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Compliance Assurance for the Safe Transport of Radioactive Material

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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 conducted in compliance with the IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition [1] (hereinafter referred to as 'the Transport Regulations').

1.2. Compliance assurance is defined in the Transport Regulations as "a systematic programme of measures applied by a competent authority that is aimed at ensuring that the provisions of these Regulations are met in practice". Paragraph 307.2 of IAEA Safety Standards Series No. SSG-26 (Rev. 1), Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition) [2] states:

> "As used in the Transport Regulations, the term 'compliance assurance' has a broad meaning which includes all of the measures applied by a competent authority that are intended to ensure that the requirements of the Transport Regulations are complied with in practice."

Therefore, essentially all activities of the competent authority are deemed part of its programme to ensure compliance with the Transport Regulations and are addressed in this Safety Guide. The recommendations provided in this Safety Guide supplement the recommendations provided in IAEA Safety Series Nos GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [3] and GSG-13, Functions and Processes of the Regulatory Body for Safety [4].

1.3. IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [5], establishes requirements for establishing, sustaining and continuously improving leadership and management for safety, and an effective management system. This Safety Guide also uses the concept of a 'management 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).

1.4. Management systems implemented by users[1] of the Transport Regulations, as required by para. 306 of the Transport Regulations, are an important component of compliance assurance, and inspections[2] by the competent authority of these management systems is an effective means of monitoring the compliance of the user with the Transport Regulations.

[1] In this Safety Guide, a 'user' is a person who, or an organization associated with and involved in the movement of radioactive material that, designs, manufactures, maintains and repairs packagings, and prepares, consigns, loads, carries (including in-transit storage), ships after storage, unloads, receives or otherwise uses a package in connection with the transport of radioactive material.

[2] In some Member States, the term 'audit' is used when referring to inspection activities related to a management system.

1.5. This Safety Guide updates the recommendations provided in the Safety Guide on compliance assurance for the safe transport of radioactive material[3], which is hereby superseded.

OBJECTIVE

1.6. The objective of this Safety Guide is to assist competent authorities in the development and maintenance of compliance assurance programmes for the transport of radioactive material. This Safety Guide is intended to assist in ensuring a uniform application of the Transport Regulations by providing recommendations on the actions that competent authorities should perform in relation to their compliance assurance programmes.

1.7. 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 compliance assurance programmes. Additionally, the Safety Guide will assist users of the Transport Regulations in their interactions with competent authorities.

SCOPE

1.8. This Safety Guide addresses compliance assurance for the safe transport of radioactive material, based on the same scope as described in paras 106–110 of the Transport Regulations.

STRUCTURE

1.9. 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 various aspects of the compliance assurance programme. Section 5 provides information on multilateral approvals. 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

REGULATORY BASIS

2.1. The government is required to assign the prime responsibility for safety to the person or organization responsible for a facility or an activity (which includes the transport of radioactive material): see Requirement 5 of IAEA Safety Standards Series GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [6]. The prime responsibility for ensuring safety in transport rests with consignors and carriers, who are required to take account of all relevant regulations.

2.2. Paragraph 307 of the Transport Regulations states that "The competent authority shall assure compliance with these Regulations." This compliance includes the oversight and enforcement of all regulations. In addition, certain activities of the competent authority are

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Compliance Assurance for the Safe Transport of Radioactive Material, IAEA Safety Guide No. TS-G-1.5, IAEA, Vienna (2009).

directly related to specific requirements of the Transport Regulations, such as the issuing of approvals and the allocation of identification marks.

2.3. A State whose framework and arrangements for the transport of radioactive material are not yet fully established may develop its compliance assurance programme in stages, depending on the size of the transport industry. IAEA Safety Standards Series No. SSG-44, Establishing the Infrastructure for Radiation Safety [7] provides recommendations on the general approach to be followed. In an effective programme for compliance assurance, all users of the Transport Regulations and regulatory bodies (which may share responsibilities with the competent authority) should be considered.

ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

2.4. GSR Part 1 (Rev. 1) [6] establishes requirements for the roles and responsibilities of competent authorities[4]. Requirement 2 of GSR Part 1 (Rev. 1) [6] states:

> "**The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.**"

2.5. Paragraph 2.5 of GSR Part 1 (Rev. 1) [6] states:

> "The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:
>
> (1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;
>
> (2) The types of facilities and activities that are included within the scope of the framework for safety;
>
> (3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;
>
> (4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;
>
> (5) Provision for the involvement of interested parties and for their input to decision making;
>
> (6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are undertaken by several persons or organizations successively;
>
> (7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;

[4] The term "competent authority" is used in the Transport Regulations for consistency with terminology used in the wider field of the regulation of the transport of dangerous goods. In the IAEA Safety Standards, the more general term "regulatory body" is used, with which competent authority is essentially synonymous.

(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;

(9) The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;

(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;

(11) Provision for appeals against decisions of the regulatory body;

(12) Provision for preparedness for and response to a nuclear or radiological emergency;

(13) Provision for an interface with nuclear security;

(14) Provision for an interface with the system of accounting for, and control of, nuclear material;

(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;

…

(18) The specification of offences and the corresponding penalties;

(19) Provision for controls on the import and export of nuclear material and radioactive material, as well as for their tracking within, and to the extent possible outside, national boundaries, such as tracking of the authorized export of radioactive sources."

2.6. Paragraph 2.6 of GSR Part 1 (Rev 1) [6] states:

"Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety."

2.7. The government is required to ensure that the competent authority is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making: see Requirement 4 of GSR Part 1 (Rev. 1) [6].

LIST OF NATIONAL COMPETENT AUTHORITIES

2.8. A list of National Competent Authorities for the Safe Transport of Radioactive Material (competent authorities responsible for approvals and authorizations related to the transport of radioactive material) is available at Ref. [8]. Competent authorities should ensure that the information provided in this list is checked at least annually to verify that it is correct.

INTERLINKED RESPONSIBILITIES

2.9. As stated in para. 207.1 of SSG-26 (Rev. 1) [2], "The competent authority is the organization defined by legislative or executive authority to act on behalf of a country in matters involving the transport of radioactive material, or an international authority on such matters.

The legal framework of a country determines how a national competent authority is designated and is given the responsibility to ensure application of the Transport Regulations. In some instances, authority over different aspects of the Transport Regulations is assigned to different agencies, depending on the transport mode (air, road, rail, sea or inland waterway) and on the package and radioactive material type (excepted, industrial, Type A, Type B(U), Type B(M) and Type C packages; special form radioactive material, low dispersible radioactive material (LDRM), fissile material or uranium hexafluoride). A national competent authority may, in some cases, delegate the approval of package designs and certain types of shipment to another organization having the necessary technical competence. National competent authorities also constitute the competent authorities referred to in any conventions or agreements on the transport of radioactive material to which the country adheres."

2.10. Recommendations regarding the liaison between the competent authority and other governmental organizations are provided in paras 4.44–4.48 of GSG-12 [3].

ORGANIZATION AND MANAGEMENT OF THE COMPETENT AUTHORITY

2.11. GSG-12 [3] provides recommendations on meeting the requirements of GSR Part 1 (Rev. 1) [6] in respect of the organizational structure, management and staffing of the competent authority to support competent authorities in performing their responsibilities and functions efficiently and effectively and in an independent manner.

2.12. GSG-12 [3] provides recommendations in relation to the following:

a) The general characteristics of a competent authority with responsibility for safety.
b) Management for safety focused on leadership for safety and safety culture aspects.
c) The organizational aspects necessary for the implementation of the core regulatory functions of a competent authority, including the following:
    i. Development and/or provision of regulations and guides;
    ii. Notification and authorization including approvals;
    iii. Regulatory review and assessment;
    iv. Regulatory inspection;
    v. Enforcement;
    vi. Emergency preparedness and response;
    vii. Communication and consultation with interested parties.
d) The organizational aspects necessary for the implementation of supporting regulatory functions of a competent authority, including the following:
    (i) Administrative support, including human resources, finance, management of documents and records, and equipment purchasing and control;
    (ii) Legal assistance;
    (iii) Arrangements for contracting external expert support, where needed;
    (iv) International cooperation.
e) The characteristics of an integrated management system necessary for an effective and efficient competent authority.
f) The necessary staffing and competences that should be in place in order for the competent authority to effectively perform its functions and to discharge its responsibilities.

2.13. GSG-12 [3] should be read in conjunction with GSG-13 [4], which covers the technical aspects of the core functions of the competent authority and the processes by which they are discharged. The core functions of the competent authority interact with one another. For

example, regulations and guides set out the regulatory requirements to be used in review and assessment, in the authorization or approval process, in inspections and when determining enforcement actions. Similarly, the findings of review and assessment guide the approach to inspection and inspection provides areas for review and assessment. Both review and assessment, and inspection may influence the development of regulations and guides.

EXPERTISE AVAILABLE TO THE COMPETENT AUTHORITY

2.14. Requirement 3 of GSR Part 1 (Rev. 1) [6] states that "The government … shall establish and maintain a regulatory body … and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities." Paragraph 2.36 (b) of GSR Part 1 (Rev. 1) [6] states that "The government: Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety". The government should make arrangements for the competent authority to have access to expertise in many different fields, which could include the following:

- Containment of the radioactive contents;
- Criticality safety;
- Radiation safety, including shielding analysis;
- Thermal analysis;
- Materials science and mechanical/structural engineering;
- Management system;
- Packaging testing;
- Packaging manufacturing;
- Packaging maintenance[5];
- Packaging and transport operations;
- Inspection and enforcement;
- Emergency preparedness and response.

2.15. If all the necessary expertise is not available within the competent authority, external expert support should be sought. GSG-12 [3] provides recommendations on the following:

(a) The development and management of the competences of the competent authority staff, including training;
(b) Managing external expert support.

2.16. Due to the international aspects of transport, attendance at international conferences and seminars is also important for the education and training of employees of the competent authority.

[5] Maintenance means the organized activity, both administrative and technical, of keeping structures, systems and components in good operating condition, including both preventive and corrective (or repair) aspects. Periodic maintenance is a form of preventive maintenance consisting of servicing, parts replacement, surveillance or testing at predetermined intervals of calendar time, operating time or number of cycles [9].

LIAISON BY THE COMPETENT AUTHORITY WITH OTHER GOVERNMENT AGENCIES

2.17. As noted in para. 2.9, more than one competent authority may be responsible for the regulatory control of transport in a State. For example, the following organizations may have roles and responsibilities concerning 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) Agencies with responsibilities for emergency preparedness and response;
(f) Law enforcement agencies;
(g) Customs agencies;
(h) Postal authorities;
(i) National research institutes and institutes for materials testing;
(j) Institutions that provide training and education.

2.18. The competent authority should facilitate regular cooperation between the parties within this complex network of agencies and persons in order to ensure the following:

(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.

2.19. The appropriate competent authority should establish formal agreements with agencies whose purview may have an interface with the transport of radioactive material. Examples of such agencies are as follows:

(a) Agencies that serve as the regulatory body for nuclear safety, radiation safety and radioactive waste safety, which includes the use and storage of radioactive material.
(b) Agencies with responsibilities for transport;
(c) Agencies with responsibilities for specific modes of transport;
(d) National agencies involved in nuclear material accounting and control;
(e) National agencies with responsibilities for the security of radioactive material (including nuclear material);
(f) Customs agencies;
(g) Environmental agencies;
(h) Agencies with responsibilities for dangerous goods;
(i) Agencies with responsibilities for radioactive and/or hazardous waste;
(j) Agencies with responsibilities for emergency preparedness and response;

(k) Other technical regulatory bodies.

2.20. In order to ensure the security of radioactive material, nuclear material accounting and control, and physical protection of nuclear material, the requirements in some States necessitate that the competent authority maintains total control over all transit, import, export and inland shipments of radioactive material (including nuclear material). In such cases, applications in connection with the transfer of such material need 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.

2.21. In addition to the cooperation described in para. 2.18, the competent authority should also be prepared to provide timely consultation for customs officers on the complex collection of documents that accompanies shipments of radioactive material at national customs points. The competent authority should establish provisions to ensure the confidentiality of sensitive information related to the transport of nuclear material and radioactive material.

2.22. The competent authority should liaise very closely with agencies involved in emergency preparedness and response. In practice, the plans of such agencies usually concern the response to accidents involving all dangerous goods or the response to a nuclear or radiological emergency. Further recommendations on planning and preparing for response to an emergency involving radioactive material in transport including situations in which a nuclear security event is confirmed to be the initiating event are provided in IAEA Safety Standards Series No. SSG-65, Preparedness and Response for an Emergency during the Transport of Radioactive Material [10].

INTERFACES OF SAFETY WITH NUCLEAR SECURITY

2.23. Requirement 12 of GSR Part 1 (Rev. 1) [6] states:

> "**The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material.**"

2.24. Paragraph 2.40 of GSR Part 1 (Rev. 1) [6] states:

> "Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."

2.25. Provisions concerning, inter alia, the physical protection of nuclear material in transport against sabotage and theft are contained in the Convention on the Physical Protection of Nuclear Material (CPPNM) [11] and its Amendment [12], which are legally binding on the Parties thereto. The CPPNM and its Amendment apply to the international and domestic transport of nuclear material used for peaceful purposes.

2.26. Security provisions for the transport of radioactive material are provided in the United Nations model regulations [13] and in modal regulations [14], [15].

2.27. Recommendations for the physical protection of nuclear material are provided in IAEA Nuclear Security Series No. 13, Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5) [16]. Recommendations for the security of radioactive material are provided in IAEA Nuclear Security Series No. 14, Nuclear Security Recommendations on Radioactive Material and Associated Facilities [17]. Furthermore, guidance on security in the transport of nuclear material and radioactive material is provided, respectively, in IAEA Nuclear Security Series Nos 26-G, Security of Nuclear Material in Transport [18] and 9-G (Rev. 1) Security of Radioactive Material in Transport [19].

2.28. To meet Requirement 12 of GSR Part 1 (Rev. 1) [6] concerning interfaces of safety with arrangements for nuclear security, the competent authority should undertake activities, including the following:

(a) Liaise closely with national agencies responsible for transport security;
(b) Establish formal agreements with national agencies involved in nuclear material accounting and control (see para. 2.19);
(c) Establish formal agreements with national agencies involved in the security of radioactive material (including nuclear material) (see para. 2.19);
(d) Review proposed and existing measures for the safe transport of radioactive material to ensure that they do not compromise nuclear security;
(e) Incorporate, as appropriate, requirements and guidance on nuclear security mentioned in paras 2.25–2.27 into national requirements for the transport of radioactive material (including nuclear material).
(f) Provide advice to national agencies responsible for transport security on the development and implementation of security arrangements, if such arrangements might affect the safe transport of radioactive material;
(g) If security arrangements are reviewed during inspections or as part of a review of an application for authorization by the competent authority, develop checklists and procedures that address security arrangements;
(h) Ensure that its staff members receive training in nuclear security and are trustworthy, as appropriate, for their duties and responsibilities;
(i) Participate, as appropriate, in activities related to emergency preparedness and response when a nuclear security event is the initiating event (see para. 2.22);
(j) As appropriate, using a graded approach, define the provisions that a user should follow for ensuring the confidentiality of sensitive information, such as routing of the shipment, scheduling, physical protection measures, response capabilities and limiting of access to sensitive information to those who need to know to perform their duties.

3. REGULATIONS AND GUIDES

3.1. Paragraph 3.3 of GSG-13 [4] states:

> "The provision of regulations and guides is subject to Requirements 32–34 of GSR Part 1 (Rev. 1) [6]. The system of regulations and guides should be in accordance with the legal system of the State, and the nature and extent of the facilities and activities to be regulated. The regulations and guides should specify the requirements and associated criteria for ensuring the protection of people and the environment."

INTERNATIONAL AGREEMENTS AND GUIDES

3.2. The regulations and guides of a State should take into account that 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.

3.3. International bodies have issued general and modal recommendations and regulations on the safe transport of dangerous goods, including radioactive material (Class 7), as follows:

(a) Recommendations on the Transport of Dangerous Goods, Model Regulations (UN Model Regulations or 'The Orange Book') [13];
(b) Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI) [14], which amplify the basic provisions of Annex 18 of the Convention on International Civil Aviation (Chicago Convention) [20];
(c) International Maritime Dangerous Goods Code (IMDG Code) [15], which provides detailed regulations for the carriage of dangerous goods in packaged form by sea under Chapter VII of the International Convention for the Safety of Life at Sea (SOLAS) [21];
(d) Regulations to the Universal Postal Convention provides detailed requirements for the exceptional sending of dangerous goods (such as radioactive material) by international postal service that are based on the provisions of the Universal Postal Convention [22].

The UN Model Regulations, ICAO-TI and IMDG Code are updated every two years. Provisions for Class 7 goods (radioactive material) contained in the UN Model Regulations are based on the IAEA Transport Regulations and are incorporated into the ICAO-TI and the IMDG Code thereafter. The application of, the ICAO-TI for air transport, the IMDG Code for sea transport and the Regulations to the Universal Postal Convention for international postal service are mandatory for states that are party to relevant conventions.

3.4. There are also regional agreements, conventions and regulations concerning the safe transport of dangerous goods, including radioactive material, which may be mandatory for states that are party to these agreements, conventions and regulations. Examples of such agreements, conventions and regulations that take due account of the Transport Regulations include the following:

(a) The Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) [23];
(b) The Convention concerning International Carriage by Rail (COTIF) [24] and its Appendix C, the Regulations concerning the International Carriage of Dangerous Goods by Rail [25];
(c) The European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) [26];
(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 [27];
(e) The Agreement on International Goods Traffic by Rail (SMGS) [28] and its Annex 2.

3.5. In the interests of international harmonization and safety, individual States should participate in the relevant international and regional conventions and agreements mentioned in paras 3.3 and 3.4 and follow and fully implement the provisions of the Transport Regulations. However, due to specific national circumstances, 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, these specific provisions should be included in relevant national regulations and guides and, if applicable, in international or regional regulations (e.g. under "State Variations" in the ICAO-TI [14]); if practicable, the competent authority should communicate such differences to relevant transport organizations, to other competent authorities as appropriate, and to the international modal organizations.

NATIONAL REGULATIONS AND GUIDES

3.6. In accordance with Requirements 32–34 of GSR Part 1 (Rev. 1) [6], the competent authority is required to establish or adopt regulations and guides. National regulations and guides for the transport of radioactive material should be appropriate to the size and type of transport industry to which they apply.

3.7. GSG-13 [4] acknowledges that the development and/or provision of regulations and guides is a core function of a competent authority and provides recommendations on this function. After describing the objectives of regulations and guides and their differences, GSG-13 [4] provides recommendations on the following:

(a) The key principles to be followed for the initial development then review and revision of regulations and guides, as necessary, including the involvement of interested parties, the consideration of international or national standards and operating experience, and developments in transport practices;
(b) Topics that should be addressed in regulations and guides, for example the authorization process, documentation to be submitted to the competent authority and enforcement policy;
(c) The promotion of regulations and guides to interested parties.

3.8. National regulations should be based on the Transport Regulations; furthermore, 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 regulations and guides 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. Recommendations on maintenance of national regulations are provided in para. 4.96.

4. COMPLIANCE ASSURANCE

4.1. The competent authority should establish a programme for compliance assurance that applies to all relevant 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.

4.2. Compliance with the Transport Regulations can be assured by the competent authority in various ways and may include the following activities:

(a) Issuing of approvals;
(b) Inspections of the management systems of users of the Transport Regulations;
(c) Training and distribution of information;
(d) Assessment of designs;
(e) Inspection of testing, which should include the direct observation of specific tests;

(f) Inspection of transport operations, which should include direct observation of transport activities;
(g) Inspection of manufacturing, which should include the direct observation of specific steps in the manufacturing process;
(h) Inspection of maintenance arrangements, which should include direct observation of maintenance activities;
(i) Emergency preparedness and response;
(j) Enforcement actions and investigations of incidents;
(k) Regular review of the national legal framework including national and international regulations.
(l) Liaison and cooperation with other government agencies (see paras 2.17–2.22);

A graphic representation of these activities is provided in Fig. 1 in the form of the 'compliance assurance circle'.

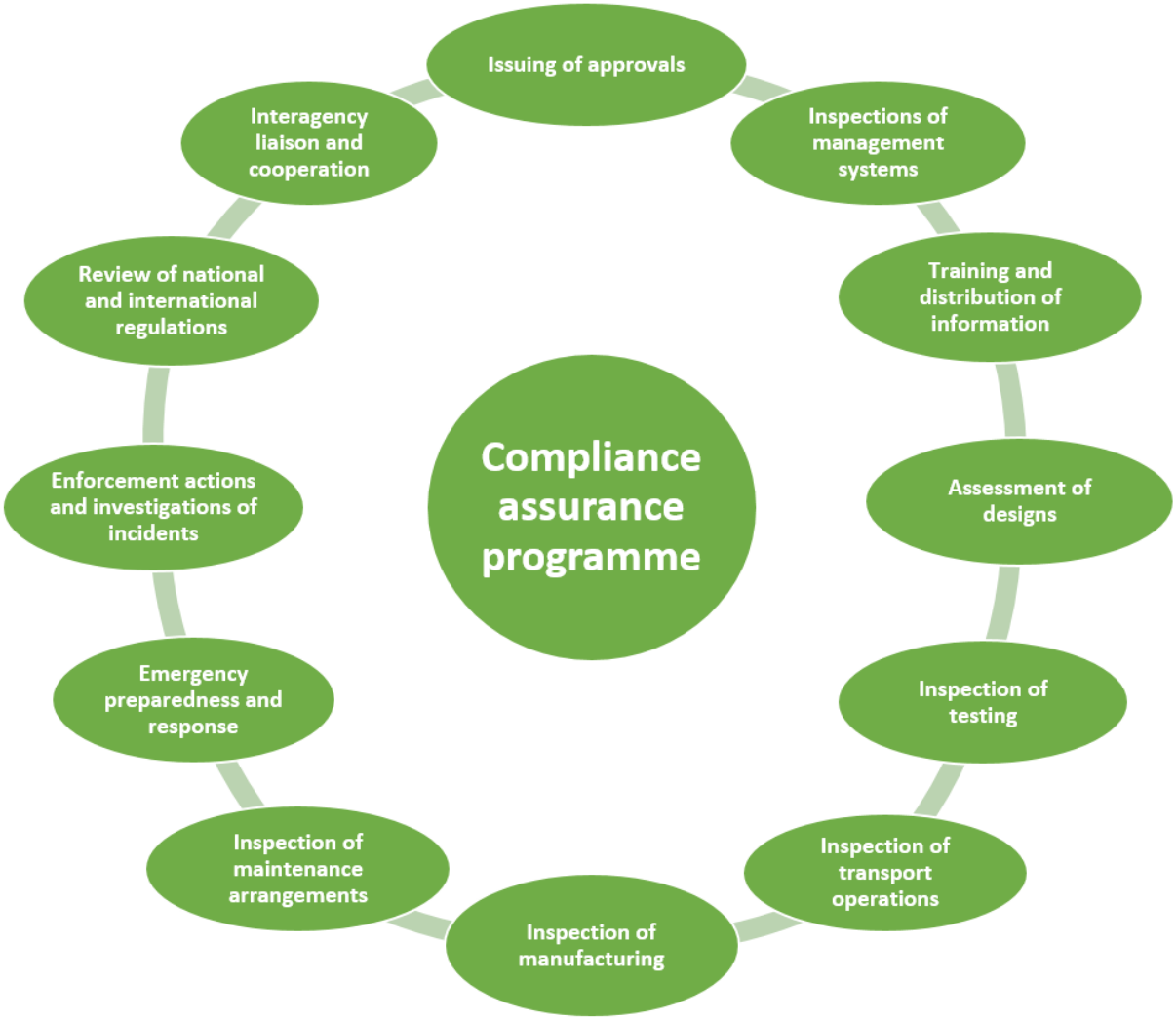

FIG. 1. Compliance assurance circle.

4.3. These activities are not meant to be implemented in any particular order and the extent of a national compliance assurance programme might not necessarily cover all of these activities.

It depends on the quantities and types of package being transported and also the size and complexity of the transport industry for which the competent authority has responsibility, as well as its own resources.

4.4. In all circumstances, a competent authority's compliance assurance programme should include, as a minimum, the following activities:

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

DEVELOPMENT AND IMPLEMENTATION OF A COMPLIANCE ASSURANCE PROGRAMME

4.5. The steps in the initial development of a compliance assurance programme can be summarized as follows:

(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, independence and other resources available to the competent authority;
(3) Establishment of liaison with government agencies 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 government agencies 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 and implementation of an initial compliance assurance programme;
(11) Distribution of information to all parts of the industry regarding the competent authority's policies, regulations and guides for the transport of radioactive material;
(12) Collection of initial evidence of compliance with the Transport Regulations by means of the applicable activities described in para. 4.2;
(13) Accumulation and review of evidence of compliance on a continual basis.

4.6. Compliance assurance programmes may be relatively simple and straightforward or may be complex and wide ranging, commensurate with the size and variety of the transport industry for which the competent authority has responsibility. At a minimum, for a simple compliance assurance programme in a State that performs a limited number of shipments including only a few types of radioactive material, account should be taken of the following:

(a) Radioactive material classification;
(b) Import and export operations;
(c) All relevant modes of transport;
(d) All relevant package types;
(e) Associated package certificates of foreign origin, if applicable;
(f) Maintenance and removal from service of a packaging.

4.7. A more complex compliance assurance programme will be needed for a State where a large number of shipments are performed within, through or into, or from, its territory, including shipments of many types and large quantities of radioactive material and where packages are designed and manufactured. For such a programme, account should additionally be taken of package design, testing, manufacture and approval.

4.8. The activities stated in para. 4.4 should be addressed in a manner that is graded in accordance with the complexity and variety of the particular responsibilities of the competent authority. Recommendations on applying a graded approach to the functions and processes of a competent authority are provided in Section 2 of GSG-13 [4].

4.9. After a compliance assurance programme has been developed and introduced, it should be reviewed periodically by the competent authority to take account of regulatory changes and the experience of users of the Transport Regulations. The compliance assurance programme should be updated in a timely manner when there are changes 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 qualified external organizations.

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 approval is required. In all cases, the Transport Regulations place the primary responsibility for compliance on the consignor. The following require competent authority approval (see para. 802 of the Transport Regulations) and for each of these an appropriate independent assessment should be made by the competent authority:

(a) Designs for:
    (i) Special form radioactive material;
    (ii) Low dispersible radioactive material;
    (iii) Fissile material excepted under para. 417(f) of the Transport Regulations;
    (iv) Packages containing 0.1 kg or more of uranium hexafluoride;
    (v) Packages containing fissile material unless excepted by paras 417(a-f), 674 or 675 of the Transport Regulations;
    (vi) Type B(U) packages and Type B(M) packages;
    (vii) Type C packages.
(b) Special arrangements.
(c) Certain shipments.
(d) Radiation protection programmes for special use vessels.
(e) Calculation of radionuclide values that are not listed in Table 2 of the Transport Regulations.
(f) Calculation of alternative activity limits for an exempt consignment of instruments or articles.

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

4.11. In accordance with paras 803, 807(b) and 808 of the Transport Regulations, unilateral approval by the competent authority of the country of origin of the design is required for the following:

(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 631–633 of the Transport Regulations;
(c) Type B(U) and Type C package designs, except package designs for fissile material and Type B(U) package designs for low dispersible radioactive material.

4.12. In accordance with paras 403(a), 803, 805, 807(a), 808(a), 808(b), 811, 814, 817, 820(a), 820(b), 825 and 829 of the Transport Regulations, multilateral approval by the competent authority is required for the following:

(a) The determination of basic radionuclide values that are not listed in Table 2 of the Transport Regulations;
(b) The design of low dispersible radioactive material;
(c) The design of material excepted from fissile classification under para. 417(f) of the Transport Regulations;
(d) The design of packages containing 0.1 kg or more of uranium hexafluoride that meet the requirements of para. 634 of the Transport Regulations;
(e) The design of packages for fissile material that are not excepted by any of the paras 417(a)-(f), 674 and 675;
(f) The design of Type B(U) packages for low dispersible radioactive material;
(g) The design of Type B(M) packages;
(h) Alternative activity limits for an exempt consignment of instruments or articles;
(i) Package designs approved by the competent authority under the provisions of the 1985 Edition or the 1985 Edition (As Amended 1990) of the Transport Regulations;
(j) Beginning after 31 December 2025, package designs approved by the competent authority under the provisions of the 1996 Edition, 1996 Edition (Revised), 1996 (As Amended 2003), 2005, 2009 and 2012 Editions of the Transport Regulations;
(k) The shipment of Type B(M) packages not conforming with the requirements of para. 639 of the Transport Regulations or designed to allow controlled intermittent venting;
(l) 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;
(m) 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, except for shipments that are excluded from this requirement in accordance with para. 825(c) of the Transport Regulations;
(n) Radiation protection programmes for shipments by special use vessels in accordance with para. 576(a) of the Transport Regulations;
(o) The shipment of SCO-III (surface contaminated object of the group SCO-III);
(p) Consignments transported under special arrangement.

Further recommendations on multilateral approvals are provided in Section 5.

4.13. It is the responsibility of the applicant to demonstrate compliance with the Transport Regulations and it is the responsibility of the competent authority to review and assess compliance. Applicants should be encouraged to contact the competent authority during the preliminary design stages to discuss the implementation of the relevant design principles and the approval process. Informal and formal discussions may be held between applicants and the competent authority on acceptable ways of demonstrating compliance. 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.

4.15. 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 described in Section VIII of the Transport Regulations (paras 803, 805, 807(c), 809, 812, 815, 817, 827, 827A and 830). Guidance on information to be included in applications for approval is provided in Annex I.

4.16. Upon receipt of an application for approval, the competent authority should evaluate whether all relevant regulatory requirements have been met. A list of items that should be included in an application is provided in Annex I of this Safety Guide. Paragraphs 3.147–3.209 of GSG-13 [4] provide recommendations on the review and assessment process including the associated documentation. If the competent authority determines that the application demonstrates compliance with the Transport Regulations, the competent authority is required to provide the applicant with a certificate of approval containing all the necessary information (see Section VIII of the Transport Regulations and Annex II of this Safety Guide).

4.17. 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 compensatory measures such as 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 might be employed are addressed in para. 830.1 of SSG-26 (Rev. 1) [2].

4.18. Whenever possible, standard formats should be utilized for each type of certificate. Minimum requirements for the contents of certificates of approval are specified in paras 834—839 of the Transport Regulations. Examples of templates for certificates of approval for use by the competent authority are provided in Annex II of this Safety Guide.

4.19. Consistent with the national practice and with regard for commercial considerations, the competent authority should supply copies or provide information on its approvals to other competent authorities and users of the Transport Regulations, in order to facilitate compliance with any specific requirements or conditions. Depending on national practice, information on certificates of approval for designs used for transport may be provided on the applicable competent authority website.

THE MANAGEMENT SYSTEM OF USERS OF THE TRANSPORT REGULATIONS IN SUPPORT OF COMPLIANCE ASSURANCE

4.20. To meet the requirements of para. 306 of the Transport Regulations and Requirements 3–8 of GSR Part 2 [5], an integrated management system is required for all transport related activities. The extent of the management system will depend on the type of transport activities being considered (design, testing, manufacture, use, maintenance); ranging from a relatively

simple system for the infrequent transport of packages that do not require approval by the competent authority, to a more complex system for the regular transport of packages subject to such approval. Annex I of IAEA Safety Standards Series No. TS-G-1.4, The Management System for the Safe Transport of Radioactive Material [29] provides information on how to address the various elements of the management system.

4.21. As stated in para. 306 of the Transport Regulations, "Where competent authority approval is required, such approval shall take into account, and be contingent upon, the adequacy of the management system." The competent authority should confirm the adequacy of the applicant's management system by reviewing the management system documentation and also by inspecting the implementation of arrangements in practice (see para. 4.24). An example of the types of information that the competent authority may consider in determining the adequacy of a management system as a pre-condition for issuing approvals is provided in Annex I. If the competent authority has confirmed the existence of a satisfactory management system, it may issue a 'certificate of compliance' for the management system, if required by national regulations.

4.22. The competent authority should establish an inspection programme to verify that the user's management system covers all the relevant aspects identified in TS-G-1.4 [29] and is implemented and followed correctly. This should include management systems that are implemented in the transport of packages that are not subject to competent authority approval. A list of items that the competent authority may consider during inspections of the management systems of users and related inspection activities is provided in Annex III. An example of a procedure and checklist for inspecting a management system is provided in Annexes IV and V, respectively.

4.23. Irrespective of the size of the organization concerned or the scale of its activities, the competent authority should verify through inspections that, consistent with the recommendations provided in TS-G-1.4 [29], the management system of 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 all procedures and instructions needed to guide, control and verify the conduct and evolution of activities in the management system;
(c) The means to develop, maintain and make accessible to the competent authority all necessary records and documentation of the management system;
(d) Undertaking activities to ensure compliance with the Transport Regulations and any additional national requirements.

4.24. 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 the following, as appropriate:

(a) The design of a package is accurately described by engineering drawings, material specifications and records of the methods of construction. For package designs requiring approval by the competent authority, this information is a required part of the application for the certificate of approval (Section VIII of the Transport Regulations). For package

designs that do not require approval by the competent authority, the information should be provided to the competent authority upon request.

(b) The packagings are manufactured in accordance with the design. For package designs that require approval by the competent authority, changes or modifications in the construction methods for the packaging, the materials of construction, are required to be approved by the competent authority before use of the package (see para. 503, first sentence, of the Transport Regulations). 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 use.

(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. All results from inspections, measurements and testing and all products of manufacturing should be fully documented.

(d) The packages are correctly prepared, packed and transported. This includes all necessary maintenance and other administrative procedures, as well as appropriate measures for radiation protection.

(e) All non-conformances are correctly documented and reviewed, and accepted or rejected, and notified to the competent authority as appropriate.

TRAINING AND DISTRIBUTION OF INFORMATION

4.25. The competent authority should ensure through its compliance assurance programme and its monitoring of management systems that all training needs of the organizations involved in transport are identified and implemented as required by paras 311–315 of the Transport Regulations. The training programme for an individual may be adjusted based on the relevant experience and responsibilities of the person. The competent authority should, as appropriate, specify and participate in the training of persons involved in the transport of radioactive material. The competent authority should also specify and participate in the training of its own staff.

4.26. In accordance with para. 314 of the Transport Regulations, each organization is required to maintain adequate records of the training provided. These records should include the performance of individual trainees and the authorizations or certificates issued. Also, records should be maintained in accordance with the recommendations for the management system provided in TS-G-1.4 [29] and these records should be inspected periodically by the competent authority. The main purposes of such records are:

(a) To provide evidence of the appropriate qualification of persons whose duties have a bearing on safety and with evidence of the required authorizations or certificates;

(b) To provide evidence of the basis for these authorizations or certificates;

(c) To provide documentation that can be used in reviews of the training programme to enable any necessary corrective actions to be taken.

In some states, the holders of certain posts within the competent authority and the organizations of the consignor, carrier and/or consignee have to be authorized or certified before they are allowed to perform their duties.

4.27. Training material applicable to personnel involved in the transport of radioactive material is provided in Ref. [30] and on the IAEA's e-learning site[6].

4.28. The preparation and distribution of information and guidance by the competent authority is necessary for the implementation 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 of the Transport Regulations. It may also involve seminars, conferences or training courses for personnel of regulatory bodies, consignors, carriers and other groups, to explain the correct application of the Transport Regulations. Further guidance concerning communication and consultation with interested parties by the competent authority can be found in IAEA Safety Standards Series No. GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [31].

ASSESSMENT OF DESIGNS

4.29. Paragraph 220 of the Transport Regulations states:

> "Design shall mean the description of fissile material excepted under para. 417(f), special form radioactive material, low dispersible radioactive material, package, or packaging that 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."

Therefore, design is 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 instructions for package preparation, instructions for maintenance, and procedures for repair or modification.

4.30. Section VI of the Transport Regulations establishes requirements for special form radioactive material, low dispersible radioactive material, material excepted from fissile classification, and for packagings and packages. In the case of the designs specified in para. 802 of the Transport Regulations, approval by the competent authority is required and hence the assessment of the design conducted by the competent authority should take account of the requirements in Section VI of the Transport Regulations.

4.31. The design assessment conducted by the competent authority should consider any aspect of the design that could adversely affect one or more of the following:

(a) Containment of the radioactive contents;
(b) Control of external dose rate;
(c) Prevention of criticality;
(d) Prevention of damage caused by heat.

4.32. 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

[6] The IAEA provides a selection of e-learning materials on a wide range of topics, including topics discussed in this publication. These can be found on the IAEA's e-learning site at: https://elearning.iaea.org.

after the detailed differences between the package designs have been identified by the applicant and confirmed by the competent authority as being of minor significance.

4.33. The assessment of the designs of packages intended to be used for shipment after storage should consider the effects of aging mechanisms during an extended time period between loading of the package and its shipment after storage to ensure that the package design meets all applicable requirements of the relevant provisions of the Transport Regulations at the time when the first shipment after storage takes place (see paras 503(e) and 613A of the Transport Regulations). This includes the assessment of appropriate ageing management and a gap analysis programme (see paras 809(f) and 809(k) of the Transport Regulations). More guidance is provided in SSG-26 (Rev. 1) [2], paras 503.3, 613A.1-613A.6 and 809.3-809.4.

TESTING OF PACKAGES AND MATERIALS

4.34. It may be necessary to test packages and scale models or representative examples of package features and materials (including special form radioactive material) to demonstrate compliance of the design with the requirements in Section VII of the Transport Regulations. Testing may be undertaken by the designer, the applicant, a third-party testing organization, or the competent authority. The following points should be considered when determining compliance with the requirements for testing:

(a) The organization performing the test should have an appropriate management system that addresses 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 (including corrective measures, if necessary) and reporting associated with the particular test or series of tests to be undertaken.

(b) The test programme should satisfy the approving body (the competent authority or other appropriate organization). The number of tests and specimens, test conditions, test sequences, measurement techniques, methods of analysis and the acceptance criteria should be clearly established. When drop tests are concerned, drop sequences and drop attitudes should be agreed with the approving body. Due to unexpected results during testing, some variation in the test 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.

(c) The objectives and parameters of the test(s) should be clearly established. It should be made clear whether the sole objective of the test(s) is a straightforward verification that the package meets all of the requirements of the Transport Regulations or only some of these requirements, whether the designer wants different (e.g. more stringent) test criteria to be applied, or whether additional information is being sought from the test(s) to improve the designer's knowledge of the design principles, safety margins and performance.

(d) It should be clearly established that the test facilities comply with the requirements of the Transport Regulations, particularly in the case of the targets used for drop and penetration tests, in which the weight of the test specimen is limited by 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 applicable national or international limits for the particular pieces of equipment. It should be verified that this equipment

works accurately, within applicable national or international limits. This should be 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 implemented and appropriate test records should be made available to the competent authority so that compliance with the requirements of the Transport Regulations can be confirmed.

(g) All test results, including any instances of damage, should be considered as part of the competent authority's assessment of the final package design.

4.35. When a scale model is used in testing to support an application for approval, the competent authority should confirm that all scaling factors have been taken into account, with all pertinent features of the package design being accurately represented.

4.36. When conducting the final design assessment, the competent authority should take into account the packages tested, the test results and any changes made to the package design after testing, which are submitted by the applicant or designer in relation to the final design.

SPECIAL FORM RADIOACTIVE MATERIAL AND LOW DISPERSIBLE RADIOACTIVE MATERIAL

4.37. The competent authority should determine whether the management system arrangements for the design, testing and manufacture of special form radioactive material or low dispersible radioactive material are appropriate and adequate for the nature of the material and the amounts that are likely to be produced.

4.38. Before the commencement of tests by the applicant, the competent authority should consider inspecting the test facilities and arrangements, especially the specimens, the target for drop tests, and the measuring and recording systems. The competent authority may also perform inspections that include direct observation of the tests. The competent authority should require that it be informed by the applicant about any deviation from the test plan and resulting consequences for the results, as applicable.

4.39. The competent authority should verify that applications for approval of the design of special form radioactive material or low dispersible radioactive material include the test programme, test results and the information described in Annex I. The application should demonstrate that the regulatory requirements have been met.

4.40. The competent authority should give consideration to 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.

4.41. When the competent authority has verified through its own design assessment (see paras 4.29 – 4.32, 4.42 and 4.53), that the design for special form radioactive material or low dispersible radioactive material meets all the applicable requirements, it is required to issue a certificate of approval that attributes to the approved design an identification mark, in accordance with para. 804 of the Transport Regulations. Examples of templates for certificates of approval are provided in Annex II.

PACKAGES NOT REQUIRING APPROVAL BY THE COMPETENT AUTHORITY

4.42. 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 should conduct assessments of designs specified in para. 802(a) of the Transport Regulations, and should 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 performed by appropriate organizations and that the necessary documentary evidence of such assessments is made available to the competent authority, if requested (see paras 801.1 – 801.3 of SSG-26 (Rev. 1) [2] and Annex I, para. I-3 of this Safety Guide and Ref. [32] for guidance on documentary evidence for packages that do not require competent authority approval). Information about the structure and contents of a package design safety report, which applies to all types of package and is intended to demonstrate compliance of the design of a package with the Transport Regulations is provided in IAEA Safety Standards Series No SSG-66, Format and Content of the Package Design Safety Report for the Transport of Radioactive Material [32].

4.43. 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, based on a graded approach.

4.44. The competent authority should verify that the user complies with the requirements in paras 306 and 801 of the Transport Regulations for package designs that do not require approval by the competent authority. In particular, the following subjects for inspection by the competent authority should be addressed:

(a) The management system under which the package is designed, manufactured and transported;
(b) The design process and the internal process to provide documentary evidence that the package design meets all applicable requirements (see para. 4.42);
(c) Control of manufacturing;
(d) The programme for maintenance of packagings (in the case of reusable packagings).

PACKAGES REQUIRING COMPETENT AUTHORITY APPROVAL

4.45. The competent authority may discuss the development and the proposed testing of a package with the applicant on the basis of the preliminary information provided. The format and content of this preliminary information should take into account the recommendations provided in SSG-66 [32]. Specifically, it might 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 might also cover the requirements of the management system for design, manufacture and testing.

4.46. The competent authority should consider special features of the package design, as well as the testing plan. If the applicant proposes 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.

4.47. The competent authority should verify that the manufacture of models or prototypes is undertaken in a controlled manner that complies with the management system used at the manufacturer so that the models or prototypes are representative of the proposed package design. Particular consideration should be given to the materials used, welding and inspections, the results of quality control tests and any deviations from the requirements and specifications.

4.48. Before the commencement of tests by the applicant, the competent authority should consider inspecting the test facilities and arrangements, especially the specimen, the target for drop tests, and the measuring and recording systems. The competent authority may also perform inspections that include direct observation of the tests.

4.49. In conjunction with the information in Annex I and in SSG-66 [32] about the structure and contents of a package design safety report, the application for approval should include the test programme, the results of testing and the evaluation report (see also paras 4.34 and 4.36). The application should describe the management system of the applicant and should state the requirements for the production of packagings and their proper maintenance and use. The applicant should demonstrate that the requirements for the package type have been met. Specifically, the following aspects should be included, if appropriate, for routine, normal and accident conditions of transport:

(a) Containment of the radioactive contents;
(b) Control of external dose rate;
(c) Prevention of criticality;
(d) Prevention of damage caused by heat.

The application for approval should demonstrate compliance with the performance standards required in Section VI of the Transport Regulations, including specific test requirements, by the methods listed in para. 701 of the Transport Regulations.

4.50. 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, which includes the design assessment (see paras 4.29 – 4.32, 4.42 and 4.53). In making these independent assessments, the competent authority should ensure that proper computer codes, methods of calculation, and models have been used, that they have been validated and that all input data have been correctly and, if appropriate, conservatively defined.

4.51. When assessing applications for approval of package design, the competent authority should ensure that full and proper provision has been made for the legibility, durability and application of identification marks and serial numbers. This is particularly important in cases where multiple or interchangeable packaging components are used.

4.52. The design of a package should be accepted or rejected on the basis of the results of the evaluation. In the case of acceptance of the proposed design by the competent authority, a certificate of approval is required to be issued. Examples of templates for certificates of approval are provided in Annex II.

4.53. Reviews and assessments by competent authorities of applications for approval usually involve extensive 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 to ensure that the design will produce a package that is safe under routine, normal and accident conditions of transport.

(b) 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 (paras 807(c), 809(j) and 815 of the Transport Regulations). Before initiating a detailed review of an application, the completeness of the design description and specification should be confirmed including information regarding the intended use of the package design (e.g. mode of transport, handling during transport or transport after storage).

(c) The assessor should thoroughly examine the thermal aspects of the package design; the assessor should consider both dissipation and absorption of heat in routine, normal and accident conditions of transport. Thermal stresses should be analysed to ensure that leak tightness or mechanical properties of the package are not unduly compromised in routine and normal conditions of transport or in thermal test conditions.

(d) The assessor should ensure that any computer codes, methods of calculation, or models used by the applicant are appropriate, have been validated, and that all input data have been correctly and, if appropriate, conservatively defined.

(e) The assessor should examine all relevant mechanical aspects of the design in order to confirm that the package will be physically able to safely carry the specified radioactive material under routine, normal and accident conditions of transport (this includes, for example, tie-down points and trunnions). The assessor should analyse the structural attributes of the package and should verify that any impact or other damage that the package might sustain in routine, normal or accident conditions of transport will not compromise its ability to meet the requirements of the Transport Regulations.

(f) 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 (e.g. temperature, pressure, irradiation, humidity) and their compatibility with other materials used.

(g) The assessor should verify that ageing mechanisms have been taken into account.

(h) The assessor should examine in detail the shielding features and radiation safety aspects of the design; the assessor should confirm that, with regard to the maximum proposed radioactive contents, the design of the package provides sufficient radiological shielding in all directions to comply with the Transport Regulations and the principle of optimization of protection. The assessor should confirm that any 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. The absence of any radiation 'shine paths' through package closures and ports used for package testing should be verified.

(i) The need to decontaminate the packagings in use should also be considered. The assessor should confirm the absence of features that might retain contamination and that materials that are difficult to decontaminate are not used.

(j) 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 determine how they might be adversely affected by routine and

normal conditions of transport, by the prescribed maintenance periods and instructions, and by the effects of accident conditions of transport and related testing.

(k) For packages designed to contain fissile material, the assessor should thoroughly examine all aspects of the package that are designed to maintain subcriticality during routine, normal and accident conditions. The assessor should specifically consider the contingencies listed in para. 673(a) and the requirements of para. 673(b) of the Transport Regulations.
(l) The assessor should examine the in-service handling and use, inspection, maintenance instructions and specifications in sufficient depth, to verify that all such instructions and specifications are appropriate for the package as designed. The assessor should verify that in-service instructions and specifications provide for authorized repairs and modifications of the packaging. The procedures for repair and modification should be agreed with the assessor. The assessor should also consider that such package instructions may have to be followed by carriers and consignees that are unfamiliar with the package and its design principles.

IDENTIFICATION OF PACKAGES AND SERIAL NUMBERS OF PACKAGINGS

4.54. Once packagings have been adequately designed, assessed and manufactured, it is required that they be appropriately identified throughout their lifetime. Paragraphs 531–537 of 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. SSG-26 (Rev. 1) [2] provides recommendations on the legibility, durability and positioning of such markings. In its activities relating to compliance assurance, the competent authority should verify the following:

(a) All required markings, serial numbers and identification marks are correctly, durably and appropriately applied to packages;
(b) The user's scheduled inspection and maintenance programme for packagings includes provisions for inspecting and, if necessary, correcting all permanent markings and for repairing any damage or defects.

4.55. The serial number on the packaging is required to uniquely identify each packaging manufactured to a package design approved by the competent authority (see para. 535(b) of the Transport Regulations). 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 (see para. 824 of the Transport Regulations). In this case, the term 'appropriate' has a broad interpretation and could mean 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 para. 820 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.

4.56. 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. 535(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.

APPROVAL OF SHIPMENTS UNDER SPECIAL ARRANGEMENT

4.57. Paragraph 310 of the Transport Regulations includes provisions for a consignment that does not satisfy all the applicable requirements to be transported under special arrangement and para. 830 describes the contents of the application for approval of such consignments. For international shipments under special arrangement, multilateral approval is required: see para. 310 of the Transport Regulations. Recommendations on multilateral approval are provided in Section 5.

4.58. For a shipment under special arrangement, the competent authority should verify 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: see para. 310 of the Transport Regulations. The competent authority should give consideration to the reasons why the shipment cannot be made in full compliance with applicable requirements.

INSPECTION OF TRANSPORT OPERATIONS

4.59. A major feature of the compliance assurance programme of a competent authority will be the performance of inspections of transport operations. Recommendations applicable to such inspections are provided in paras 3.210–3.294 of GSG-13 [4] and address the objectives, organization, types, planning, performance and records of inspections and follow-up of inspection findings. As well as producing evidence of compliance, such inspections can be used to verify the degree of compliance by the user and also the adequacy and suitability of the regulatory requirements. Such inspections may be undertaken during any phase of the transport or during storage in transit and may be announced or unannounced (see paras 3.247–3.249 of GSG-13 [4]). Inspections should, however, be planned sufficiently in advance and their frequency should be determined in accordance with a graded approach based on the scope of the transport activities of the organization being inspected, as well as with the complexity and radiological significance of these activities. Examples of checklists that could be used for such inspections are provided in Annexes VI and VII.

4.60. Inspections of transport operations should be undertaken by the competent authority or by an organization nominated by it. In some States such inspections are undertaken on a modal basis, by examining all types of dangerous goods, for example, the aviation authority inspects air shipments and the maritime department inspects marine shipments. In such cases, the competent authority may act as an adviser to the organizations that conduct inspections. Users involved in all types and aspects of transport should be periodically inspected, in accordance with a graded approach.

4.61. During inspections of transport operations of users, the competent authority should verify that the following recommendations have been met:

(a) The user's management should provide the necessary personnel and resources to implement an effective programme for compliance with the Transport Regulations. This programme should be a part of the management system of the user. The persons who are responsible for fulfilling specific requirements should be clearly identified. The management system should clearly delegate authority to those responsible persons.
(b) Suitable training should be provided for those persons who are responsible for implementing the programme for compliance with the Transport Regulations and this training should be documented.
(c) Proper packagings for the contents of packages should be used.
(d) The user should have all the documentation required by the Transport Regulations, including the relevant certificates of approval of the competent authority and any associated instructions for emergency arrangements, 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 certificate of approval, 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.
(g) Procedures should be established and followed, and appropriate and properly calibrated instruments should be provided to monitor dose rates and contamination levels.
(h) Procedures for the preparation and control of transport documents, for the placarding of vehicles, for the provision of documentation for carriers and for notification of competent authorities should be established and followed.
(i) During transport, carriers should be performing the required actions for placarding and for the stowage and separation of packages in accordance with the Transport Regulations. Carriers should also undertake any administrative controls relating to exclusive use shipments, or supplementary operational controls specified in the certificate of approval of the competent authority.
(j) Procedures should be established to respond to cases of non-compliance, in order to meet the requirements of para. 309 of the Transport Regulations.

More detailed guidance on the corresponding inspection activities of the competent authority are provided in paras 4.68-4.83.

4.62. When preparing for inspections of transport operations, the competent authority should consider those requirements that apply to industrial packages in the Transport Regulations and those requirements that originate from the provisions of international conventions and standards (see Refs [13], [33]).

4.63. The requirements for notification of the competent authority regarding certain packages and shipments are established in paras 557–560 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. This need for additional notification should be determined in accordance with the package types and the number of shipments made and received. Furthermore, if users are required by national regulations to submit reports to the competent authority concerning the transport of radioactive material, the information in these reports should be used by the competent authority to assess the status of the transport of radioactive material within the country and should be considered in establishing the nature and extent of its activities related to compliance assurance.

4.64. Recommendations on inspection performance and follow-up actions are provided in GSG-13 [4].

RADIATION PROTECTION

4.65. 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 these requirements have been met, for example, by requesting information on and inspecting the radiation protection programmes for transport. Specific recommendations on radiation protection programmes for the safe transport of radioactive material are provided in IAEA Safety Standards Series No. TS-G-1.3, Radiation Protection Programmes for the Safe Transport of Radioactive Material [34], which includes items to be reviewed to evaluate the contents and effectiveness of radiation protection programmes.

4.66. When necessary, the competent authority should require the inclusion of information on radiation protection programmes in applications for approval of shipments or special arrangements.

4.67. 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: see 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.

INSPECTION OF MANUFACTURING

4.68. During the manufacture of special form radioactive material or low dispersible radioactive material, as part of the compliance assurance programme, the competent authority should conduct inspections of the management system of the manufacturer (see Annexes IV and V) and inspections of the manufacturing operations to ensure that all the requirements have been correctly implemented.

4.69. The competent authority should give particular consideration to how the management system is applied before the manufacture of packagings begins, such as during the development of manufacturing processes and procedures. The inspection programme for the manufacture of a single packaging may be different from that for the continuous manufacture of packagings.

4.70. Packagings should be manufactured in accordance with the design specifications through a process that is subject to the management system. To confirm this, the competent authority should perform inspections of the manufacturing process, including the actual implementation and effectiveness of the management system. The management system may be inspected by the competent authority before the commencement of manufacturing of a packaging and periodically thereafter (see also para. 4.24 (b) and (c)). An example checklist for inspections of the manufacturing of packagings is provided in Annex VIII.

4.71. Facilities operated by manufacturers and their subcontractors may be inspected by the competent authority. The frequency and extent of such inspections should be determined in accordance with a graded approach based on the confidence that the competent authority has in the manufacturing arrangements and the importance to safety of the items being manufactured.

4.72. The inspection process may include taking samples for independent non-destructive or destructive testing. The purpose is to verify that the packaging is manufactured in compliance with the Transport Regulations and in accordance with the design specification.

4.73. Reports of deviations from specifications and reports of repairs that have been performed should be made available to the competent authority for review. The competent authority should have the authority to accept or reject any deviations from the approved specifications.

4.74. The results of inspections by the competent authority should be recorded and communicated to the manufacturer (see GSG-13 [4]) and other responsible parties, for example the packaging owner or the packaging designer, for information and for possible action.

4.75. During inspections of manufacturers, compliance with the requirements of para. 501 of the Transport Regulations regarding the first use of a packaging should be verified. Based on the results of quality control tests, reports on deviations and other measures within the management system, the manufacturer should verify that the packaging has been manufactured in compliance with the specification issued by the package designer in accordance with the package design safety report and the certificate of approval, if the certificate has been issued.

INSPECTION OF MAINTENANCE OPERATIONS

4.76. The competent authority should verify that maintenance operations, as specified by the original designer or the competent authority, have been conducted by a person or organization that has an appropriate management system: see para. 306 of the Transport Regulations. In particular, any proposed modifications to a packaging during maintenance operations should be implemented only when the necessary modification specifications are available to the person or organization implementing the modification. Any departure from these specifications might render the packaging unusable and might compromise the original design intent. An example checklist for inspections of maintenance operations is provided in Annex IX.

4.77. The competent authority should verify that appropriate records of all maintenance operations demonstrate that the package fully complies with the requirements specified in the certificate of approval and the relevant requirements of the Transport Regulations.

4.78. Inspections by the competent authority should include the packaging, the storage locations for both the packaging and records, the packaging maintenance facility and any other factors that could affect the lifetime of the packaging. Special attention should be given to the correct implementation of the maintenance instructions which contribute to ageing management for packages intended to be used for shipment after storage (para. 503(e) of the Transport Regulations). Inspections should include the verification of the appropriate use of records and logbooks (as described in TS-G-1.4 [29]) if maintenance operations are performed at different locations.

4.79. The user should record all safety related deviations from the design specifications, as well as any significant damage noted during the use of the packages. Reports of deviations from specifications and repairs that have been performed should be made available to the competent authority for review in accordance with the requirements of the competent authority. The competent authority should have the authority to accept or reject any deviations from the approved specifications. Corrective measures or modification proposals, including any plans for repairs, might be subject to the agreement of the competent authority. In such cases, any packages undergoing repairs, modifications or changes should not be returned to use until the competent authority has agreed to or approved the change.

INSPECTION OF CONSIGNORS

4.80. The consignor may be the owner of the package, or the manufacturer of the package, or the user or operator of a package owned by a third party. The consignor may delegate some of the actions needed to prepare a package for transport in accordance with the Transport Regulations, but the consignor retains overall responsibility for these actions. The declaration on the transport documents signed by the consignor attests to this responsibility.

4.81. The competent authority should assure that the consignor's responsibilities, as defined in paras 545–561 of the Transport Regulations, are followed (see also para. 4.24(d)). An example of a checklist that could be used for inspections of consignors is provided in Annex VI. The competent authority should inspect compliance with the following, as appropriate:

(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. If a consignor consigns only one type of package infrequently, the consignor may control and conduct all activities directly. A 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 a clear understanding of the nature, form and activity of the radioactive material to be consigned.
(c) The consignor should fill or load the material into the packaging for transport in accordance with the package requirements and instructions. This could involve, for example, verifying that the contents of the package have been positioned correctly within the packaging to maximize the shielding protection afforded by the packaging.
(d) The consignor should use the appropriate packaging for which there is a valid certificate of approval or appropriate documentary evidence of compliance. 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 certificate of approval is required to cover the entire radioactive contents permitted to be carried and the consignor is required to have the correct certificate for the contents being transported in accordance with the Transport Regulations.
(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 and the tightening torques of fasteners, to be followed by the consignor.
(f) The consignor should ensure that the package used for transport conforms to its specifications, including those indicated on a certificate of approval for a package design that requires competent authority approval, and the packaging is in an acceptable condition based on written procedures. For packagings, the consignor should have evidence, such as certificates of conformity or inspection reports, which indicate that the packagings conform to their specifications, including those indicated on an certificate of approval for a package design that requires competent authority approval. In the case of reusable packagings, the consignor should have evidence (e.g. in the form of inspection reports, release notes and certificates of conformity) that all necessary and specified maintenance work has been performed and that the packaging is suitable for the next complete transport operation or programme of movements. The consignor should not use

a package that does not comply with the approved specifications or that has not been subjected to the required maintenance.

(g) The consignor should complete and apply the correct labels and markings for packages when it is presented for transport. For example, the consignor should determine the transport index and should have correctly functioning and calibrated monitoring instruments for measuring the dose rates of the package, the overpack, the freight container and the vehicle.

(h) The consignor should have appropriate, calibrated monitoring instruments and trained staff so that they can measure dose rates and radioactive contamination associated with the transport of radioactive material. For example, the consignor should be able to satisfy the competent authority that its staff is knowledgeable on the operation of the monitoring instruments and is capable of conducting correct measurements of dose rates and radioactive contamination as required by the Transport Regulations.

(i) Subject to national legislations, the consignor should have the necessary licences or other permissions, granted by the competent authority or by other governmental bodies, to function as a consignor of radioactive material. Also, the competent authority should be satisfied that the consignor has the applicable approval(s) required for the transport of radioactive material (e.g. shipment approval, special form approval). Multiple approvals may be necessary for transport of radioactive material where considerations of security and considerations for the nuclear material accounting and control apply.

(j) The consignor is required to complete the required transport documents, giving the appropriate information, as specified in paras 546–555 of the Transport Regulations. The consignor should also provide the transport documents to the carrier to enable the carrier or any subsequent carrier(s) to meet any other applicable national or international modal regulations. The consignor is required to retain a copy of each transport document for a minimum period of three months: see para. 555 of the Transport Regulations. During inspections by the competent authority it should be verified that complete and accurate information is given in the transport documents (sometimes called 'shipper's certificates' or 'consignment notes'). It should be verified that the transport documents take account of any variations imposed by national or international modal regulations. It should also be verified that the transport documents cover the entire journey of the consignment.

(k) The consignor is required to provide information to the carrier(s), in accordance with para. 554 of the Transport Regulations. The competent authority should verify that the required information and documents have been provided to the carrier(s) by inspecting both the consignor and the carrier(s) (see para. 4.82).

(l) The consignor should notify the competent authorities of transport movements, as required by paras 557–560 and summarized in Annex I of the Transport Regulations. 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 is required, before each shipment of any package, to ensure that the requirements specified in the relevant provisions of the Transport Regulations and in the applicable certificates of approval have been fulfilled: see para. 503 of the Transport Regulations. During the lifetime of a packaging, the consignor should maintain records demonstrating that the requirements of para. 503 of the Transport Regulations have been met. The competent authority should verify that the consignor's management system

provides controls to ensure all required pre-dispatch activities have been specified and completed and that the declaration and signature of the final consignor is valid.

(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 activities of the consignor are covered by a radiation protection programme that meets the requirements of para. 302 of the Transport Regulations. Further recommendations on radiation protection programmes are provided in paras 4.65–4.66.

INSPECTION OF CARRIERS

4.82. Carriers contribute significantly to the safe transport of radioactive material. The competent authority should conduct inspections (see para. 4.60) to verify the following:

(a) The carrier should have an appropriate management system that meets the requirements of para. 306 of the Transport Regulations and covers all relevant aspects of the carrier's responsibilities and activities in the transport of radioactive material. A carrier that occasionally carries one type of package, using one mode of transport within national boundaries, may have a relatively simple management system. In contrast, a national or international carrier that frequently carries large numbers of packages and operates a multimodal carriage and distribution service will need a more comprehensive management system to control its activities and to ensure compliance with the Transport Regulations.

(b) The carrier should have sufficient knowledge of national and international regulations to understand the information and documents provided by the consignor. The carrier should have knowledge and understanding of the requirements for transport documents established in paras 546–554 of the Transport Regulations and implement procedures for checking the validity and accuracy of such documents.

(c) The carrier should have knowledge of, and the ability and the resources to meet additional provisions concerning loading, stowage, transport, handling and unloading of packages, as well as the ability to comply with any restrictions on routeing, means of conveyance or mode of transport. For conveyances such as trucks or railway wagons, the carrier should have the necessary facilities or equipment for achieving secure tie-down arrangements and should comply with any additional speed limits that are specified. Also, if escort vehicles and personnel are required for the transport operations, the carrier should demonstrate to the competent authority that it can provide them.

(d) The carrier should be able to identify damaged or poorly prepared packages. The carrier should be familiar with the required placards, package labels and markings, and should understand their meaning and purpose and be able to relate the information displayed to the details given in the transport documents. The carrier should have the appropriate procedures and the necessary understanding to ensure that any damaged, poorly prepared or incorrectly labelled packages are rejected or quarantined, that packages are 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. The carrier should ensure that, when required, the number, type, size and location of placards on the conveyance meet the regulatory requirements.

(f) The carrier is required to establish appropriate arrangements for a nuclear or radiological emergency (see paras 304–305 of the Transport Regulations). These arrangements should take account of the types of radioactive material being carried and the type of conveyance being used. 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 familiar with the arrangements in place and all personnel involved should receive the necessary training in the emergency arrangements.

(g) The carrier should have the capability to implement appropriate controls in connection with storage in transit, in particular with regard to the safety of workers and the public. The carrier is required to implement the provisions established in paras 562–563 of the Transport Regulations concerning the segregation of packages during transport and storage in transit.

(h) The carrier should have appropriate procedures in place to identify cases of non-compliance and to take appropriate action in accordance with the requirements of para. 309 of the Transport Regulations.

(i) The activities of the carrier are covered by a radiation protection programme that meets the requirements of para. 302 of the Transport Regulations. Further recommendations on radiation protection programmes are provided in paras 4.65–4.66 of this Safety Guide.

An example of a checklist that could be used for inspections of carriers is provided in Annex VII.

INSPECTION OF CONSIGNEES

4.83. During inspection of the transport operations of the consignee, the responsible competent authority should verify the following:

(a) The consignee should have a management system that meets the requirements of para. 306 of the Transport Regulations and which covers all applicable activities.

(b) A radiation protection programme should be established and implemented that meets the requirements of para. 302 of the Transport Regulations. Further recommendations on radiation protection programmes are provided in paras 4.65–4.66 of this Safety Guide.

(c) Workers of the consignee should receive appropriate training commensurate with their duties.

(d) The consignee should be able to take appropriate actions in cases of non-compliance in accordance with the requirements of para. 309 of the Transport Regulations.

CONTENTS OF PACKAGES WITH OTHER DANGEROUS PROPERTIES

4.84. In addition to the radioactive and fissile properties, any other dangerous properties of the contents of the package, such as chemical toxicity and corrosiveness, are required to be addressed through compliance with the relevant transport regulations for dangerous goods: see para. 507 of the Transport Regulations. This may involve liaison and cooperation between the competent authority and other governmental bodies that have a responsibility in such matters.

EMERGENCY PREPAREDNESS AND RESPONSE

4.85. Activities related to emergency preparedness and response are among the fundamental activities of the competent authority (see para. 4.4). Requirements for emergency preparedness and response are established in IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [35]. The competent authority has several relevant roles and responsibilities with regard to emergency preparedness and response including reviewing the arrangements for emergency preparedness and response of users during inspections (see para. 4.82(f) and Annexes III, VI and VII) and during the review of applications for approvals, issuance of approvals (Annex I), establishing roles and responsibilities and liaising with other relevant governmental agencies (see paras 2.17, 2.18, 2.19 and 2.22), participating in exercises, participating in training and maintaining appropriate expertise (see para 2.15). Detailed recommendations on emergency preparedness and response in the transport of radioactive material are provided in SSG-65 [10].

4.86. International cooperation might be necessary when States are affected by accidents that occur during the transport of radioactive material. Certain types of transport accident are covered by the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency [36].

ENFORCEMENT ACTIONS AND INVESTIGATIONS OF INCIDENTS

4.87. The compliance assurance programme should include provisions for enforcement consistent with the requirements established in GSR Part 1 (Rev. 1) [6], especially para. 4.68 and with the recommendations provided in GSG-13 [4].

4.88. Paragraph 2.5 of GSR Part 1 (Rev. 1) [6] requires that the government promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety, including provision for the enforcement of regulations, in accordance with a graded approach.

4.89. Requirement 30 of GSR Part 1 (Rev. 1) [6] states:

> **"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."**

4.90. Paragraph 4.55 of GSR Part 1 (Rev. 1) [6] states:

> "Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance."

4.91. Recommendations on the objectives of enforcement, methods of enforcement, factors in determining enforcement actions, the inspector's authority in relation to enforcement, use of the enforcement process and records of enforcement are provided in GSG-13 [4].

4.92. The enforcement activities of the competent authority should be applicable to all activities that are important to safety in transport, irrespective of whether a certificate of approval from the competent authority is required.

4.93. Users should be required by national regulations to report to the competent authority all significant incidents, including accidents or significant non-compliance with the Transport Regulations. The competent authority should investigate any reported incidents, in accordance with a graded approach. Such investigations may include gathering information through special inspections and/or during routine inspections.

4.94. In Section 2 it is recommended 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 enforcement measures relating to compliance assurance.

4.95. Recognising the international aspect of transport, incident investigation and enforcement may necessitate international cooperation between States.

MAINTENANCE OF REGULATIONS AND FEEDBACK TO THE COMPETENT AUTHORITY

4.96. Recommendations for the development, review and revision of regulations and guides are provided in paras 3.51–3.71 of GSG-13 [4]. Consistent with these recommendations, the competent authority should periodically review national and international regulations for the transport of radioactive material and should make any necessary changes to the national regulations. The competent authority should maintain awareness of developments in international organizations (such as the International Maritime Organization and International Civil Aviation Organization) and conventions and of any associated mandatory timescales for changes to be introduced (see also Section 3).

5. MULTILATERAL APPROVALS

5.1. Under the Transport Regulations, multilateral approval of the items listed in para. 4.12 may be effected by either of the following:

(a) Independent approval by the responsible competent authority of each country through or into which the consignment is to be transported (i.e. a chain of multilateral competent authority approvals);
(b) Validation of the original certificate issued by the competent authority of the country of origin of the design or shipment in accordance with para. 840 of the Transport Regulations.

Both an independent approval 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). The issued certificate of approval or validation of each competent authority involved in such a multilateral approval process is only applicable within its territory of jurisdiction (see also paras 5.8-6.4). It is the responsibility of the consignor to receive all applicable multilateral approvals for each country through or into which its consignment is to be transported before the transport takes place.

5.2. 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 approval 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.

5.3. Independent approval 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 approval of the original competent authority is deemed necessary, or if new provisions are to be added to the approval. In such cases, an independent assessment of the application should be performed by the relevant competent authority.

5.4. The essential difference between an independent approval and a validation is that the latter is not self-contained; that is, some reference to the original certificate of approval 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 certificate of approval, in translation if necessary.

5.5. 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 might arise because of supplementary or divergent local regulations or different practices of the competent authorities.

5.6. An endorsement is a special kind of validation that simply states that all provisions of the original certificate of approval are endorsed. An endorsement may contain supplementary provisions or information if they do not conflict with the provisions of the original certificate and do not modify the design. An endorsement should use the identification mark of the original certificate (i.e. not a separate identification mark).

5.7. The competent authority of any country where the shipment is to be transported through or into, should take part in any chain of multilateral approvals by competent authorities. The competent authorities of the countries from which a vessel or aircraft departs and at which it arrives may be involved in the multilateral approval process, as well as the competent authority of the flag state of the vessel or aircraft (considered to be part of the territory of the flag State).

5.8. Multilateral approvals should not be issued before the certificate of approval is issued by the competent authority of the country of origin of the design or shipment. However, 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.

6. INTERNATIONAL COOPERATION BETWEEN COMPETENT AUTHORITIES CONCERNING PACKAGES AND SHIPMENTS OF FOREIGN ORIGIN

INTERNATIONAL COOPERATION RELATING TO COMPLIANCE ASSURANCE

6.1. The national competent authority is responsible for compliance assurance within its territory. However, many shipments of radioactive material involve packages of foreign origin. Each such instance of transport should also comply with national regulatory requirements (see also paras 3.5 and 3.8).

6.2. To ensure 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 consider inspecting such packages or shipments. Cooperation with other national competent authorities should also be considered.

6.3. National competent authorities should cooperate to further develop the Transport Regulations and its associated advisory and explanatory Safety Guides for the safe transport of radioactive material [2], [10], [29], [34], [32], [37]. One objective of such cooperation is the uniform application of the requirements of the Transport Regulations in all Member States.

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

6.4. Foreign packages and shipments listed in para. 4.12 require multilateral approval by the competent authority of each country through or into which the consignment is to be transported. For such cases, the competent authority that is requested to issue a validation of the original certificate of approval can request that it be informed of the details relating to the design assessment as well as the management system, before it issues a certificate of validation. Cooperation between the validating competent authority and the competent authority that issued the original certificate of approval, will contribute to ensuring that the necessary compliance assurance is 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 relevant details of inspections. Where important shipments or large scale operations are concerned, efforts to ensure international cooperation may involve 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, the competent authority should verify that the validating mark, as required by para. 833(b) of the Transport Regulations, is legibly and durably marked on the packaging.

6.7. For operations associated with foreign packages and shipments, notifications to the competent authority of each country through or into which the consignment is to be transported are also required, in accordance with paras 557–559 of the Transport Regulations.

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

6.8. 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. International cooperation between competent authorities can be used to inform interested parties about such transports, but competent authorities may also identify such packages and shipments in the same way as the transport of other dangerous goods.

6.9. The competent authority might receive only the notifications required under paras 557 and 558 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

546—554 of the Transport Regulations. The competent authority should check this information as part of its compliance assurance programme.

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

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NOTE ON ANNEXES

The annexes provide examples of guidance, templates, procedures and checklists that may be used by a competent authority in performing various functions and activities that are part of a compliance assurance programme. If this material is used by a Member State, it will need to be adapted in accordance with national regulatory requirements, working practices and methods. The material in the annexes has not been endorsed by the IAEA or its Member States.

The information in the section titled "Information on Management Systems" in Annex I has been adapted from US Nuclear Regulatory Commission Regulatory Guide 7.10, Rev. 2, Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material[1]. The checklists in Annexes VI–IX have been adapted from the European Association of Competent Authorities for the Safe Transport of Radioactive Material's Technical Guide: Compliance Inspections by the European Competent Authorities on the Transport of Radioactive Material, Issue 1 [2].

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ANNEX I: INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVALS

I–1. This annex provides details of the information to be included in applications for approval:

(a) Design of packages;
(b) Design of special form radioactive material and low dispersible radioactive material;
(c) Shipments;
(d) Shipments under special arrangement;
(e) Management systems.

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVAL OF DESIGN OF PACKAGES

I–2. The applicant seeking approval needs to provide the competent authority with all necessary information to demonstrate that the package design meets all applicable regulatory requirements. The corresponding application document, which is sometimes referred to as the package design safety report, needs to at least contain the information as specified in paras 807(c), 809, 812 and 815 of IAEA Safety Standards Series No. SSR-6 (Rev.1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition (the Transport Regulations) [I–1].

I–3. Specific recommendations on the formatting and contents of a package design safety report are provided in SSG-66 [I–2]. SSG-66 [I–2] covers all types of package and assists in the preparation of the package design safety report to demonstrate compliance of a design of a package with all applicable requirements of the Transport Regulations [I–1]. It provides detailed guidance on the structure and the contents of a package design safety report. It includes all package designs requiring competent authority approval (Type B(U), Type B(M), Type C, packages containing fissile material and packages designed to contain 0.1 kg or more of uranium hexafluoride). In addition, recommendations are also provided for package designs not requiring competent authority approval (excepted package, industrial package (Type IP-1, Type IP-2, Type IP-3), Type A package) to demonstrate compliance with all applicable requirements of SSR-6 (Rev. 1) [I–1].

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVAL OF DESIGN OF SPECIAL FORM RADIOACTIVE MATERIAL AND LOW DISPERSIBLE RADIOACTIVE MATERIAL

General information

I–4. General description of the design and of the intended use of the special form or low dispersible radioactive material.

I–5. List of applicable national and international regulations and specifying the edition of the Transport Regulations [I–1] under which competent authority approval is sought.

Administrative information

I–6. Administrative information including the following:

- Name, address, telephone number and email address of the applicant;

- Name, address, telephone number and email address of the designer;
- Type of approval required (special form or low dispersible radioactive material);
- Identification mark of the competent authority, if previously allocated;
- General arrangement drawing number;
- Date of application;
- Date by which approval is desired.

Specific information as required by para. 803 of the Transport Regulations [I–1]

I–7. A detailed description of the radioactive material or, if a capsule, the contents, which include the following:

- Radionuclides present;
- Total activity;
- Nature of emitted radiation;
- Heat output;
- Physical and chemical state;
- Overall dimension and mass.

I–8. A detailed statement of the design of any capsule to be used.

I–9. A statement of the tests that have been performed and their results, or evidence based on calculations, to show that the radioactive material is capable of meeting the performance standards, or other evidence that the special form radioactive material or low dispersible radioactive material meets the applicable requirements of the Transport Regulations [I-1].

I–10. A specification of the applicable management system, as required by para. 306 of the Transport Regulations.

I–11. Any proposed pre-shipment actions for use in the consignment of special form radioactive material or low dispersible radioactive material.

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVAL OF SHIPMENTS

General information

I–12. General description of the shipment from consignor to consignee, including loading, carriage and unloading of the consignment, stowage arrangements, storage in transit and provisions for exclusive use, if applicable.

I–13. Number of shipments.

I–14. List of applicable national and international regulations and specifying the edition of the Transport Regulations [I–1] under which competent authority approval is sought.

I–15. Specification of the applicable management system, radiation protection programme and emergency procedure.

I–16. Radiation protection programme in case of shipments by special use vessels in accordance with para. 576(a) of the Transport Regulations [I-1].

I–17. Applicable package design certificates of approval (Type B(M) packages or packages containing fissile material).

Administrative information

I–18. Administrative information including the following:

- Name, address, telephone number and email address of the applicant;
- Name, address, telephone number and email address of the consignor;
- Name, address, telephone number and email address of the consignee;
- Name, address, telephone number and email address of the carrier;
- Type of shipment approval required as specified in para. 825 of the Transport Regulations [I–1];
- Identification mark of the competent authority, if previously allocated;
- Date of application;
- Date by which approval is desired.

Specific information for shipments described in paras 825(a)–(c) and (e) of the Transport Regulations [I-1] (paras 827(a)–(c) of the Transport Regulations [I–1])

I–19. The actual radioactive contents including:

- Radionuclides present;
- Total activity;
- Nature of emitted radiation;
- Heat output;
- Physical and chemical state;
- Quantity in mass units; for packages containing fissile material the quantity of fissile material or fissile nuclides in mass units and the enrichment in percentage and for irradiated fuel the burnup, irradiation time, cooling time and initial enrichment.

I–20. The modes of transport.

I–21. The type of conveyance and the probable or proposed route.

I–22. The details of how the precautions and administrative or operational controls, referred to in the certificates of approval for the package design, if applicable, issued under paras 810, 813 and 816 of the Transport Regulations [I–1], are to be put into effect.

Additional specific information for SCO-III shipments (paras 827A(a)–(g) of the Transport Regulations [I-1])

I–23. The period of time, related to the shipment, for which the approval is sought.

I–24. A statement of the respects in which, and of the reasons why, the consignment is considered SCO-III.

I–25. Justification for choosing SCO-III by demonstrating that:

- No suitable packaging currently exists;
- Designing and/or constructing a packaging or segmenting the object is not practically, technically or economically feasible;
- No other viable alternative exists.

I–26. A detailed description of the proposed radioactive contents with reference to their physical and chemical states and the nature of the radiation emitted.

I–27. A detailed statement of the design of the SCO-III, including complete engineering drawings and schedules of materials and methods of manufacture.

I–28. All information necessary to satisfy the competent authority that the requirements of paras 520(e) and 522 of the Transport Regulations [I–1], if applicable, are satisfied.

I–29. A transport plan that describes various aspects of the shipment as required by para. 520(e)(iii) of the Transport Regulations [I-1].

I–30. A specification of the applicable management system, as required in para. 306 of the Transport Regulations [I–1].

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVAL OF SHIPMENTS UNDER SPECIAL ARRANGEMENT

General information

I–31. General description of the shipment from consignor to consignee, including loading, carriage and unloading of the consignment, stowage arrangements, storage in transit and provisions for exclusive use, if applicable.

I–32. Number of shipments.

I–33. List of applicable national and international regulations and specifying the edition of the Transport Regulations [I–1] under which competent authority approval is sought.

I–34. Specification of the applicable management system, radiation protection programme and emergency procedure.

Administrative information

I–35. Administrative information that includes the following:

- Name, address, telephone number and email address of the applicant;

- Name, address, telephone number and email address of the consignor;
- Name, address, telephone number and email address of the consignee;
- Name, address, telephone number and email address of the carrier;
- Identification mark of the competent authority, if previously allocated;
- Date of application;
- Date by which approval is desired.

Specific information as required by paras 310 and 830 of the Transport Regulations [I–1]

I–36. An application for approval of shipments under special arrangement needs to include all the information necessary to satisfy the competent authority that the overall level of safety in transport is at least equivalent to that which would be provided if all the applicable requirements of these Regulations had been met. The application also includes the following:

- A statement of the respects in which, and of the reasons why, the shipment cannot be made in full accordance with the applicable requirements;
- A statement of any special precautions or special administrative or operational controls that are to be employed during transport to compensate for the failure to meet the applicable requirements.

I–37. This information also needs to include a detailed description of the radioactive material, the packaging and all compensatory measures (technical, operational and administrative).

INFORMATION ON MANAGEMENT SYSTEMS

I–38. The extent of the management system will depend on the type of transport activities being performed by the organization. These include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, shipment after storage, unloading and receipt at the final destination of loads of radioactive material and packages.

I–39. Although this subsection focuses on information on management systems to be included in applications for approval of: the designs of packages, special form radioactive material and low dispersible radioactive material, and shipments and shipments under special arrangement, it provides comprehensive information that can be adapted to any of the transport activities mentioned above.

I–40. Information on management systems that is included with applications for approval might include the following information in accordance with international, national or other standards acceptable to the competent authority:

Management System Organization

I–41. Documentation of the formal structure of the organization by organization charts that identify each organizational element that functions under the management system.

I–42. Documentation of the commitment of top management stating that it is the policy of the organization to perform work on items important to transport safety in accordance with the management system.

Management System Programme

I–43. Scope of the management system: a description of measures established for identifying the following:

- The structures, systems and components covered by the management system;
- The approach for verifying that the applicable structures, systems and systems meet the objectives of the management system.

I–44. A description of measures implemented to ensure that:

- Activities important to safety are performed using specific instructions and specified equipment and under suitable environmental conditions;
- Management system manuals specify the designated responsibilities for implementation of activities important to safety;
- The user of the management system has established indoctrination and training programmes to ensure that personnel performing activities important to safety are trained and qualified to perform those activities.

Package Design Control

I–45. A description of measures implemented to ensure the following:

- Cooperation among those responsible for preparing design documentation;
- Appropriate design analyses including independent design verification;
- Coordinating interfaces between involved personnel;
- Maintenance of lines of communication during the design process.

Procurement Document Control

I–46. A description of measures to control the preparation, review, concurrence and approval of all procurement documents

Instructions, Procedures, and Drawings

I–47. A description of measures implemented to ensure that:

- Activities important to safety are prescribed and accomplished in accordance with current documented instructions, procedures, or drawings that have been approved by appropriate levels of management.
- All work activities are coordinated with management system personnel to ensure that the work controlling documents incorporate appropriate inspection and hold points to verify that initial work, planned work, effective repairs, or rework have been performed satisfactorily.
- Instructions, procedures, and drawings include quantitative acceptance criteria (e.g. dimensions, tolerances, and operating and regulatory limits) and qualitative acceptance criteria (e.g. workmanship samples) to verify that activities important to safety have been satisfactorily accomplished.

- Written procedures address the use, management, storage, and protection of electronic records and data.
- Information is maintained on the specific software applications and storage or computing hardware.

Document Control

I–48. A description of the measures implemented to ensure that each of the documents under the control of the management system reflects its current status.

I–49. A description of controls that have been established to ensure that all documents and changes thereto are adequately reviewed and approved prior to their issuance.

Control of Purchased Material, Equipment, and Services

I–50. A description of measures implemented to ensure that materials, equipment and services conform to procurement documents.

Identification and Control of Materials, Parts and Components

I–51. A description of the measures implemented to ensure that materials, parts and components, including partially fabricated assemblies, are adequately identified to preclude the use of incorrect or defective items.

Control of Special Processes[1]

I–52. A description of measures to ensure that special processes are controlled so that:

- Procedures, equipment, and personnel are qualified in accordance with applicable codes, standards and specifications;
- The operations are performed by qualified personnel and accomplished in accordance with written process or procedure sheets that direct the recording of evidence of verification;
- Qualification records of procedures, equipment, and personnel are established, filed and kept current.

Internal Inspection

I–53. A description of measures to ensure that the following measures concerning internal inspections are implemented:

- Inspection procedures, instructions or checklists are available for each work operation, where necessary to ensure quality.
- Documents developed include methods for identifying characteristics and activities to be inspected, acceptance and rejection criteria, and the individuals or groups responsible for performing the inspection.

[1] Special processes may involve packaging maintenance by using certain processes (e.g. welding or heat treating) or non-destructive testing, or if specific processes are necessary to meet certificate of approval requirements.

- Objective evidence of inspection results is recorded.
- Hold or witness points are identified.
- The appropriate personnel approve data to ensure that all inspection requirements have been satisfied.
- The prerequisites to be satisfied prior to inspection are identified, including operator qualification and equipment calibration. Where sampling is used to verify acceptability of a group of items, the standard used as the basis for acceptance needs to be identified.
- Inspectors are qualified in accordance with applicable codes, standards and training programmes.
- Appropriate inspections are performed during various phases of operation, such as receiving inspections, in-process inspections, final inspections and maintenance inspections.

Test Control

I–54. A description of measures established to ensure that applicable test programmes, including prototype qualification tests, production tests, proof tests and operational tests, are accomplished in accordance with written procedures. This includes measures established to ensure that modifications, repairs, and replacements are tested in accordance with the original design and testing requirements.

Control of Measuring and Test Equipment

I–55. A description of measures established to ensure that measurement and test equipment (e.g. gauges, fixtures, reference standards, and devices used to measure product characteristics) is calibrated, adjusted and maintained at prescribed intervals or prior to use.

Handling, Storage and Shipping Control

I–56. A description of measures established to ensure that cleaning, handling, storage and shipping are accomplished in accordance with design requirements to preclude damage or deterioration by environmental conditions such as temperature and humidity.

Inspection, Test and Operating Status

I–57. A description of measures established to ensure that the status of inspections, tests and operating conditions (including maintenance of items) is known by organizations responsible for ensuring quality.

Nonconforming Materials, Parts or Components

I–58. A description of measures for controlling nonconforming items that includes the following principal elements:

- Proper identification;
- Segregation of discrepant or nonconforming items;
- Disposition of the nonconforming items;
- Evaluation of the nonconforming items.

Corrective Actions

I–59. A description of measures established to ensure that the causes of conditions detrimental to quality (e.g. those resulting from failures, malfunctions, deficiencies, deviations, or defective material and equipment) are promptly identified and reported to appropriate levels of management. Also, a description of measures established to obtain corrective actions from suppliers and ensure that follow-up actions are documented to verify that the corrective actions were implemented and effective.

Management System Records

I–60. A description of measures to ensure that management system records provide documentary evidence of the activities that affect quality and provide sufficient information to allow each record to be identified with the items or activities to which it applies. At a minimum, management system records might include the following information:

- Design, procurement, manufacturing and installation records;
- Supplier evaluations;
- Non-conformance reports;
- Results of inspections and tests;
- Failure analyses;
- As-built drawings and specifications;
- Qualification of personnel, procedures and equipment;
- Calibration procedures;
- Training and retraining records;
- Corrective action reports;
- Records demonstrating evidence of operational capability;
- Records verifying repair, rework and replacement;
- Audit plans, audit reports and corrective actions;
- Records that are used as a baseline for maintenance.

Audits

I–61. A description of measures implemented to ensure that internal audits are performed that address the following elements:

- Assurance of authority and organizational independence of the auditors;
- A commitment to adequate manpower, funding and facilities to implement the audit;
- Identification of audit personnel and their qualifications;
- Provisions for reasonable and timely access of audit personnel to facilities and documents, and qualified personnel necessary for performing audits;
- Use of established procedures and checklists;
- Methods for reporting audit findings to responsible management of both the audited and auditing organizations;
- Provisions for the audit team to gain access to levels of management that have responsibility and authority for corrective action;
- Methods for verifying that effective corrective action has been accomplished on a timely basis.

REFERENCES TO ANNEX I

[I–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6, (Rev. 1), IAEA, Vienna (2018).

[I–2] INTERNATIONAL ATOMIC ENERGY AGENCY, Format and Content of the Package Design Safety Report for the Transport of Radioactive Material, IAEA Safety Standards Series No. SSG-66, IAEA, Vienna (Publication in preparation)

ANNEX II: EXAMPLES OF TEMPLATES FOR CERTIFICATES OF APPROVAL

II–1. This annex provides examples of templates for certificates of approval by the competent authority for the following:

- Design of packages;
- Design of special form radioactive material and low dispersible radioactive material;
- Shipments;
- Shipments under special arrangement.

CERTIFICATE OF APPROVAL 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]
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, 2018 Edition, SSR-6 (Rev. 1) [hereafter referred to as 'SSR-6 (Rev. 1)'], and in the regulations listed in Section 17 of this certificate. This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.	
Issue Date [Signature of the certifying official(s)] Address, telephone number and email address of the competent authority	
5. Package identification (a) Reproducible illustration not larger than 21 cm × 30 cm showing the make-up of the package. (b) Packaging: (i) Model name or number (ii) Description (e.g. use, dimensions, materials, closures, penetrations, gross mass) (iii) Reference to drawings or specification of design (iv) Description of the containment system (c) Radioactive contents (non-fissile): (i) Radioisotopes (ii) Physical and chemical form (including special form radioactive material or low dispersible radioactive material, if applicable) and the mass in grams (iii) Maximum activity per package (including activities of the various isotopes) (iv) Any other restrictions on the radioactive contents that might not be obvious from the nature of the packaging (d) For package designs containing fissile material that require multilateral approval of the package design in accordance with para. 814 of SSR-6 (Rev. 1): (i) Type and form of fissile material (ii) The maximum total mass of fissile nuclides or the mass for each fissile nuclide, when appropriate (iii) Description of the confinement system (iv) Criticality safety index (v) Reference to the documentation that demonstrates the criticality safety of the package	

(vi) Special features on the basis of which the absence of water from certain void spaces has been assumed in the criticality assessment (vii) Any allowance (based on para. 677(b) of SSR-6 (Rev. 1)) 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. If deemed appropriate, a statement authorizing shipment, where approval of shipment is required under para. 825 of SSR-6 (Rev. 1)
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, including any special stowage provisions for safe dissipation of heat
11. Reference to information provided by the applicant relating to the use of the packaging or to specific actions to be taken prior to shipment
12. A statement regarding ambient conditions assumed for purposes of design, if these are not in accordance with those specified in paras 656, 657 and 666, as applicable, of SSR-6 (Rev. 1)
13. For Type B(M) packages, a statement specifying those prescriptions of paras 639, 655-657 and 660-666 of SSR-6 (Rev. 1), with which the package does not conform and any amplifying information that might be useful to other competent authorities
14. For package designs subject to para. 820 of SSR-6 (Rev. 1), a statement specifying those requirements of the current regulations with which the package does not conform.
15. For packages containing more than 0.1 kg of uranium hexafluoride, a statement specifying those prescriptions of para. 634 of SSR-6 (Rev. 1), that apply, if any, and amplifying information that may be useful to other competent authorities
16. Emergency arrangements deemed necessary by the competent authority
17. Applicable regulations concerning the transport of radioactive material (a) Road: (b) Rail: (c) Sea: (d) Inland waterways: (e) Air: (f) International: (g) Other:
18. Table summarizing past and current revisions of the certificate of approval

CERTIFICATE OF APPROVAL FOR DESIGN OF SPECIAL FORM RADIOACTIVE MATERIAL AND 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 and number)	
5. Description of the special form radioactive material or low dispersible radioactive material (means of encapsulation (if applicable), shape and dimensions)	
6. Radioactive material (radionuclide(s), physical and chemical forms)	7. Maximum activity
8. Design specifications (reference to drawings)	9. Reference to the applicable management system
10. Specific actions to be taken prior to shipment	
11. 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 2018 Edition, SSR-6 (Rev. 1) and in the regulations listed in Section 12 of this certificate.	
Issue Date [Signature of certifying official(s)] Address, telephone number and email address of the competent authority	
12. Applicable regulations concerning the transport of radioactive material (a) Road: (b) Rail: (c) Sea: (d) Inland waterways: (e) Air: (f) International: (g) Other:	
13. Table summarizing past and current revisions of the certificate of approval	

CERTIFICATE OF APPROVAL 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]
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, 2018 Edition, SSR-6 (Rev. 1) [hereafter referred to as 'SSR-6 (Rev. 1)'] and in the regulations listed in Section 12 of this certificate. This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.	
Issue Date [Signature of the certifying official(s)] Address, telephone number and email address of the competent authority	
5. Identification of the applicable certificate(s) of approval of design	
6. Specification of actual radioactive contents, including: (a) Radioisotopes (including fissile material) (b) Physical and chemical form (special form radioactive material, low dispersible radioactive material, or fissile material excepted under para. 417(f) of SSR-6 (Rev. 1), if applicable) (c) Total activity per package and per conveyance (including activities of the various isotopes, if appropriate) and total mass in grams per package and conveyance (d) Total amount in grams of fissile material (or for each fissile nuclide, when appropriate) per package and per conveyance (e) Any restrictions on the radioactive contents that might not be obvious from the nature of the packaging	
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	
9. Operational controls required for preparation, loading, carriage, unloading and handling of the consignment, including any special stowage provisions for the safe dissipation of heat or maintenance of criticality safety	
10. Reference to information provided by the applicant relating to specific actions to be taken prior to shipment.	
11. Emergency arrangements deemed necessary by the competent authority	

12. Applicable regulations concerning the transport of radioactive material (a) Road: (b) Rail: (c) Sea: (d) Inland waterways: (e) Air: (f) International: (g) Other:
13. Table summarizing past and current revisions of the certificate of approval

CERTIFICATE OF APPROVAL 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]
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, 2018 Edition, SSR-6 (Rev. 1) [hereafter referred to as 'SSR-6 (Rev. 1)'] and in the regulations listed in Section 16 of this certificate. This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.	
Issue Date [Signature of the certifying official(s)] Address, telephone number and email address of the competent authority	
5. Package identification (a) Reproducible illustration not larger than 21 cm × 30 cm showing the make-up of the package (b) Packaging: (i) Model name or number (ii) Description (e.g. use, general external dimensions and appearance, materials of manufacture, closures, penetrations, gross mass) (iii) Reference to drawings or a specification of the design (iv) Description of the containment system (c) Radioactive contents (non-fissile): (i) Radioisotopes (ii) Physical and chemical form (including special form radioactive material, low dispersible radioactive material, or fissile material excepted under para. 417(f) of SSR-6 (Rev. 1), if applicable) (iii) Maximum activity per package (including activities of the various isotopes, if appropriate) and total mass in grams per package (iv) Any restrictions on the radioactive contents that might not be obvious from the nature of the packaging (d) Additionally, for packages containing fissile material: (i) Type and form of fissile material (ii) The maximum total mass of fissile nuclides or the mass for each fissile nuclide, when appropriate (iii) Description of the confinement system (iv) Reference to the documentation that demonstrates the criticality safety of the package (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) Any allowance [based on para. 677(b) of SSR-6 (Rev. 1)] 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 special arrangement 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, freight container and any necessary routeing instructions
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, including any stowage provisions for the safe dissipation of heat
11. Reference to information provided by the applicant relating to the use of the packaging or to specific actions to be taken prior to shipment
12. Reasons for the special arrangement
13. Compensatory measures to be applied as a result of the shipment being under special arrangement
14. Ambient conditions assumed for purposes of design if these are not in accordance with those specified in paras 656, 657 and 666, as applicable, in SSR-6 (Rev. 1)
15. Emergency arrangements deemed necessary by the competent authority
16. Applicable regulations concerning the transport of radioactive material (a) Road: (b) Rail: (c) Sea: (d) Inland waterways: (e) Air: (f) International: (g) Other:
17. Table summarizing past and current revisions of the certificate of approval

ANNEX III: INSPECTIONS OF MANAGEMENT SYSTEMS AND RELATED INSPECTION ACTIVITIES PERFORMED BY THE COMPETENT AUTHORITY

III–1. The following is a list of general items to which the competent authority can direct its attention during inspections to ensure the following:

(a) The management of the organization has provided the necessary personnel and resources to implement an effective programme for compliance with IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition (the Transport Regulations) [III–1]. 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 implementing the programme for compliance with the Transport Regulations [III–1]. Documentation of the training that has been provided needs to 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 perform direct examination of packages being prepared for shipment.
(e) The organization has in its possession all the required documentation in accordance with the Transport Regulations [III–1], 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 certificate of approval, 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 [III–1]. This includes the proper determination and application of the correct transport index. When practicable, the competent authority may directly observe such actions.
(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, 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 actions have been taken, and the necessary reporting and communicative action is being achieved.

(m) The organization has developed and continues to maintain appropriate emergency arrangements and conducts exercises for emergency preparedness and response periodically, as appropriate.

III–2. Examples of procedures and checklists that can be used by competent authorities for their inspection activities are given in Annexes IV–IX. These checklists are not comprehensive and can 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.

REFERENCE TO ANNEX III

[III–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

ANNEX IV: EXAMPLE OF A PROCEDURE FOR INSPECTING A MANAGEMENT SYSTEM

INSPECTION 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

PURPOSE

IV–1. To define the method used by the competent authority to perform inspections 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, 2018 Edition, SSR-6 (Rev. 1) (the Transport Regulations) [IV–1].

SCOPE

IV–2. The procedure covers the inspection activities of the competent authority and its agents in connection with an inspection 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 inspection, additional inspection activities can be arranged if this is requested by other organizational units of the competent authority.

Inspection activities include the following:

(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 adequately implemented;
(c) Evaluating the adequacy, effectiveness and efficiency of the management system;
(d) Identifying non-compliance, requesting and verifying corrective actions.

DEFINITIONS

IV–3. Inspection checklist

A listing of the enquiries to be raised by the inspection team, which constitutes the inspection scope.

IV–4. Inspection matrix

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

IV–5. Inspection plan

A timetable of inspecting activities.

IV–6. Inspector(s)

The person(s) responsible for undertaking the inspection.

IV–7. Inspection

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

IV–8. Corrective actions

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

IV–9. 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.

IV–10. Observation

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

IV–11. Record of non-compliance or observation

Recorded evidence, details and resulting corrective action(s) of non-compliance regarding the standards or procedures on which the inspection is based or observation where the management system has been found inadequate, which is provided during the inspection.

IV–12. Inspection report

A document summarizing the inspection results, which includes the inspection findings and corrective actions to be undertaken, issued by the competent authority to the organization being inspected after the inspection.

IV–12. Inspection 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.

RESPONSIBILITIES

IV–13. The head of compliance is responsible for the management of all inspections of the management system and for inspection by the competent authority. The head of compliance is responsible for appointing the inspection team leader.

IV–14. The team leader is responsible for the planning, preparation, documentation and reporting of all quality inspection activities. In undertaking inspections of the management system, the following are developed:

(a) The inspection plan;
(b) Checklists;
(c) The inspection matrix;
(d) The inspection report;
(e) A statement of completion of the inspection.

IV–15. The organization being inspected is responsible for implementing the corrective actions noted on documented requests for corrective action.

IV–16. The team leader is responsible for verifying that requests for corrective action have been implemented.

PROCEDURE

Inspection preparation

IV–16. The head of compliance, or the designate, prepares and issues to management an overall inspection programme. The programme is reviewed and updated periodically.

IV–17. The head of compliance selects the inspection team and nominates a team leader. The team leader may delegate preparatory and follow-up activities to team members. Team members other than observers have received training in appropriate inspection techniques.

IV–18. The team leader opens an inspection file (all commercial information being confidential), allocates a sequential reference number and arranges initial contact with the

organization being inspected. If other government departments have an interest in the inspection, they may be informed in accordance with any extant interdepartmental agreements.

IV–19. The general arrangements and plans for the inspection are prepared by correspondence and, if necessary, by means of a pre-inspection meeting of the team leader and the organization being inspected.

IV–20. The team leader records the proposed inspection activities in an inspection plan. A questionnaire (inspection checklist) is used, which covers the scope of the inspection to be undertaken.

IV–21. An inspection matrix is drawn up, reflecting the criteria of the codes or standards against which the organization being inspected will be inspected.

IV–22. The agreed dates for the inspection are confirmed by means of correspondence with the organization being inspected; other interested parties are also notified. In all instances the notification includes the following points:

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

IV–23. Prior to the inspection, an inspectors meeting is convened at which the inspection plan, the inspection checklist and the inspection matrix are discussed. Any other relevant information, such as the results of previous inspections or reviews, is included.

Performance of the inspection

IV–24. The inspection is opened by a meeting between the inspection team and the representatives of the organization being inspected. The topics covered at the meeting include the following:

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

IV–25. The inspection is conducted objectively so as to establish whether the areas under examination have a satisfactory management system and whether the organization being inspected is adhering to it.

IV–26. An inspection matrix is completed by each inspector, indicating the criteria that have been inspected. In the final inspection review, the team leader checks all the inspected criteria against the criteria of the respective codes and standards. Areas not inspected are then highlighted, and the team leader can decide what actions have to be taken. The completed inspection matrix is then included in the inspection record, which can be used when future inspections are planned, for example, for criteria not inspected or areas considered weak.

IV–27. Evidence and details of non-compliance regarding the standards or procedures on which the inspection is based are recorded. The record of non-compliance indicates whether the

necessary corrective action needs to be taken immediately or within a given time. This record is signed by a representative of the organization being inspected to confirm that it is factual and correct. However, if the representative of the organization being inspected does not countersign the non-compliance record, it can still be considered to be admissible if the team leader so decides.

IV–28. The team leader regularly reviews the progress of the inspection, discussing non-compliance, changes of the inspection 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 by the inspection team. Also, the inspection matrix is completed, recording the areas and topics covered during the inspection. (This completed inspection matrix is considered to constitute evidence of compliance with the Transport Regulations [IV–1].)

Closing meeting

IV–29. A closing meeting (as decided upon at the opening meeting) is convened with the management of the organization being inspected and the inspection team. The team leader presents a balanced summary of the inspection undertaken, referring to the positive aspects emerging from the inspection, 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 records on non-compliance and observations are presented to the organization being inspected.

IV–30. The representatives of the organization being inspected are invited to comment on the findings; any disagreement or clarification concerning corrective actions is discussed and resolved if possible. The organization being inspected is advised by the team leader that a written report of the inspection will be sent by the competent authority in due course.

Inspection report

IV–31. The inspectors prepare an inspection report that summarizes the inspection results and includes the findings of the inspection 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 inspection report, covering only the findings, may be prepared and sent to the organization being inspected for prompt information.

IV–32. The inspection report is sent to the organization being inspected, together with a covering letter referring to follow-up and verification of corrective actions. Organizations being inspected are requested to respond formally to the findings of the inspection, stating the timescale for the completion of corrective actions.

IV–33. The progress of corrective actions is monitored by the team leader. If problems are encountered in connection with these actions, the head of compliance and management may also be involved in this process. Where necessary, follow-up reports are issued to inform the appropriate senior management of the organization being inspected that a potential problem remains. When the inspection is complete, the team leader confirms this in a letter to the organization being inspected. The team leader also checks that all necessary documentation and records are filed and indexed. Completion of the inspection is certified by a written statement of inspection completion, which is signed by the team leader.

RECORDS

IV–34. The following inspection records are retained by the competent authority:

(a) Inspection programmes;

(b) Individual inspection files, containing inspection plans, inspection matrices, inspection reports, follow-up letters, correspondence and statements of completion of the inspection;

(c) Index of completed inspections.

DECLARATION

IV–35. This procedure does not preclude the competent authority from any enforcement action deemed necessary in accordance with its management framework for enforcement.

REFERENCE TO ANNEX IV

[IV–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

ANNEX V: EXAMPLE OF A CHECKLIST FOR INSPECTING A MANAGEMENT SYSTEM

MANAGEMENT SYSTEM AND STRATEGIC PLANNING

V–1. Is there an established and appropriately documented management system?

V–2. Is the organization's policy and statement of authority with respect to the management system documented?

V–3. Does the management system fully identify those processes and activities covered by the management system and provide for their effective control?

V–4. Is involvement in and commitment to the management system and its objectives evident on the part of senior management?

V–5. Does the management system fully cover the activities undertaken by the organization (these activities might include the design, manufacture, maintenance and repair of packagings, and the preparation, consigning, loading, carriage (including in-transit storage), shipment after storage, unloading and receipt at the final destination of loads of radioactive material and packages)?

V–6. Is there a defined organizational structure and management responsibilities consistent with the size and complexity of the organization and its functions?

V–7. Are the functional responsibilities and levels of authority clearly defined at all levels within the organization?

V–8. How does the organization manage organizational changes to ensure that it remains effective and that quality and compliance remain unaffected?

V–9. Are the provisions 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 (i.e. a graded approach)?

V–10. Is the management system subject to review and evaluation and, if so, how frequently?

V–11. Who is responsible for reviewing the management system?

V–12. Does the management system review process provide for an appropriate scope and include all necessary inputs?

V–13. Does the review process include a confirmation that the management system demonstrates compliance with the Transport Regulations [V–1] relating to the transport of radioactive material by the modes of transport used by the organization?

V–14. Does a radiation protection programme exist within the organization?

V–15. What processes are used to encourage and manage a safety culture within the organization?

V–16. Do the strategic plans of the organization include the development of its policies, objectives and processes?

DOCUMENTATION AND CONTROL OF RECORDS

V–17. 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?

V–18. Are there documented procedures to control all necessary documentation and records (paper, electronic or other acceptable media)?

V–19. Do the procedures cover the preparation, approval and issuing of such documentation?

V–20. Has a system for the release, distribution and withdrawal of documents been established?

V–21. How are personnel made aware of changes to documents?

V–22. How are suppliers made aware of changes to documents?

V–23. Are applicable codes, standards and regulations updated as amendments are issued?

V–24. How are essential personnel made aware that amendments to documents, including codes and standards, have been issued?

V–25. Are copies of redundant or out of date documents suitably marked, withdrawn or destroyed?

V–26. Are superseded or redundant documents retained, and if so, how are they controlled to prevent their accidental use?

V–27. 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?

V–28. How are incoming and/or external documents controlled?

V–29. Are records of changes to documentation retained?

V–30. Does the system cover the maintenance of essential records of the management system?

V–31. Does the system cover the identification, collection, indexing, filing, storage, maintenance and disposal of records?

V–32. Are records readily retrievable and maintained in a suitable environment?

V–33. Are retention periods for records defined?

V–34. Are records and/or logbooks available for each package and/or packaging?

V–35. Do logbooks contain the necessary information such as movement or transport records, authorized modifications to the package, and operating and maintenance instructions?

V–36. Are records available for maintenance performed at other locations?

MANAGEMENT RESPONSIBILITY

V–37. Has a management representative been appointed and given appropriate authority to manage, monitor, evaluate and coordinate the management system?

V–38. Are measurable objectives of the management system established at relevant functions and levels within the organization?

SATISFACTION OF INTERESTED PARTIES

V–39. Are the interested parties clearly identified?

V–40. Are the needs and expectations of interested parties identified?

V–41. What processes exist within the organization to monitor and measure the satisfaction of interested parties?

RESOURCE MANAGEMENT

V–42. Is there a commitment to the timely identification and provision of necessary resources, including personnel, to meet the needs of the organization and regulatory requirements?

V–43. Are the following items described in processes and/or procedures?

(a) Human resources;
(b) Infrastructure and working environment;
(c) Financial resources;
(d) Involvement of individuals;
(e) Managing information and knowledge.

TRAINING

V–44. How does the organization encourage the involvement and development of its personnel?

V–45. How is this measured?

V–46. Does the organization provide an appropriate training programme for all personnel involved in the transport of radioactive material?

V–47. How are training needs identified?

V–48. How are training records maintained?

INFORMATION AND KNOWLEDGE MANAGEMENT

V–49. How does the organization characterize, monitor and manage information and knowledge?

V–50. Is the procedure developed for information and knowledge management appropriate for the organization’s transport related activities and is it being followed?

COMMUNICATION AND INTERFACES

V–51. Does the organization provide for the effective communication of its policies, needs of customers and regulatory needs to all personnel within the organization?

V–52. Are internal and external lines of communication established and defined in processes and/or procedures?

V–53. Interfaces:

(a) Are the interfaces between organizations, including the responsibilities of each organization, been clearly defined in processes and/or procedures?
(b) Are these interfaces regularly reviewed?

DEVELOPMENT OF PROCESSES

V–54. Is there evidence that the organization has developed the management and work processes associated with the transport activities of the organization (design and manufacture, 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

V–55. 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

V–56. Are there sufficient measures in place to control the design process, and are they described in processes and/or procedures?

V–57. Have appropriate responsibilities been assigned for the whole design process?

V–58. Are there suitable procedures established for communicating design information, including changes, between the following:

(a) Design disciplines?
(b) Different units within the same organization?
(c) External interfaces including manufacturing and maintenance and/or repair facilities?

V–59. 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 dictate design verification to be accomplished by:
    (i) Formal design review or prototype testing;
    (ii) Calculations; or
    (iii) Computer codes?

Grade 2

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

Grade 3

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

V–60. Have provisions been made to ensure that all necessary design input — including customers' needs— has been identified and included in the design process?

V–61. 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 performed before submitting design information to the competent authority and to suppliers, or before commencing manufacture?

V–62. Have all acceptance and verification criteria been identified in design output and included in design input?

V–63. Is design output sufficiently well-defined to demonstrate its conformance with design input specifications?

V–64. What measures are established for the selection and for the review of the suitability of application of any materials, equipment and 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?

V–65. 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?

V–66. 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?

V–67. Do the design process procedures provide for the control of changes, deviations and/or concessions regarding the design specifications?

(a) Are changes, deviations and/or concessions documented?
(b) Do such documents need 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?

V–68. 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 necessary 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

V–69. Does the management system clearly identify the different phases of transport applicable to the organization — namely, design and manufacture, 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

V–70. Have effective and efficient purchasing processes been described in procedures and suitable controls implemented?

V–71. Do the purchasing processes and/or procedures provide for all necessary purchase criteria to be identified and specified on purchase orders and/or documents?

V–72. Do the purchasing processes and/or procedures ensure that the relevant design documents and regulatory requirements are included or referenced in procurement documents?

V–73. 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?

V–74. Do the procurement documents specify that design and quality specifications be passed on to sub-suppliers?

V–75. Do the procurement documents specify that material traceability be maintained throughout fabrication and assembly as necessary?

V–76. Are suppliers selected and evaluated for their ability to supply products in accordance with specific criteria?

V–77. Who conducts this evaluation, and is it recorded?

V–78. How is the past performance of suppliers recorded?

V–79. How often is a supplier assessed?

V–80. Are audits of supplier management systems conducted as part of the evaluation process?

V–81. Are supplier audits planned and documented?

V–82. Do purchasing documents provide for adequate access by the purchaser and the competent authority to the plants of the suppliers and sub-suppliers?

V–83. What controls are established to ensure that purchased items conform to the specifications of procurement documents?

V–84. Are such controls documented?

V–85. Are suitable arrangements provided for the care and control of customer supplied materials or items?

IDENTIFICATION, TRACEABILITY AND PRESERVATION OF MATERIALS

V–86. Are suitable arrangements in place to determine when identification and traceability of materials, items and software, are necessary?

V–87. Are the necessary identification and traceability of such items being achieved?

V–88. Are measures established to control the handling, storage and shipping of materials both at initial delivery and during use in transport operations?

V–89. Are suitable provisions in place for the preservation and protection of products, materials and packagings to ensure their fitness for use when needed?

PROCESS CONTROL

V–90. Have all relevant processes, including those necessary for the management system, been identified and their control provided for (e.g. design, procurement, manufacturing, delivery processes and transport operations)?

V–91. Do process control arrangements, including procedures, instructions and drawings, include appropriate qualitative and quantitative acceptance criteria for determining that important activities have been satisfactorily accomplished?

V–92. Are documents such as quality plans produced to support process control? Are such plans available?

V–93. Are any design, production or other processes performed by sub-suppliers controlled, and how is this done?

V–94. How are process control arrangements and procedures reviewed, controlled and issued?

V–95. Do sub-suppliers use their own process control procedures or those of the purchasing organization (e.g. process procedures and work instructions)?

V–96. Are inspections or other process control checks performed at defined points during the process (e.g. manufacturing, maintenance)?

V–97. Are special processes controlled (e.g. welding or non-destructive testing)?

V–98. How are these special processes controlled and monitored?

V–99. Are only suitably qualified and experienced people used to control or perform special processes?

V–100. Are all necessary controls or supporting processes available for controlling special processes (e.g. heat treatment)?

CONTROL OF INSPECTIONS, MEASUREMENTS AND TESTS

Inspection

V–101. Have programmes for inspection of items and services been established?

V–102. Do the procurement documents request that suppliers establish inspection programmes?

V–103. Have programmes for in-service inspections been established?

V–104. Who authorizes inspection programmes?

V–105. Are such inspections conducted by qualified personnel other than those persons performing the activities?

V–106. Have inspection procedures been established?

V–107. What processes ensure that non-conforming in-service items are removed from use until the situation is rectified?

V–108. Are inspection hold points defined?

V–109. How is it ensured that work does not proceed beyond a hold point?

Measurement and monitoring

V–110. 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?

V–111. What process(es) does the organization use to release a packaging, package and/or conveyance to its customer?

Testing

V–112. Have test programmes (e.g. prototype qualification, production, proof and operational tests) been established?

V–113. How is it ensured that the test programmes demonstrate the adequacy of the specification(s) and that all parts will perform satisfactorily in service?

V–114. Is testing conducted against written test procedures, and are the acceptance criteria specified?

V–115. Who evaluates the test results?

V–116. Does testing cover normal and accident conditions of transport?

V–117. Does the management system cover calibration and control of the measuring and test equipment?

V–118. Are calibration records available, and can they be traced back to a national standard?

V–119. Are measuring and test equipment calibrated, adjusted and maintained at prescribed intervals or prior to use?

V–120. Are measuring and test equipment labelled or tagged to indicate calibration status?

V–121. If equipment is found to be non-compliant, how is acceptance of the items reassessed?

V–122. Are controls established for the handling, storage and use of equipment?

V–123. How is inspection and test status identified, and is it maintained throughout the manufacture and use of an item?

PROCEDURES AND PROCESSES FOR CERTAIN ACTIVITIES RELATED TO PACKAGES

V–124. Have systems and control processes for handling, labelling, dispatch, carriage, receipt, unloading and storage of packages and/or packagings been established?

V–125. Do procedures and/or processes include controls for:

(a) The contents;
(b) Cleaning of packages;
(c) Preserving;
(d) Leaktightness;
(e) Dose rates and radioactive contamination;
(f) Turnaround and periodic inspection of package and/or packaging;
(g) Consumable and spare packaging components;
(h) Transport documents?

SELF-ASSESSMENT

V–126. Has a programme been established to perform organizational self-assessments at all levels of management to evaluate the performance of work?

INDEPENDENT ASSESSMENT

V–127. Is there a programme for internal and external audits?

V–128. Is the audit programme documented?

V–129. Are audits conducted by qualified persons who have not been involved in the activity being audited?

V–130. Are effective corrective and preventive actions taken when the system is found to be incorrect?

V–131. Are internal audit reports used for management system reviews?

V–132. Is the organization subjected to independent assessment by any of its interested parties?

V–133. How do the findings of any independent assessments compare with the findings made by internal auditing?

NON-CONFORMANCE, AND CORRECTIVE AND PREVENTIVE ACTIONS

V–134. Is there an effective system for controlling non-conforming material?

V–135. Are the procedures for rework, use-as-is and repair of non-conforming material documented and acceptable?

V–136. Is the responsibility for the review and acceptance of non-conforming items specified?

V–137. Are accepted non-conformities reported to the purchaser and, if necessary, to the competent authority?

V–138. Does the system provide for the detection of inferior quality and for the correction of its causes?

V–139. Is adequate action taken to correct the causes of inferior quality (i.e. design faults, defective material)?

V–140. Are analyses made to identify trends towards material non-conformance?

V–141. Does corrective action extend to material supplied by sub-contractors?

V–142. Are data analysis and material examination conducted on failed items to determine the extent and causes of defects?

V–143. Is there an effective system for registration of corrective and preventive actions and events?

V–144. Is the effectiveness of corrective and preventive actions reviewed and monitored?

IMPROVEMENT

V–145. Are appropriate arrangements in place to review and confirm that the needs of customers and other interested parties are being met?

V–146. Does the organization have a process or procedure for continuous improvement and is it being adequately implemented?

REFERENCE TO ANNEX V

[V–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

ANNEX VI: EXAMPLE OF A CHECKLIST FOR INSPECTING CONSIGNORS

Inspection details:

Inspector(s) name(s):

Inspection reference file(s):

Date/time:

Location:

Company details and organization:

Company name:

Address:

Telephone:

Fax:

E-mail:

Web:

Name of persons met:

Name	Title / Function	Telephone	E-mail

List of packages used:

Model	Manufacturer of packaging	Type/Certificate of approval	Serial numbers

Activities performed by the consignor:

Activity	Comment
Receipt of radioactive material	
Package or special form radioactive material design	
Package manufacturing	
Radioactive material classification	
Selection of package type and of package design	
Preparation and/or handling of packages; loading, unloading, stowage of packages on conveyance	
Transport	
Maintenance and/or repairing of packaging	
Does the consignor subcontract above activities associated with the transport of radioactive material? (Identify what activities are subcontracted)	

Subject/Inspection aspect	Paras in SSR-6 (Rev.1), 2018 Edition	Compliance			Comments
		YES	NO	Not Applicable	
Company details and organization					
Does the consignor adequately define the interfaces with subcontractors and the respective responsibilities? (identify how)	(306)				
Does the consignor perform a previous evaluation of subcontractors as service suppliers? (Identify the applicable procedure)	(306)				
Does the consignor have a procedure to cover the relationship with suppliers? (the relationship could be written in specific accordance document, not necessarily in procedures)	(306)				
Does the consignor have a list of approved suppliers? (Ask for and check some suppliers' documentation. Verify the evaluation is in accordance with the procedure)	(306)				

Does the consignor undertake periodical inspections of the subcontractor's activities? (Check procedures and records on these inspections)	(306)				
Do the suppliers comply with other requirements like specific licences? (e.g. carrier's registration or authorization, laboratory's authorizations.)	(306) National regulations				
Are there written procedures to cover transport activities? (identify them)					
Is the content of those procedures in compliance with the applicable Transport Regulations (see next item) as well as with the certificate of approval and the Safety Analysis Report of the package? (Whenever possible, check the fulfilment of the procedures)	545-561 (306)				
Awareness of applicable Transport Regulations					
Is the company aware of the latest edition of the applicable modal, international and national regulations?	(306)				
Does the company hold a copy or copies? (List those held)	(306)				
How are copies controlled and updated? (Is there a document system applied?)	(306)				
Are the transport documents retained for a minimum of 3 months?	555				
Types of transport and package					
Modes of transport generally used by the consignor: (Identify the more usual consignments, consignees and transport routes)					
By road					
By rail					
By air					
By sea					
By inland waterways					
Types of package used by the consignor:					
Excepted packages					
Industrial packages					
Type A					

Type B					
Type C					
Unpackaged radioactive material					
Other dangerous properties of contents:					
Toxicity (UF6)					
Fissile					
Others					
Is the radioactive material transported under exclusive use?					
Evidence of conformity of the packages					
Radioactive Material Classification:					
Does the consignor do the classification?	401, 546, 408-434				
If yes, does the consignor have procedures for this activity? (Note reference(s))	(306)				
If not, does the consignor conduct any control over the classification process? (Identify the procedure and the way the consignor does this control: Verification, inspection, calculation validation.)	(306)				
In case of special form radioactive material or low dispersible radioactive material are the certificates of approval available? Are they still valid?	561, 556				
Is the radioactive material transported as "fissile excepted"? (Identify the criteria used and the procedures applied by the consignor to confirm the criteria fulfilment)	Table 1, footnote "b", 417, 546j				
Packages:					
Does the consignor have procedures for selecting the packaging depending on the radioactive material to be transported? (Identify the package designs, the number of packagings of each design used and their suppliers)	(306) 401, 408-434				
For package designs subject to approval, are the certificates of approval in force in possession of the consignor? Are they still valid?	561, 556 802				

Has the consignor implemented a procedure to be informed about changes of certificates of approval?	(306)				
For packages the design of which is not subject to approval, has the consignor in his possession the documentary evidence of the compliance of the package design? (Identify the documentation presented) Is this documentation still valid? (i.e.no design change)	801				
Is the general state of the packagings adequate?	502, 503				
Are the components of the packagings in good state?	502, 503				
Are the packagings and their components in accordance with the package design?	502, 503				
Is the marking method of packages adequate?	507, 531-537, 545, 547				
Is the labelling method of packages adequate?	507, 538-542, 545, 547				
Are the radiological measures conducted on the packages in accordance with regulations?	508, 509, 516, 523-524A, 526-529				
Package maintenance/repair (Use Annex IX)					
Operating/handling processes					
Does the consignor possess the operation procedure referenced in the certificate of approval or in the compliance documentation? (Verify how the requirements included in those documents are transferred to consignor's instructions or procedures)	561				
Does the consignor fulfil the predefined inspection requirements before each shipment?	502, 503				
Does the consignor fulfill inspection requirements before the first use of a packaging?	501				
Package marking and labelling					
Do the procedures include the requirements about marking and labelling activities? (Check)	531-542				
Is the marking on the packages in accordance with the Transport Regulations?	531-537				

Is the methodology for the determination of transport index clearly defined and in accordance with the Transport Regulations?	523-524				
Whenever possible, it is useful to do visual inspections					
Transport documentation and notification					
Do the procedures include the documentation required and are they in compliance with the Transport Regulations? (Check for different modes, check shipment records and verify they are in accordance with the procedures)	546-556				
Does the documentation include:					
The list of information provided in para 546 (a) - (n) of the Transport Regulations	546 (a) - 546 (n)				
The consignor's declaration?	547-553				
Name and address of the consignor?	546				
Name and address of the consignee?	546				
Does the consignor provide supplementary transport requirements? (Handling, stowage, temperature measurements, if necessary)	554(a)				
Does the consignor provide restriction on the mode of transport or conveyance and any necessary routing instructions? (If necessary)	554(b)				
Does the consignor provide instructions on the mixed loading prohibition?	506, 507				
Does the consignor provide emergency arrangements appropriate to the consignment?	554(c)				
Is the documentation language used in accordance with the Transport Regulations?	554				
Does the consignor fulfil the notification requirements?	557, 558				
Radiation protection					
Does the consignor have a radiation protection programme (RPP)? If yes, record reference.	302				
Is the RPP maintained up-to-date?	301				
Is there adequate documentary evidence of the RPP?	302				
Is there a brief description of the operations?	302				

Are the responsibilities for radiation protection within the organization well defined?	302				
Is there a person assigned by the company having overall responsibility for the RPP? (Identify who, which department, and his/her responsibility)	302				
Is that person responsible for the following areas? (if not, identify the responsible individual) - Training - Implementation of work procedures - Assessment of workers' exposures	311 306 301, 303				
Are there working instructions and procedures in place adequate to optimize doses? (Identify the procedures implemented)	301, 302				
Is there a structured and systematic approach to dose assessment?	301, 303				
Have dose assessments been undertaken? (Identify the procedure applied for the assessments)	301-303				
Are records of individual monitoring of workers maintained, if required?	303				
Has radiological surveillance been undertaken? (If yes, describe; if no, justify)	303				
Are the results of radiological surveillance recorded? (Check records)	303				
Are contamination checks performed? (Describe method, check records)	301, 508 509, 512				
Are contamination check records kept?	306				
Does the company know the applicable limits for dose rates and contamination?	508-514 526-529				
Is there a protocol in case of non-compliance with the above limits for dose rates and contamination?	309				
Does the programme consider appropriate segregation distances between packages and areas regularly occupied by members of the public and/or workers?	562, 563, 506				
Are storage areas shielded in accordance with the RPP?	301, 562				
Is shielding used on the vehicles and freight containers?	566				
Is segregation used on the conveyances?	566-569				

For the preparation of packages and their transport from in-transit storage to the loading area, are the necessary radiation protection measures and the optimization principle applied?	301				
Does the RPP incorporate requirements related to emergency response in the event of a nuclear or radiological emergency during the transport of radioactive material?	302, 304, 305				
Does the RPP include training? (Identify training programmes, contents, initial and periodic training frequencies, who performs the training)	302, 311				
Is the training documented? (Identify how and check records)	311, 314				
Are radiation monitoring devices - available? - appropriate for the measurements to be taken? - calibrated?	306				
Emergency arrangements					
Who is the person assigned by the company having overall responsibility for emergency preparedness and response? (Identify who and in which department, and his/her responsibility)	304-306				
Which resources are provided in case of emergency? (e.g. at site or during transport, relations with service suppliers as carriers)	304-306				
Does the consignor have emergency arrangements appropriate to the consignment in place and do they include details about contact points in case of emergency? (Identify, possibly in RPP)	304-306 554(c)				
Do these provisions consider potential events that might happen during transport activities? (Identify, possibly in RPP)	304, 305				
Are these provisions regularly reviewed? (Check how the emergency provisions are implemented and maintained, if operative experience is considered)	305, 306				
Was there any recent emergency? (Whenever possible, check the fulfilment of the emergency provisions during the emergency)					

Training					
Does the consignor provide an appropriate training programme for all personnel involved in the transport of radioactive material?	311-315				
Does the consignor maintain records of the training and competence?	314				
Management system (Use Annexes IV and V)					

ANNEX VII: EXAMPLE OF A CHECKLIST FOR INSPECTING CARRIERS

Inspection details:

Inspector(s) name(s):

Inspection reference file(s):

Date/time:

Location:

Company details and organization:

Company name:

Address:

Telephone:

Fax:

E-mail:

Web:

Name of the persons met:

Name	Title / Function	Telephone	E-mail

List of packages:

Model	Manufacturer of packaging	Type/ Certificate of approval	Serial numbers

Activities performed by the carrier:

Topic	Comment
Number of personnel involved with radioactive material transport and their status	
Percentage of business involving radioactive material transport	
Frequency of radioactive material transport (per month)	
Is there radioactive material transport in-house?	
Which modes of transport does the company use? (Road, rail, inland waterway, sea, air)	

Subject/Inspection aspect	Paras in SSR-6 (Rev.1), 2018 Edition	Compliance			Comments
		YES	NO	Not Applicable	
Awareness of applicable Transport Regulations					
Is the company aware of the latest edition of the applicable modal, international and national regulations?	306				
Does the company hold a copy or copies? (List those held)	306				
How are copies controlled and updated? (Document system?)	306				
Radiation Protection					
Does the carrier have a radiation protection programme (RPP)? If yes, record reference.	302				
Is the RPP maintained up-to-date?	301				
Is there adequate documentary evidence of the RPP?	302				
Is there a brief description of the operations?	302				
Are the responsibilities for radiation protection within the organization well defined?	302				
Is there a person assigned by the company having overall responsibility for the RPP? (Identify who, which department, and his/her responsibility)	302				

Are there working instructions and procedures in place adequate to optimize doses? (Identify the procedures implemented)	301, 302				
Is there a structured and systematic approach to dose assessment?	301, 303				
Have dose assessments been undertaken? (Identify the procedure applied for the assessments)	301-303				
Are records of individual monitoring of workers maintained, if required?	303				
Are the results of radiological surveillance recorded? (Check records)	303				
Are contamination checks performed? (Describe method, check records)	301, 505, 508, 509, 512, 513				
Are contamination check records kept?	306				
Does the company know the applicable limits for dose rates and contamination?	508-514 526-528, 566				
Is there a protocol in case of non-compliance with the above limits for dose rates and contamination?	309				
Does the carrier maintain appropriate segregation distances between packages and areas regularly occupied by members of the public and/or workers in accordance with the RPP?	562, 563, 506				
Are storage areas shielded in accordance with the RPP?	301, 562				
Is shielding used on the vehicles?	566				
Is segregation used on the conveyances?	566-569				
For the loading and unloading of conveyances, are the necessary radiation protection measures and the optimization principle applied?	301-302				
Does the RPP include training? (Identify training programmes, contents, initial and periodic training frequencies, who performs the training)	302, 311				
Is training documented? (Identify how and check records)	311, 314				

Are radiation monitoring devices - available? - appropriate for the measurements to be taken? - calibrated?	306				
Emergency Arrangements					
Who is the person assigned by the company having overall responsibility for emergency preparedness and response? (Identify who and in which department, and his/her responsibility)	304-306				
Which resources are provided in case of emergency? (e.g. at site or during transport, relations with consigners)	304-306				
Are there provisions and procedures for radiological emergencies and do they include details about contact points in case of emergency?	304, 305				
How are the emergency procedures tested?	306				
Driver/ Company					
Is the vehicle crew supplied with written instructions regarding emergency procedures?	554				
Have arrangements and procedures been established regarding packages that are damaged or leaking that include the: identification of, assessment of contamination and dose rates associated with, and protective measures related to, such packages?	510, 511				
Does the crew have instructions or procedures to cover any trans-shipment, segregation or en-route storage requirements?	554, 562, 563				
Are accumulations of packages on conveyances monitored for dose rates, transport index (TI) and criticality safety index (CSI)?	566, Table 10, 569, Table 11				
Is the mixed loading prohibition verified?	506, 507				
Does the company know the applicable conveyance activity limits for Low specific activity (LSA) and Surface Contaminated Object (SCO)	522, Table 6				
If a consignment has been transported under special arrangement, has the carrier implemented all relevant compensatory measures related to its carriage? Have arrangements been made concerning relevant compensatory measures for planned shipments under special arrangement?	310				

Training						
Does the company provide an appropriate training programme for all personnel involved in the transport of radioactive material?	311-315					
Does the company maintain records of the training and competence?	314					
Does the driver have any necessary documents to confirm his/her proficiency in handling radioactive material in accordance with national regulations? (Training certificate, driving licence)	National regulations					
Transport documentation						
Is the driver supplied with all required transport documentation?	554,584, 585					
Are the transport documents retained for a minimum of 3 months?	587					
Package and Material Transport Activity						
Package and Material Type: - The company will have / use / carry one or more of the following (Enter the number for each type of package carried each month)						
Excepted	IP 1, 2 or 3	Type A	Type B (state which subtype)	Special Form Material	Special Arrangement	Fissile
For Type B and Type C packages, and Special Form, Low Dispersible and Fissile materials						
Does the company ask the consignor to make available copies of package and/or material certificates of approval?						
Shipment Approval Certificates						
Is a procedure in place to meet shipment approval requirements, if necessary?	852, 829					
Are there shipment certificates of approval in place? If yes, Certificate/Authorization Number:	825, 829					
Placarding, Fire Extinguishers, Miscellaneous Equipment and Stowage						
For road and rail: are the vehicles correctly placarded?	571, 572					
Are large freight containers carrying unpackaged LSA-I material or SCO-I or packages other than excepted packages and tanks placarded?	543, 544					

Are vehicles subject to a maintenance programme?	306				
Are records kept of vehicle maintenance?	306				
Are all tie-down and anchorage systems of the vehicle subject to regular testing?	306				
Have arrangements and procedures been established that take account of the requirements related to the surface heat flux of the package or overpack during carriage and stowage?	565				
For road: are the fire extinguishers carried complying with the existing national provisions?	National regulations				
For road: are other miscellaneous equipment carried complying with the existing national provisions?	National regulations				
Management System (Use Annexes IV and V)					

ANNEX VIII: EXAMPLE OF A CHECKLIST FOR INSPECTING THE MANUFACTURING OF PACKAGINGS

Inspection details:

Inspector(s) name(s):

Inspection reference file(s):

Date/time:

Location:

Company details and organization:

Company name:

Address:

Telephone:

Fax:

E-mail:

Web:

Name of the persons met:

Name	**Designation / Function / Company**	Telephone	E-mail

List of packages:

Model	Type	Reference of certificate of approval or documentation of compliance	Serial numbers (if applicable)

Subject/Inspection aspect	Paras in SSR-6 (Rev. 1), 2018 Edition	Compliance			Comments
		YES	NO	Not Applicable	
Management System (Use Annexes IV and V)					
Management of Resources					
Are human resources in development, manufacturing and quality assurance periodically evaluated for the work to be done by the company?	306				
Does the company provide an adequate training programme for the personnel? Is the staff sufficiently trained (qualification and competence preservation, knowledge of rules and standards, guidelines and state of the art)? (Ask for documentation of staff qualification)	311 - 315				
Are tools and machines properly controlled, maintained and calibrated?	306				
Production and Manufacturing of Packagings					
Are the responsibilities for different production steps clearly stated?	306				
Are specifications (drawings, material) up to date and available to relevant personnel?	306				
Do all drawings used conform to those specified in the relevant certificate of approval of the competent authority or other compliance document?	306, 838				
Is there a valid and internally approved fabrication and test sequence plan?	306				
Are the realized test steps documented in the fabrication and test sequence plan?	306				
Has the manufacture been undertaken in accordance with the approved design specifications?	501				
Are the components of the packaging classified accordingly?	306				
Is the production of classified components documented accordingly? (How is the production of classified components witnessed and documented?)	306				
Is the qualification of subcontractors monitored during procurement? Are there supporting documents?	306				

Only for competent authority approved packages: Are the fabrication and test plan organized with hold-points, quality checks, and are they sufficiently documented? Only for non-competent authority approved packages: Is the organization of accompanying checks during manufacturing sufficient?	306, 801				
Are there compliance checks regarding specifications of the materials needed for production? (Ask for a list of material suppliers)	306				
Are there certificates for materials in accordance with classified packaging components?	306				
Are the used materials traceable?	306				
Are the materials adequately stored and tested to ensure conformance with specifications?	306				
Are measuring and monitoring devices controlled?	306				
Is the measuring and test equipment calibrated?	306				
Are measures established in order to handle deviations and/or changes?	306				
Only for competent authority approved packages: Has the manufacturer a procedure to inform the competent authority about deviations and changes having impact on safety?	306				
Inspection before Commissioning					
Do all manufactured packagings undergo the required acceptance inspections to ensure compliance with the design specifications?	501				
Is the package marked permanently?	531 – 536A				
Is the date of the next periodic inspection clearly visible?					
Are the results of inspections documented?	306				
Is there a control of completeness of documentation?	306				
Operation and Maintenance of Packagings (if applicable)					
How are the documents for operation of packages (instructions for use and maintenance) forwarded to the operator?					
Is it ensured that the operator obtains instructions for use and maintenance of the packaging?	501 – 503				

Management of changes and Improvement					
Are there procedures for ensuring feedback on operational experience of delivered packagings?	306				
Are changes in regulations and standards tracked? Are existing documents updated accordingly?	306				
Are changes in the design tracked? Are existing documents updated accordingly?	306				
Are deviation reports systematically evaluated and appropriate corrective and preventive measures implemented?	306				

ANNEX IX: EXAMPLE OF A CHECKLIST FOR INSPECTING MAINTENANCE OPERATIONS

Inspection details:

Inspector(s) name(s):

Inspection reference file(s):

Date/time:

Location:

Company details and organization:

Company name:

Address:

Telephone:

Fax:

E-mail:

Web:

Name of the persons met:

Name	Designation / Function / Company	Telephone	E-mail

List of packages:

Model	Manufacturer of packaging	Model Type	Serial numbers

Subject/Inspection aspect	Paras in SSR-6 (Rev. 1), 2018 Edition	Compliance			Comments
		YES	NO	Not Applicable	
Management System (Use Annexes IV and V)					
Instructions for maintenance operations					
Are there instructions, procedures, plans or drawings for maintenance operations for each type of package?	306				
Are there procedures available related to periodic maintenance referenced in the certificate of approval or in the compliance documentation for each type of package?	306, 801, 838				
Are specified maintenance operations performed in due time and in accordance with the certificate of approval or compliance documentation for each type of package?	306, 801, 838				
Are records kept of maintenance operations?	306				
Are these records or logbooks correctly completed, verified or certified by authorized personnel?	306				
Regulations					
Are the organization and personnel involved in the transport of radioactive material aware of the regulatory requirements?	312				
Resource					
Are the defined roles and responsibilities adequately resourced?	306				
Do the tools and equipment (in good conditions and calibrated) comply with the relevant regulations?	306				
Training					
Does the company provide an adequate training programme for the personnel?	313				
Does the company maintain records of the training and qualifications of the personnel?	314				
Documentation, control of documents and records					
Is all requisite documentation completed and recorded by designated personnel?	306				
Are the necessary documents kept as records?	306				
Maintenance operations: controls, tests and inspections					

Does the company or facility have necessary permits/licences for use or maintenance operations of packages and/or packaging?	National regulations				
Have the maintenance operations been undertaken in accordance with the packages and/or packaging's specifications?	306, 801, 838				
Is evidence available to show that specified controls, tests and inspections have been performed?	306				
For the case of repairing, are there specific procedures or instructions to evaluate if the repairing may affect the requirements defined for the package design in the certificate of approval and/or the package design safety report?	306, 838				
Radiation Protection Programme					
Is there an adequate radiation protection programme (doses evaluation, optimization, radiological surveillance, radiation protection procedures)?	302				
Is the radiation protection programme periodically reviewed?	302, 306				

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