintenance and repair of packagings, and the preparation, consigning, loading, carriage (including in-transit storage), unloading and receipt at the final destination of loads of radioactive material and packages)?
6. Does the review process include all necessary inputs?
7. Is there a defined organizational structure?
8. Are the requirements of the management system commensurate with the complexity of the packaging or its components and with the degree of hazard associated with the material being transported?
9. Is the management system subject to review and evaluation, and, if so, how frequently?
10. Who is responsible for reviewing the management system?
11. Does the review process include all necessary inputs?

12. Does the review process include a confirmation that the management system demonstrates compliance with the regulations relating to the transport of radioactive material by the modes of transport used by the organization?

13. Do the strategic plans of the organization include the development of its policies, objectives and processes?

14. Are the functional responsibilities and levels of authority clearly defined at all levels within the organization?

ORGANIZATIONAL POLICIES

15. Has the organization established a quality policy?

16. How does the organization manage organizational changes to ensure that it remains effective and that quality and compliance remain unaffected?

STRUCTURING THE MANAGEMENT SYSTEM

17. Does the structure of the management system reflect the size and complexity of the organization and its functions?

18. Does the structure of the management system include a complete description of all transport activities of the organization relating to the transport of radioactive material (maintenance and/or repair, assembly and/or disassembly, loading, handling, labelling, dispatch, carriage, receipt, unloading and storage of packages and/or packagings, as appropriate)?

SAFETY CULTURE

19. Does a radiation protection programme exist within the organization?

20. What processes are used to encourage and manage a safety culture within the organization?

GRADING THE APPLICATION OF REQUIREMENTS UNDER THE MANAGEMENT SYSTEM

21. Is there a graded approach to the management system and, if so, is it defined?
22. Are the requirements of the management system commensurate with the complexity of the packaging or its components and with the degree of hazard associated with the material being transported?

DOCUMENTATION AND CONTROL OF RECORDS

23. Has the management system documentation been sufficiently well defined, and are all essential documents supporting the effective and efficient operation of the management system in place?
24. Are there documented procedures to control all necessary documentation (paper, electronic or other acceptable media)?
25. Do the procedures cover the preparation, approval and issuing of such documentation?
26. Has a system for the release, distribution and withdrawal of documents been established?
27. How are personnel made aware of changes to documents?
28. How are suppliers made aware of changes to documents?
29. Are applicable codes, standards, regulations, etc., updated as amendments are issued?
30. How are essential personnel made aware that amendments to documents, including codes and standards, have been issued?
31. Are copies of redundant or out of date documents suitably marked, withdrawn or destroyed?

32. Are superseded or redundant documents retained, and if so, how are they controlled to prevent their accidental use?
33. Are changes to documents subject to review and approval:
 - (a) In accordance with documented procedures?
 - (b) By designated persons or organizations having relevant background information and knowledge and understanding of the original document?
34. How are incoming and/or external documents controlled?
35. Are records of changes to documentation retained?
36. Does the system cover the maintenance of essential records of the management system?
37. Does the system cover the identification, collection, indexing, filing, storage, maintenance and disposal of records?
38. Are records readily retrievable and maintained in a suitable environment?
39. Are retention periods for records defined?
40. Are records and/or logbooks available for each package and/or packaging?
41. Are the records and/or logbooks available for inspection?
42. Do logbooks contain the information as movement or transport records, authorized modifications to the package, and operating and maintenance instructions?
43. Are records available for servicing or for maintenance carried out at other locations?

COMMITMENT BY MANAGEMENT

- 44. Has a management representative been appointed and given appropriate authority to manage, monitor, evaluate and coordinate the management system?
- 45. Are management reviews held within the organization?
- 46. Are measurable objectives of the management system established at relevant functions and levels within the organization?

SATISFACTION OF INTERESTED PARTIES

- 47. What processes exist within the organization to monitor and measure the satisfaction of interested parties?

RESOURCE MANAGEMENT

- 48. Is there a commitment to the timely identification and provision of necessary resources, including personnel, to meet the needs of customers and regulatory needs?
- 49. Who identifies training needs?
- 50. Who maintains training records?

INVOLVEMENT OF PERSONNEL

- 51. How does the organization encourage the involvement and development of its personnel?
- 52. How is this measured?

INFORMATION AND KNOWLEDGE MANAGEMENT

- 53. How does the organization characterize, monitor and manage information and knowledge?

COMMUNICATION AND INTERFACES

54. Does the organization provide for the effective communication of its policies, needs of customers and regulatory needs to all personnel within the organization?

55. Are internal and external lines of communication established and defined?

56. Interfaces:

(a) Are the interfaces between organizations defined?

(b) Are these interfaces regularly reviewed?

(c) Have the responsibilities of each organization been clearly defined?

DEVELOPMENT OF PROCESSES

57. Is there evidence that the organization has developed the management and work processes associated with the transport activities of the organization relating to the transport of radioactive material (maintenance and/or repair, assembly and/or disassembly, loading, handling, labelling, dispatch, carriage, receipt, unloading and storage of packages and/or packagings, as appropriate)?

PROCESS MANAGEMENT AND CONTROL OF PRODUCT

58. Are common processes such as document control, non-conformance control and corrective actions, management review and internal audits identified and adopted throughout the organization?

DESIGN CONTROL

59. Are there sufficient measures in place to control the design process, and are they documented where necessary?

60. Have appropriate responsibilities been assigned for the whole design process?

61. Are there suitable procedures established for communicating design information, including changes, between:

- (a) Design disciplines?
- (b) Departments?
- (c) External interfaces including manufacturing and maintenance and/or repair facilities?

62. Is a graded approach to design used? If so, is each grade defined? For example:

Grade 1

- (a) Are the relevant regulations, industrial standards and codes defined?
- (b) Does the management system require design verification to be accomplished by:
 - (i) Design review and prototype testing;
 - (ii) Calculations;
 - (iii) Computer codes?

Grade 2

- (a) Are the relevant regulations, industrial standards and codes defined?
- (b) Does the management system require design verification to be accomplished by:
 - (i) Calculations;
 - (ii) Computer codes?

Grade 3

- (a) Does the design follow accepted engineering or industrial practice?

63. Have provisions been made to ensure that all necessary design input – including customers' needs and other needs and requirements – has been identified and included in the design process?

64. Is the design input documented in a way that permits adequate evaluation by technical personnel other than those persons performing the original design?

- (a) Are such evaluations planned?
 - (b) Are such evaluations documented?
 - (c) Are such evaluations carried out before submitting design information to the competent authority and to suppliers, or before commencing manufacture?
65. Have all acceptance and verification criteria been identified in design output and included in design input?
66. Is design output sufficiently well defined to demonstrate its conformance with design input requirements?
67. What measures are established for the selection and for the review of the suitability of application of any:
- Materials;
 - Equipment;
 - Processes?
- (a) Are such measures defined in procedures or instructions?
 - (b) Are such selections and/or reviews documented?
 - (c) Are such selections and/or reviews evaluated by technical personnel other than those performing the original design work?
68. Are there suitable arrangements for review of the design output to confirm the adequacy of the design?
- (a) Are design reviews conducted?
 - (b) Are they planned and systematic?
 - (c) Are they documented?
 - (d) Do they include technical personnel other than those persons performing the design work?
 - (e) Are alternative calculational methods employed?
69. Are there appropriate arrangements for verification and subsequent validation of the adequacy of the design, such as a programme of model and/or prototype or full scale testing in accordance with the requirements of the Transport Regulations?

70. Do the design process procedures provide for the control of changes, deviations and/or concessions regarding the design requirements?

- (a) Are changes, deviations and/or concessions documented?
- (b) Do such documents require authorization by the person responsible for the design?
- (c) Do such documents, after authorization, state the justification for acceptance of such changes, deviations and/or concessions?
- (d) Are suitable records retained?

71. Are design related changes to existing and/or in-service equipment covered by appropriate process controls?

- (a) Is there a procedure for controlling in-service changes or modifications?
- (b) Are such in-service changes or modifications documented?
- (c) Are in-service changes or modifications subject to the approval of the person responsible for the design?
- (d) Are the justifications for accepting in-service changes and modifications and the required actions documented?
- (e) Is information concerning changes sent to:
 - (i) All affected persons and organizations?
 - (ii) All personnel or organizations holding the original design?
- (f) Are suitable records retained?

MANAGEMENT SYSTEMS AND THE DIFFERENT PHASES OF TRANSPORT

72. Does the management system clearly identify the different phases of transport — namely, maintenance and/or repair, assembly and/or disassembly, loading, handling, labelling, dispatch, carriage, receipt, and unloading and storage of packages and/or packagings — and the interfaces between them?

PURCHASING

73. Have effective and efficient purchasing processes been defined and suitable controls implemented?

74. Do the purchasing arrangements provide for all necessary purchase requirements to be identified and specified on purchase orders and/or documents?

75. Does the system ensure that the relevant design documents and regulatory requirements are included or referenced in procurement documents?

76. Are purchasing arrangements commensurate with the importance or safety related aspects of the product being procured? Is a graded approach to products and suppliers being taken?

77. Do the procurement documents require that design and quality requirements be passed on to sub-suppliers?

78. Do the procurement documents require that material traceability be maintained throughout fabrication and assembly?

79. Are suppliers selected and evaluated for their ability to supply products in accordance with specified requirements?

80. Who carries out this evaluation, and is it recorded?

81. How is the past performance of suppliers recorded?

82. How often is a supplier assessed?

83. Are audits of supplier management systems carried out as part of the evaluation process?

84. Are supplier audits planned and documented?

85. Do purchasing documents provide for adequate access by the purchaser and the competent authority to the plants of the suppliers and sub-suppliers?

86. What controls are established to ensure that purchased items conform to the requirements of procurement documents?

87. Are such controls documented?

88. Are suitable arrangements provided for the care and control of customer supplied materials or items?

IDENTIFICATION, TRACEABILITY AND PRESERVATION OF MATERIALS

89. Are suitable arrangements in place to determine when identification and traceability of materials, items, software, etc., are necessary?

90. Are the necessary identification and traceability of such items being achieved?

91. Are measures established to control the handling, storage and shipping of materials?

92. Are suitable provisions in place for the preservation and protection of products, materials, packagings, etc., to ensure their fitness for use when needed?

PROCESS CONTROL

93. Have all relevant processes, including those necessary for the management system, been identified and their control provided for?

94. Do process control arrangements, including procedures, instructions, drawings, etc., include appropriate qualitative and quantitative acceptance criteria for determining that important activities have been satisfactorily accomplished?

95. Are documents such as quality plans produced to support process control? Are such plans available?

96. Are any design, production or other processes carried out by sub-suppliers controlled, and how is this done?

97. How are process control arrangements, procedures, etc., reviewed, controlled and issued?

98. Do sub-suppliers use their own process control procedures or those of the purchasing organization (e.g. process procedures and work instructions)?

99. Are inspections or other process control checks carried out at defined points during the process (e.g. manufacturing, servicing)?

100. Are special processes controlled (e.g. welding)?

101. How are these special processes controlled and monitored?

102. Are only suitably qualified and experienced people used to control or perform special processes?

103. Are all necessary controls or supporting processes available for controlling special processes (e.g. heat treatment)?

CONTROL OF INSPECTIONS, MEASUREMENTS AND TESTS

Inspection

104. Have programmes for inspection of items and services been established?

105. Do the procurement documents require suppliers to establish inspection programmes?

106. Have programmes for in-service inspections been established?

107. Who authorizes inspection programmes?

108. Are such inspections conducted by qualified personnel other than those persons performing the activities?

109. Have inspection procedures been established?

110. What processes ensure that non-conforming in-service items are removed from use until the situation is rectified?

111. Are inspection hold points defined?

112. How is it ensured that work does not proceed beyond a hold point?

Measurement and monitoring

113. What process(es) does the organization use to measure and monitor the effectiveness of its management system processes?

114. What process(es) does the organization use to measure and monitor the characteristics of its packagings, packages and/or conveyances to verify that the needs of customers and regulatory requirements have been met?

115. What process(es) does the organization use to release a packaging, package and/or conveyance to its customer?

Testing

116. Have test programmes been established?

117. How is it ensured that the test programme demonstrates the adequacy of the specification and that all parts will perform satisfactorily in service?

118. Is testing carried out against written test procedures, and are the acceptance criteria specified?

119. Who evaluates the test results?

120. Does testing cover normal and accident conditions of transport?

121. Does the system cover calibration and control of the measuring and test equipment?

122. Are calibration records available, and can they be traced back to a national standard?

123. If equipment is found to be non-compliant, how is acceptance of the items reassessed?

124. Are controls established for the handling, storage and use of equipment?

125. How is the inspection status identified, and is it maintained throughout the manufacture and use of an item?

SERVICING

126. Have systems and control processes for handling, labelling, dispatch, carriage, receipt, unloading and storage of packages and/or packagings been established?

127. Do procedures include controls for:

- (a) The contents;
- (b) Cleaning of packages;
- (c) Preserving;
- (d) Leaktightness;
- (e) Radiation and contamination levels;
- (f) Turnround and periodic inspection of package and/or packaging;
- (g) Consumable and spare packaging components?

SELF-ASSESSMENT

128. Is there a programme for internal and external audits?

129. Is the audit programme documented?

130. Are audits conducted by qualified persons who have not been involved in the activity being audited?

131. Are effective corrective actions taken when the system is found to be incorrect?

132. Are internal audit reports used for system reviews?

INDEPENDENT ASSESSMENT

133. Is the organization subjected to independent assessment by any of its interested parties?

134. How do the findings of any independent assessments compare with the findings made by internal auditing?

NON-CONFORMANCE, AND CORRECTIVE
AND PREVENTIVE ACTIONS

135. Is there an effective system for controlling non-conforming material?
136. Are the procedures for rework and repair of non-conforming material documented and acceptable?
137. Is the responsibility for the review and acceptance of non-conforming items specified?
138. Are accepted non-conformities reported to the purchaser and, if necessary, to the competent authority?
139. Does the system provide for the detection of inferior quality and for the correction of its causes?
140. Is adequate action taken to correct the causes of inferior quality (i.e. design faults, defective material)?
141. Are analyses made to identify trends towards material non-conformance?
142. Does corrective action extend to material supplied by sub-contractors?
143. Are data analysis and material examination conducted on failed items to determine the extent and causes of defects?
144. Is the effectiveness of corrective actions reviewed and monitored?

IMPROVEMENT

145. Are appropriate arrangements in place to review and confirm that the requirements of customers and other interested parties are being met?
146. Does the organization have a process for continuous improvement?

Annex VI

**EXAMPLE/MODEL OF A CHECKLIST FOR
INSPECTING TRANSPORT DOCUMENTATION**

Company or organization:				
Location:				
Management system reference:				
Report No.:		Date:		
1. Checks		Yes	No	N/A
<p>The competent authority may decide to implement checks of transport documentation at any stage of the operation, for example:</p> <p>(a) Prior to dispatch;</p> <p>(b) During shipment;</p> <p>(c) During trans-shipment;</p> <p>(d) During storage in transit upon arrival at destination.</p>				
2. Driver's instructions/handbook				
<p>(a) Are drivers provided with written instructions?</p> <p>(b) Do these instructions contain emergency response procedures compiled by the consignor and/or the carrier?</p> <p>(c) Do these instructions and/or procedures cover any trans-shipment or en route storage requirements?</p> <p>(d) Does the driver carry or have in his or her possession the documents necessary to confirm his or her proficiency in handling radioactive material (e.g. a training certificate)?</p>				

3. Consignment documentation (load manifest)	Yes	No	N/A
(a) Is the driver supplied with a completed load manifest? (b) Does the load manifest contain shipment details? (c) Does the load manifest contain load details, such as source types and activity, package types and category labelling of packages? (d) Are the individual package transport and/or criticality safety indices correct and entered on the load manifest? (e) Is the total load transport index and/or criticality safety index correct and entered on the load manifest? (f) Is the statement of compliance made as required in the Transport Regulations, and is it correct?			
4. Particulars of the consignment (a) Have all of the regulatory aspects of the particular consignment been complied with? (b) Are competent authority certificates available? (c) Are provisions and conditions for shipment under special arrangement being complied with? (d) Are all requisite documents, certificates, etc., correct, complete and authorized?			
5. Records (a) Are the necessary documents kept as records?			

Annex VII

EXAMPLE/MODEL OF A CHECKLIST FOR INSPECTING TRANSPORT OPERATIONS

Inspections of transport operations can be carried out during any phase of transport (preparation, consigning, carriage, transfer, in-transit storage, unloading and receipt). The terms ‘transporter’ and ‘operator’ can apply to any responsible organization involved in the transport operations.

Company or organization:			
Location:			
Management system reference:			
Report No.:	Date:		
1. Company details	Yes	No	N/A
(a) Does the transporter require national licensing such as an operator licence or transport licence?			
(b) Is the licence authorized and valid?			
2. Modes of transport			
(a) What modes of transport does the operator offer? Land (road/rail) – sea – air			
(b) Is the operator familiar with these modes of transport?			
(c) Is the operator aware of the regulations relating to the modes of transport?			

3. Vehicles	Yes	No	N/A
<p>(a) Are vehicles subject to a maintenance programme?</p> <p>(b) Are records kept of vehicle maintenance?</p> <p>(c) Are the vehicles suitable for the transport of the particular consignments (e.g. weight limitations)?</p> <p>(d) Are all tie-down and anchorage points subject to testing, and are records kept of the test results?</p> <p>(e) Are the vehicles correctly placarded?</p> <p>(f) How are the stowage conditions met?</p> <p><i>Note:</i> The above questions relate to road or rail transport; similar questions can be developed for other modes of transport.</p>			
<p>4. Operators</p> <p>(a) Does the operator provide an adequate training programme for all personnel?</p> <p>(b) Does the operator maintain records of the training and of the levels of proficiency obtained?</p> <p>(c) Does the operator have an appropriate radiation protection programme in place?</p>			
<p>5. Documentation</p> <p>(a) Is all requisite documentation completed and recorded by designated personnel?</p> <p>(b) Where certification is required, are copies of certificates kept, and are the conditions stated in them being met?</p>			
<p>6. Regulations</p> <p>(a) Is the operator aware of all necessary regulations (national, international), and are they complied with?</p> <p>(b) Are all necessary current certificates available?</p>			

7. Procedures	Yes	No	N/A
(a) Does the operator document its operations through written procedures and instructions, as part of an effective management system?			
8. Emergency arrangements			
(a) Are adequate emergency response plans or procedures in place?			
(b) Are the plans of the carrier and those of the consignor compatible?			
9. Security arrangements			
(a) Where applicable, are appropriate security arrangements in place?			

Annex VIII

EXAMPLE/MODEL OF A CHECKLIST FOR INSPECTING THE MANUFACTURING OF PACKAGINGS

Company or organization:			
Location:			
Management system reference:			
Report No.:	Date:		
1. Management system	Yes	No	N/A
(a) Does the manufacturer have a management system for the manufacturing process? (b) Does the manufacturer apply a graded approach to the manufacturing, and how are such grades obtained and specified? (c) Are the quality assurance programmes verified/ audited by appropriate agencies?			
2. Equipment			
(a) Does the manufacturer have sufficient production equipment (tools), and is it suitable? (b) Does the manufacturer have sufficient and adequate inspection and test equipment, and is it suitable?			
3. Personnel			
(a) Does the manufacturer have sufficient qualified and trained personnel? (b) Where qualification is required, how is this carried out (e.g. welder qualification by provision of certified test pieces; certifiable skills of inspectors in non-destructive testing), and what records are kept?			

4. Documentation	Yes	No	N/A
<p>(a) Are documented procedures or plans available (e.g. written instructions for manufacturing, testing and inspection; records of deviations or concessions and modifications)?</p> <p>(b) Are all drawings, specifications and records adequate, current and available?</p> <p>(c) Are all documents subject to control procedures?</p> <p>(d) Do all drawings used conform to the numbers and the issue category stated on the relevant approval certificate of the competent authority or other approval certificate?</p> <p>(e) Are all package serial numbers controlled and are they traceable to the approval certificate of the competent authority, and is the competent authority notified of the numbers?</p>			
<p>5. Materials</p> <p>(a) Does the manufacturer exercise sufficient control over all materials used in the manufacture of packages?</p> <p>(b) Does the manufacturer procure materials from sources verified against national or international standards?</p> <p>(c) Are the materials adequately stored and tested to ensure conformance with specifications?</p>			
<p>6. Manufacture</p> <p>(a) Has the manufacture been carried out in accordance with the approved design specifications?</p> <p>(b) Have any modifications been made to the finished package relative to the approved design?</p> <p>(c) Have all process controls, tests and inspections necessary during manufacture been carried out?</p>			

7. Regulations	Yes	No	N/A
(a) Is the manufacturer aware of the regulatory requirements, and are these understood and being observed?			
8. Records			
(a) Does the manufacturer maintain adequate records of its operations (e.g. reports of manufacture, testing, materials specification, deviations or concessions)?			

Annex IX

**EXAMPLE/MODEL OF A CHECKLIST FOR
INSPECTING MAINTENANCE AND SERVICE OPERATIONS**

Company or organization:				
Location:				
Management system reference:				
Report No.:		Date:		
1. Documentation		Yes	No	N/A
(a) Are maintenance and service instructions and schedules available, and do they correspond to the requirements of the competent authority approval certificate?				
(b) Do the instructions and schedules specify disassembly and assembly procedures and maintenance frequency or periods?				
(c) Are records kept of maintenance and service (e.g. package logbook)?				
(d) Are these records or logbooks correctly completed, verified or certified by authorized personnel?				
2. Specification of components or features				
(a) Are package components or features identified or divided into categories (indicating major or minor importance to safety)?				
(b) Are these categories consistent, and are they interpreted correctly?				

3. Testing and inspection	Yes	No	N/A
(a) Is evidence available to show that specified tests and inspections have been performed? Examples are: – Functional or operational tests of components; – Visual inspection for condition, wear, damage, failure; – Dynamic testing; – Pressure tests; – Leak tests; – Non-destructive testing, radiographic testing, ultrasonic testing and dye penetrant testing.			
4. Packaging components (a) Are there specified procedures for the repair, reconditioning, refurbishment and disposal of packaging components?			
5. Equipment and tools (a) Is the specified test equipment available? (b) Is all required test and inspection equipment in good condition, and is it calibrated? (c) Is calibration carried out by a certified organization for calibration, and are the applied calibration standards and procedures traceable to recognized national or other acceptable standards? (d) Is the specified or required special equipment available, and does it conform to the specifications?			
6. Training (a) Do all personnel performing tasks receive appropriate training? (b) Are the training programmes adequate for the required tasks? (c) Are the training programmes effective in helping personnel to acquire the necessary skills and understanding?			
3. Records (a) Are records generated and appropriately maintained?			

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