

IAEA Safety Standards

For protecting people and the environment

Compliance Assurance for the Safe Transport of Radioactive Material (DS515)

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Contents

1. INTRODUCTION.....	1
BACKGROUND.....	1
OBJECTIVE.....	1
SCOPE	2
STRUCTURE.....	2
2. RESPONSIBILITIES AND FUNCTIONS	2
REGULATORY BASIS.....	2
ESTABLISHMENT OF A FRAMEWORK FOR SAFETY	2
LIST OF NATIONAL COMPETENT AUTHORITIES	4
INTERLINKED RESPONSIBILITIES	4
ORGANIZATION AND MANAGEMENT OF THE COMPETENT AUTHORITY	4
RESOURCES AVAILABLE TO THE COMPETENT AUTHORITY	5
LIAISON BY THE COMPETENT AUTHORITY WITH OTHER GOVERNMENT AGENCIES ..	6
INTERFACES OF SAFETY WITH NUCLEAR SECURITY	7
3. REGULATIONS AND GUIDES.....	7
GENERAL	7
INTERNATIONAL REGULATIONS AND GUIDES	8
NATIONAL REGULATIONS AND GUIDES	8
4. COMPLIANCE ASSURANCE	9
GENERAL	9
DEVELOPMENT AND IMPLEMENTATION OF A COMPLIANCE ASSURANCE PROGRAMME	10
ISSUING OF APPROVALS BY THE COMPETENT AUTHORITY	12
SPECIAL FORM RADIOACTIVE MATERIAL AND LOW DISPERSIBLE RADIOACTIVE MATERIAL	14
PACKAGES REQUIRING COMPETENT AUTHORITY APPROVAL.....	14
DESIGN ASSESSMENTS.....	15
PACKAGES NOT REQUIRING APPROVAL BY THE COMPETENT AUTHORITY	17
IDENTIFICATION OF PACKAGES AND SERIAL NUMBERS OF PACKAGINGS	18
APPROVAL OF SHIPMENTS UNDER SPECIAL ARRANGEMENT	18
THE MANAGEMENT SYSTEM OF USERS OF THE TRANSPORT REGULATIONS IN SUPPORT OF COMPLIANCE ASSURANCE.....	19
TESTING OF PACKAGES AND MATERIALS.....	20
INSPECTION OF MANUFACTURING	21
MAINTENANCE AND SERVICING ARRANGEMENTS	21
INSPECTION OF TRANSPORT OPERATIONS	22

INSPECTION OF CONSIGNORS	23
INSPECTION OF CARRIERS	25
INSPECTION OF CONSIGNEES.....	26
ENFORCEMENT ACTIONS AND INVESTIGATIONS OF INCIDENTS	26
RADIATION PROTECTION.....	27
CONTENTS OF PACKAGES WITH OTHER DANGEROUS PROPERTIES	27
EMERGENCY PREPAREDNESS AND RESPONSE	28
TRAINING AND DISTRIBUTION OF INFORMATION	28
MAINTENANCE OF REGULATIONS AND FEEDBACK TO THE COMPETENT AUTHORITY	28
5. MULTILATERAL APPROVALS.....	29
6. INTERNATIONAL COOPERATION BETWEEN COMPETENT AUTHORITIES CONCERNING PACKAGES AND SHIPMENTS OF FOREIGN ORIGIN.....	30
INTERNATIONAL COOPERATION RELATING TO COMPLIANCE ASSURANCE.....	30
PACKAGES AND SHIPMENTS OF FOREIGN ORIGIN THAT ARE SUBJECT TO MULTILATERAL APPROVAL	30
PACKAGES AND SHIPMENTS OF FOREIGN ORIGIN THAT DO NOT REQUIRE NOTIFICATION OF THE COMPETENT AUTHORITY	30
REFERENCES.....	32
NOTE ON THE ANNEXES	1
Annex I. INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVALS.....	2
Annex II. EXAMPLES OF TEMPLATES FOR CERTIFICATES OF APPROVAL.....	13
Annex III. INSPECTIONS OF MANAGEMENT SYSTEMS AND RELATED INSPECTION ACTIVITIES PERFORMED BY THE COMPETENT AUTHORITY	20
Annex IV. EXAMPLE OF A PROCEDURE AND CHECKLIST FOR INSPECTING A MANAGEMENT SYSTEM	22
ANNEX V. EXAMPLE OF A CHECKLIST FOR INSPECTING CONSIGNORS	36
Annex VI. EXAMPLE OF A CHECKLIST FOR INSPECTING CARRIERS.....	44
Annex VII. EXAMPLE OF A CHECKLIST FOR INSPECTING THE MANUFACTURING OF PACKAGINGS	49
Annex VIII. EXAMPLE OF A CHECKLIST FOR INSPECTING MAINTENANCE AND SERVICE OPERATIONS	53
CONTRIBUTORS TO DRAFTING AND REVIEW.....	56

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 (the Transport Regulations) [1].

1.2 Compliance assurance is defined in the Transport Regulations [1] 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, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 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 provisions of the Transport Regulations are complied with in practice.”

Therefore, essentially all activities of the competent authority¹ are deemed part of its programme to ensure compliance with the Transport Regulations [1] and are discussed in this Safety Guide. The recommendations provided in this Safety Guide supplement the general recommendations in 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 of the transport regulations are an important component of compliance assurance, and inspections² by the competent authority of these management systems is an effective means of monitoring the compliance of the user with the Transport Regulations [1].

1.5 This Safety Guide updates the guidance given in the Safety Guide on compliance assurance for the safe transport of radioactive material³, 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

¹ In this Safety Guide, the term “competent authority” may refer to one or more competent authorities or entities within a State that have been delegated specific roles and responsibilities by a competent authority.

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

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).

Guide is intended to assist in ensuring a uniform application of the Transport Regulations [1] 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 [1]. The recommendations provided will also be useful to competent authorities with established compliance assurance programmes. Additionally, the Safety Guide will assist users⁴ of the Transport Regulations [1] in their interactions with competent authorities.

SCOPE

1.8. This Safety Guide addresses compliance assurance for the transport of radioactive material, based on the same scope as described in paras 106–110 of Transport Regulations [1].

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 carrying out compliance assurance, and 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. Paragraph 307 of the Transport Regulations [1] states that “The competent authority shall assure compliance with these Regulations.” 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 safe transport of radioactive material) (Requirement 5 of IAEA Safety Standards Series GSR Part 1 (Rev. 1) [6]).

2.2. The prime responsibility for ensuring safety in transport rests with consignors and carriers, who are required to take account of all relevant regulations. Competent authorities are responsible for assuring compliance with the Transport Regulations [1] (which includes the oversight and enforcement of all regulations). In addition, certain activities of the competent authority are directly related to specific requirements of the Transport Regulations [1], 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. SSG-44 [7] provides guidance on the general approach to be followed. In an effective programme for compliance assurance, all users of the Transport Regulations [1] should be considered: consignors, carriers, consignees, suppliers and/or manufacturers of packagings, and regulatory bodies (which may share responsibilities with the competent authority).

ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

⁴ In this Safety Guide, a “user” is a person who or an organization that designs, tests, assesses, manufactures, services, maintains, consigns, carries or otherwise uses a package in connection with the transport of radioactive material.

2.4. 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.”

GSR Part 1 (Rev. 1) [4] establishes requirements for the roles and responsibilities of regulatory bodies, which includes competent authorities. Among the activities and authorizations referred to in GSR Part 1 (Rev. 1) [4] are the transport of radioactive materials and the issuance of approvals.

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 [of GSR Part 1 (Rev.1)];
- (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;
- (16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;

- (17) The criteria for release from regulatory control;
- (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 (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 is maintained by the IAEA National Competent Authorities for the Safe Transport of Radioactive Material (Competent Authorities responsible for approvals and authorizations related to the transport of radioactive material) [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. More than one competent authority may be responsible for the regulatory control of the transport of radioactive material in a State, depending on:

- (a) The existing regulations;
- (b) The mode of transport (e.g. for the design of packages that are subject to restrictions on the mode of transport);
- (c) The type of radioactive material (e.g. fissile or non-fissile material).

2.10. Recommendations regarding 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. IAEA Safety Standard No. 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 regulatory body to support regulatory bodies in carrying out their responsibilities and functions efficiently and effectively and in an independent manner. In the context of the transport of radioactive material, a “regulatory body” is to be understood as a “competent authority”.

2.12. IAEA Safety Standard No. IAEA GSG-12 [3]:

- a) sets out the general characteristics of a regulatory body with responsibility for safety;
- b) provides specific recommendations on management for safety focused on leadership for safety and safety culture aspects;
- c) describes the organizational aspects required for the implementation of the core regulatory functions of a regulatory body, including:
 - i. development and/or provision of regulations and guides (see also section 3 of this Safety Guide),
 - ii. notification and authorization or approval,
 - iii. regulatory review and assessment;

- iv. regulatory inspection,
 - v. enforcement,
 - vi. emergency preparedness and response,
 - vii. communication and consultation with interested parties
- b) describes the organizational aspects required for the implementation of supporting regulatory functions of a regulatory body, including:
- 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;
- d) outlines the characteristics of an integrated management system necessary for an effective and efficient regulatory body;
- e) provides recommendations on the necessary staffing and competences that should be in place in order for the regulatory body to effectively perform its functions and to discharge its responsibilities.

2.13. It also provides more detailed guidance on the use of external expert support, generic processes of the integrated management system, the basic elements of a regulatory body training programme, and the structure of information in the integrated management system.

2.14. IAEA Safety Standard No. GSG-12 [3] should be read in conjunction with GSG-13 [4] that covers the technical aspects of the core functions of the regulatory body and the processes by which they are discharged. The core functions of the regulatory body 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 carrying out 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.

RESOURCES AVAILABLE TO THE COMPETENT AUTHORITY

2.15. The competent authority is required to be provided by the government with adequate resources for carrying out its duties according to Requirement 3 of GSR Part 1 (Rev. 1) [6].

2.16. To carry out these activities, the competent authority will need to have access to expertise in many different fields, which could include:

- Criticality safety;
- Radiation safety, including shielding analysis;
- Thermal analysis;
- Materials science and mechanical/structural engineering;
- Management system;
- Emergency preparedness and response;
- Transport operations;
- Inspection and enforcement.

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

2.18. Should all expertise not be available within the competent authority, external expert support may be needed. IAEA Safety Standard No. GSG-12 [3] provides recommendations on:

- the development and management of the competences of the competent authority staff, including training, and
- managing external expert support.

LIAISON BY THE COMPETENT AUTHORITY WITH OTHER GOVERNMENT AGENCIES

2.19. 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) Law enforcement agencies;
- (f) Customs agencies;
- (g) Post offices;
- (h) National research institutes and institutes for materials testing;
- (i) Institutions that provide training and education.

2.20. The competent authority should arrange regular meetings for the parties within this complex network of agencies and persons in order to facilitate 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 [1];
- (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 [1] and compliance assurance.

2.21. The appropriate competent authority should put in place formal agreements with agencies responsible for national regulations that may have an interface with the Transport Regulations [1]. Examples of such agencies are as follows:

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

2.22. In the case of agencies responsible for security of nuclear and other radioactive material, accounting for and control of nuclear material, 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 relating to nuclear material and other radioactive material. In such cases, some applications in connection with the transfer of such material are required to be checked by the competent authority prior to shipment, to confirm that all proposed shipments and packages are in compliance with the Transport Regulations [1]. Such checks are often required by national regulations irrespective of whether the proposed shipment or package requires approval in

accordance with the Transport Regulations [1]. In such cases the liaison between the supervising authorities should be extremely close.

2.23. In addition to the meetings described in 2.20, 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. Provisions for the protection of confidential information related to the transport of nuclear material and radioactive material should be established.

2.24. 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 dangerous goods in general or the response to emergencies involving radiation and nuclear facilities, or both. Further recommendations on planning and preparing for response to an emergency involving radioactive material in transport are provided in TS-G-1.2 [9].

INTERFACES OF SAFETY WITH NUCLEAR SECURITY

2.25. 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.”

2.26. 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.”

2.27. The competent authority for transport safety should liaise very closely with the regulatory body responsible for transport security to meet Requirement 12 of GSR Part 1 (Rev. 1) [6].

2.28. Information about international agreements and guidance on nuclear security can be found in the following:

- The Convention on the Physical Protection of Nuclear Material and the Amendment thereto [10] provides for the protection of nuclear material in transport against sabotage and theft. The convention concerns specifically the international transport of nuclear material and is in conformity with the provisions of Ref. [11].
- Security provisions for the transport of radioactive material are provided in the United Nations model regulations [12], and in modal regulations [13, 14]. Guidance for the security for transport of radioactive material is provided in the IAEA Nuclear Security Series Nos 9, Security in the Transport of Radioactive Material [15], and 26-G, Security of Nuclear Material in Transport [16].

3. REGULATIONS AND GUIDES

GENERAL

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.”

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 [1], apply to such transport.

INTERNATIONAL REGULATIONS AND GUIDES

3.3. International bodies have issued many general and modal regulations and recommendations on the safe transport of dangerous goods. With regard to the transport of radioactive, these regulations and recommendations are based on the Transport Regulations [1]. International regulations and recommendations have been issued by the United Nations [12], the International Civil Aviation Organization [13], the International Maritime Organization [14] and the Universal Postal Union [17]. These regulations and recommendations are updated periodically.

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

- (a) The European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) [18];
- (b) The Convention Concerning International Carriage by Rail (COTIF) [19];
- (c) The European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) [20];
- (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 [21];
- (e) The Agreement on International Goods Traffic by Rail (SMGS) [22].

The foregoing agreements and conventions take due account of the Transport Regulations [1].

3.5. In the interests of international harmonization and safety, individual States should follow and fully implement the provisions of the Transport Regulations [1]. However, due to specific national circumstances, a State may need to deviate from, or add to, the provisions of the Transport Regulations [1] 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 [13]).

NATIONAL REGULATIONS AND GUIDES

3.6. In accordance with Requirements 32 to 34 of GSR Part 1 (Rev. 1) [6], one of the duties of a regulatory body is 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. IAEA Safety Standards No GSG-13 [4] acknowledges that the development and/or provision of regulations and guides is a core function of a regulatory body (i.e. a competent authority according to IAEA Safety Standard SSR-6 [1]) and provides recommendations on this function. After describing the objectives of regulations and guides and their differences, GSG-13:

- elaborates on key principles to be followed for their initial development then review and revision as necessary, including the involvement of interested parties, the consideration of international or national standards and operating experience, and developments in transport practices;
- identifies topics that should be addressed in regulations and/or guides, for example the authorization process, documentation to be submitted to the regulatory body, and enforcement policy;

- addresses promotion of regulations and guides to interested parties.

3.8. In the preparation of national regulations and guides for the transport of radioactive material, all relevant international agreements, regulations and recommendations should be taken into account. The language used in the preparation of such documents should be appropriate to ensure correct and unambiguous understanding by the users of the regulations. If international regulations and/or modal conventions are adopted or used as national regulations, they should be translated into the official national language(s), and the accuracy of the translations should be verified. See para. 4.93 for information on maintenance of national regulations.

4. COMPLIANCE ASSURANCE

GENERAL

4.1. The competent authority should put in place 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 [1].

4.2. Compliance with the Transport Regulations [1] can be assured by the competent authority in various ways and may include the following activities:

- (a) Issuing of approvals by the competent authority;
- (b) Assessment of designs;
- (c) Inspections of the management systems of users of the Transport Regulations [1];
- (d) Inspection of testing, which should include the direct observation of specific tests;
- (e) Inspection of manufacturing, which should include the direct observation of specific steps in the manufacturing process;
- (f) Inspection of maintenance and servicing arrangements, which should include direct observation of maintenance and servicing activities;
- (g) Inspection of transport operations, which should include direct observation of transport activities;
- (h) Emergency preparedness and response;
- (i) Training and distribution of information;
- (j) Enforcement actions and investigations of incidents;
- (k) Liaison and cooperation by the competent authority with other government agencies;
- (l) Regular review of the national legal framework including national and international regulations.

A graphic representation of the above activities is provided in Fig. 1.

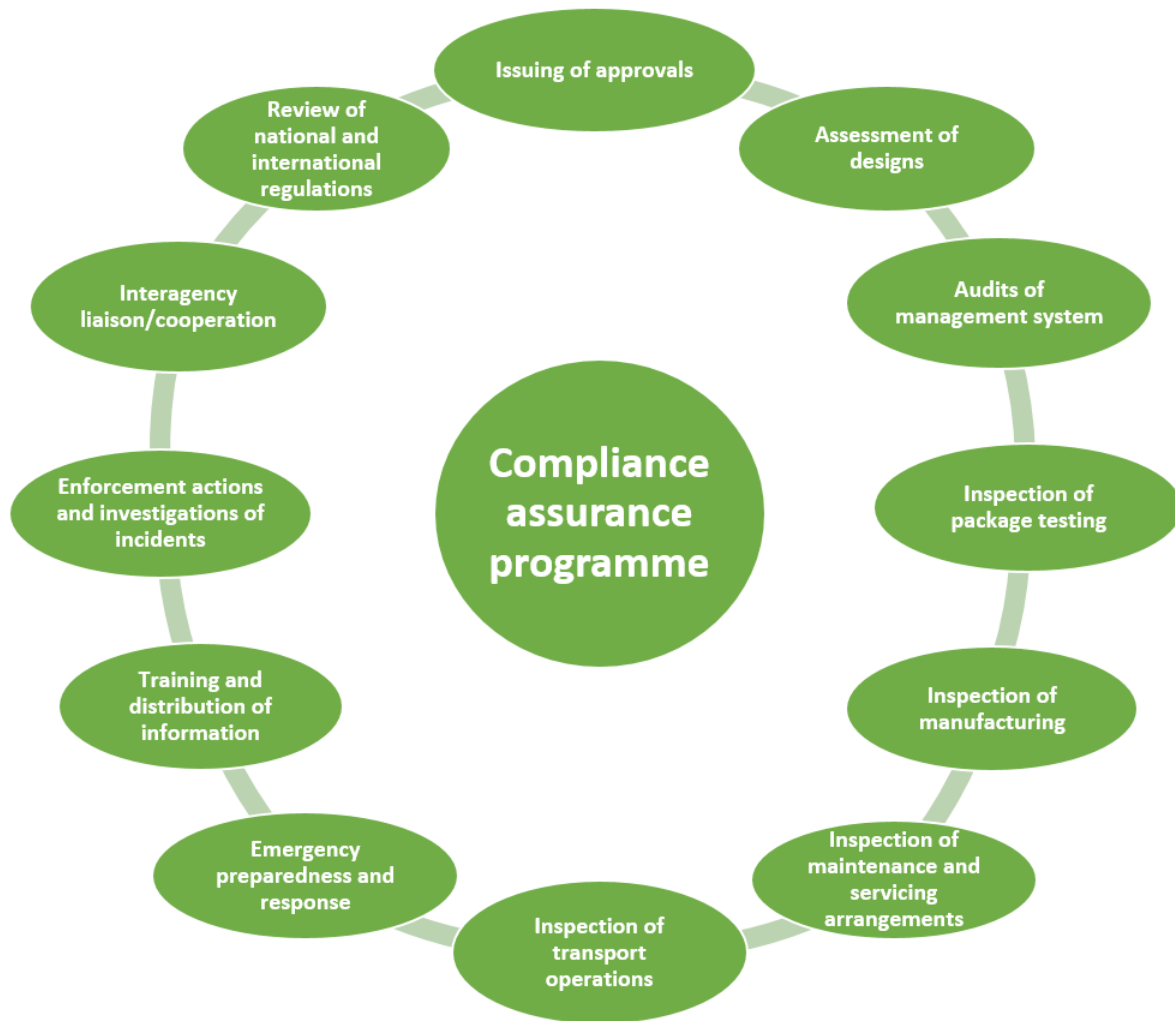


FIG. 1. Compliance Assurance circle.

4.3. These activities are not meant to be implemented in any particular order, and the extent of a national compliance assurance programme may not necessarily cover all of these activities. It depends on the quantities and types of packages 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 three activities:

- (a) Activities relating to review and assessment, including the issuing of approval certificates;
- (b) Activities relating to inspection and enforcement;
- (c) Activities relating to emergency 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 departments or organizations having a legitimate interest in or an interface with aspects of the transport of radioactive material;
- (4) Provision of a sound legal framework to enable the effective functioning of the competent authority;
- (5) Formal confirmation of the working relationships between other governmental bodies and other organizations in respect of the transport of radioactive material;
- (6) Gathering of further detailed information on the size of the industry for the transport of radioactive material, including information on package types and numbers of movements;
- (7) Formal specification of the size, structure and resources of the competent authority, and development of a management system for the competent authority;
- (8) Initial training of personnel of the competent authority and other personnel involved in the enforcement of regulations;
- (9) Creation or adoption of national regulations for the transport of radioactive material (with provision for all package types, transport operations and modes of transport);
- (10) Development 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 [1] by means of the applicable activities shown in Fig. 1;
- (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) Service, maintenance, and removal from service of a packaging.

4.7. A more complex compliance assurance programme will be needed for a State that performs a high number of shipments, including many types and large quantities of radioactive material, and which designs and manufactures packagings. For such a programme, account should additionally be taken of package design, testing, manufacture, and approval.

4.8. The three activities stated in para. 4.4 should be addressed in a manner that is graded according to the complexity and variety of the particular responsibilities of the competent authority. Guidance on applying a graded approach to the functions and processes of a competent authority is 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 [1]. The compliance assurance programme should be updated in a timely fashion when there are changes to the Transport Regulations [1], 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 [1] distinguish between cases in which radioactive material can be transported without approval by the competent authority and cases in which some kind of approval is required. In all cases, the Transport Regulations [1] place the primary responsibility for compliance on the consignor. The following require competent authority approval (see para. 802 of the Transport Regulations [1]), 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) Excepted fissile material;
 - (iv) Packages containing 0.1 kg or more of uranium hexafluoride;
 - (v) Packages containing fissile material;
 - (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 [1];
- (f) Calculation of alternative activity limits for an exempt consignment of instruments or articles.

As described in Section VIII of the Transport Regulations [1], some of the items listed above may be subject to the approval of several competent authorities.

4.11. In accordance with paras 803, 807(b) and 808 of the Transport Regulations [1], unilateral approval by the competent authority 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 [1] (in this case, unilateral approval by the competent authority of the country of origin of the design is required);
- (c) Type B(U) and Type C package designs, except package designs for fissile material.

4.12. In accordance with paras 803, 805, 807(a), 808(a), 808(b), 811, 814, 817, 820(a), 820(b), 825 and 829 of the Transport Regulations [1], multilateral approval by the competent authority is required for the following:

- (a) The design of low dispersible radioactive material;
- (b) The design of material excepted from fissile classification;
- (c) The design of packages containing 0.1 kg or more of uranium hexafluoride that meet the requirements of para. 634 of the Transport Regulations;
- (d) The design of packages for fissile material;
- (e) The design of Type B(U) packages for low dispersible radioactive material;
- (f) The design of Type B(M) packages;
- (g) Alternative activity limits for an exempt consignment of instruments or articles;
- (h) Package designs approved by the competent authority under the provisions of the 1985 Edition and the 1985 Edition (As Amended 1990) of the Transport Regulations;
- (i) 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 these Regulations;
- (j) The shipment of Type B(M) packages not conforming with the requirements of para. 639 of the Transport Regulations [1] or designed to allow controlled intermittent venting;

- (k) The shipment of Type B(M) packages containing radioactive material with an activity greater than 3000A₁ or 3000A₂ as appropriate, or 1000 TBq, whichever is lower;
- (l) 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;
- (m) Radiation protection programmes for shipments by special use vessels according to para. 576(a) of the Transport Regulations [1];
- (n) The shipment of SCO-III (Surface Contaminated Object-III);
- (o) Consignments transported under special arrangement.

Further guidance on multilateral approvals is provided in Section 5 of this Safety Guide.

4.13. It is the responsibility of the applicant or licensee to demonstrate compliance with the Transport Regulations [1], and it is the responsibility of the competent authority to review and assess compliance. Applicants and licensees 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 or licensees 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.

4.14. Many applicants make their first submission to the competent authority for a specific need, which can be rather narrow in scope, and later make several requests for amendments to the approval certificate, trying to expand its scope in order to be able to use the packaging for other types of material and/or shipment. Whenever possible, applicants should be encouraged to first submit an application for a comprehensive approval certificate that anticipates and covers their future needs.

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 [1]. Depending on the type of approval, the corresponding application should contain at least the information described in Section VIII of the Transport Regulations [1] (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 or not all relevant regulatory requirements are fulfilled. Information regarding the structure and contents of a package design safety report, which should be submitted to the competent authority with applications for approval of package designs is provided in Ref. [23]. A list of items that should be included in an application is provided in Annex I of this Safety Guide. GSG-13 [4] provides recommendations on the review and assessment process including the associated documentation [paras 3.147 – 3.209]. 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 required information (see Section VIII of the Transport Regulations [1] 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 the supplementary operational controls during transport is at least equivalent to that which would be achieved if all applicable regulatory requirements were met. Possible additional operational controls that might be employed are discussed in para. 830.1 of SSG-26 [2].

4.18. Whenever possible, standard formats should be utilized for each type of certificate. Minimum requirements for the contents of approval certificates are specified in paras 834—839 of the Transport Regulations [1]. Examples of templates for approval certificates 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 [1], in order to facilitate compliance with any specific requirements or conditions. Depending on national practice, information on approval certificates for designs used for transport may be provided on the applicable competent authority website.

SPECIAL FORM RADIOACTIVE MATERIAL AND LOW DISPERSIBLE RADIOACTIVE MATERIAL

4.20. 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.

4.21. 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.

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

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

4.24. When the competent authority has verified through its own design assessment (see paras 4.34 – 4.39), 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. Examples of templates for approval certificates are provided in Annex II.

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

PACKAGES REQUIRING COMPETENT AUTHORITY APPROVAL

4.26. 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 possible content of this preliminary information is described in Ref. [23] and Annex I. 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 and testing.

4.27. 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 [1] 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.

4.28. 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.

4.29. Before the commencement of tests by the applicant, the competent authority should consider verifying the test 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.

4.30. In conjunction with the guidance described in Annex I, the application for approval should include the test programme, the results of testing and the evaluation report [see also paras 4.35-4.54]. 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, and should be verified by analyses (for routine, normal and accident conditions of transport):

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

In accordance with the Transport Regulations [1], compliance with the specific test requirements may also be demonstrated by means of analyses if suitable criteria or established comparative data are available.

4.31. 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 4.34 – 4.39). In making such assessments, the competent authority should ensure that proper computer codes and models have been used, that they have been validated and that all input data have been correctly and, if appropriate, conservatively defined.

4.32. 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, as well as for the proper notification to the competent authority of the serial numbers of packages. This is particularly important in cases where multiple or interchangeable packaging components are used.

4.33. 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 approval certificates are provided in Annex II.

DESIGN ASSESSMENTS

4.34. Design is defined in para. 220 of the Transport Regulations [1] as follows:

“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’ should be considered to include much more than the drawings and specifications that enable the packaging to be manufactured. The design to be assessed includes the supporting reports and documents that substantiate or verify statements or assumptions made by the designer. It also

includes instructions for package preparation, instructions for maintenance and servicing, and procedures for repair or modification.

4.35. Section VI of the Transport Regulations [1] 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 [1], 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 [1].

4.36. 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 [1]. Therefore, the competent authority should not only conduct assessments of designs specified in para. 802(a) of the Transport Regulations [1], but should also ensure that similar assessments of package designs that do not require approval by the competent authority (such as Type A packages or industrial packages) are 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 [2] and Annex I of this Safety Guide for guidance on documentary evidence for packages that do not require competent authority approval).

4.37. 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.

4.38. 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 [1] 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.
- (c) 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 finished package will provide sufficient radiological shielding in all directions to comply with the Transport Regulations [1] and the principle of optimization of protection. The assessor should confirm that computer codes or other methods of calculation used by the applicant are appropriate, valid and quality assured. The assessor should 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. 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.
- (d) The assessor should thoroughly examine the thermal aspects of the package design; the assessor should consider both dissipation and absorption of heat in normal and accident conditions of transport. Thermal stresses should be analysed to ensure that leak tightness or mechanical properties of the package are not unduly compromised in normal conditions of transport or in thermal test conditions. Any computer codes or other methods of calculation used by the applicant

should be verified by the assessor and should be confirmed to be appropriate, valid and quality assured.

- (e) 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 normal transport operations, by the prescribed servicing and maintenance periods and instructions, and by the effects of accident conditions of transport and related testing.
- (f) The assessor should thoroughly examine the design to ensure that all factors affecting radiation safety in respect of the design have been identified and addressed.
- (g) The assessor should examine all relevant physical and mechanical aspects of the design in order to confirm that the package will be physically able to safely carry the specified radioactive material under both normal and accident conditions of transport (this includes, 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 [1].
- (h) 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.
- (i) The assessor should examine the in-service handling and use, inspection, maintenance and servicing 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 consignees that are unfamiliar with the package and its design principles.)
- (j) When scale modelling is used in testing to support an application for approval, the assessor should confirm that all scaling factors have been taken into account, with all pertinent features of the package design being accurately represented.
- (k) The assessor should verify that ageing mechanisms have been taken into account.

4.39. Where a number of very similar package designs exist, the assessor may make comparisons relating to the final acceptability of the designs; however, this should be done only after the detailed differences between the package designs have been identified by the applicant and confirmed by the competent authority as being of minor significance.

PACKAGES NOT REQUIRING APPROVAL BY THE COMPETENT AUTHORITY

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

4.41. The competent authority should verify that the user complies with the requirements in paras 306 and 801 of the Transport Regulations [1] 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. 4.36);
- (c) Control of manufacturing;
- (d) The programme for maintenance of packagings (in the case of reusable packagings).

IDENTIFICATION OF PACKAGES AND SERIAL NUMBERS OF PACKAGINGS

4.42. 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 [1] 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 [2] provides recommendations on the legibility, durability and positioning of such markings. In its activities relating to compliance assurance, the competent authority should verify that:

- all required markings, serial numbers and identification marks are correctly, durably and appropriately applied to packages, and
- 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.

4.43. The serial number on the packaging is required to uniquely identify each packaging manufactured. For packagings manufactured to an approved Type B(U), Type B(M) or Type C package design, and for packagings designed to contain fissile material, it is required that the appropriate competent authority be informed of the serial number (para. 824 of the Transport Regulations [1]). 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 [1], all competent authorities involved in the multilateral approval process should be provided with and should retain information on the serial numbers of the packagings.

4.44. 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 [1], 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

4.45. The Transport Regulations [1] include provisions for a consignment that does not satisfy all the applicable requirements to be transported under special arrangement (para. 310 of the Transport Regulations) and describes the contents of the application for approval in para. 830 of the Transport Regulations [1]. For international shipments under special arrangement, multilateral approval is required (Para. 310 of the Transport Regulations [1]). Recommendations on multilateral approval are provided in Section 5.

4.46. For a shipment under special arrangement, the competent authority needs to 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 [1] had been met (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.

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

4.47. To meet the requirements of para. 306 of the Transport Regulations [1] and Requirements 3–8 of GSR Part 2 [5], an integrated management system is required for all transport related activities. Before issuing approvals, the competent authority is required to consider the adequacy of the applicable management system. The extent of the management system will depend on the type of transport activities being considered (design, testing, manufacture, use, servicing and 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 TS-G-1.4 [24] provides information on how to address the various elements of the management system.

4.48. 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. 4.52). If the competent authority has confirmed the existence of a satisfactory management system, it may issue an approval certificate for the management system, if required by national regulations.

4.49. 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 [24] 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 Annex IV.

4.50. 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 package may be different from that for the continuous manufacture of packages.

4.51. 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 [24], 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 required 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 documents of the management system;
- (d) Undertaking activities to ensure compliance with the Transport Regulations [1] and any additional national requirements.

4.52. 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 approval certificate (Section VIII of the Transport Regulations [1])). 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 (Para. 503 of the Transport Regulations [1]). 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 servicing, 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.

TESTING OF PACKAGES AND MATERIALS

4.53. 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 [1]. 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 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, the test sequences, and the measurement techniques and methods of analysis 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 [1] 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 [1], 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 [1] 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.

4.54. When carrying out 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.

INSPECTION OF MANUFACTURING

4.55. 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. An example checklist for inspections of the manufacturing of packagings is provided in Annex VII.

4.56. 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.

4.57. 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 [1] and in accordance with the design specification.

4.58. Reports of deviations from specifications and 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.

4.59. 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 designer, for information and for possible action.

4.60. During inspections of manufacturers, compliance with the requirements of para. 501 of the Transport Regulations [1] 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 Transport Regulations [1].

MAINTENANCE AND SERVICING ARRANGEMENTS

4.61. The competent authority should check that the user verifies, before each use of a packaging, that the requirements of para. 503 of the Transport Regulations [1] have been met. The competent authority should also check that maintenance and servicing 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 (para. 306 of the Transport Regulations [1]). In particular, any proposed modifications to a packaging during maintenance and servicing operations should be implemented only when the necessary modification specifications are available to the person or organization carrying out the modification. Any departure from these specifications may render the packaging unusable and may compromise the original design intent. An example checklist for inspections of maintenance and servicing operations is provided in Annex VIII.

4.62. The competent authority should verify that it is indicated on the packagings when the last maintenance or servicing operation was performed or, preferably, when the next maintenance or servicing operation is due. This, in conjunction with appropriate records of all such maintenance and servicing operations, can help to demonstrate that the package fully complies with the requirements specified in the certificate of approval and the relevant requirements of the Transport Regulations [1].

4.63. The competent authority should verify that during the lifetime of the packaging, the user maintains sufficient records to demonstrate that the requirements of para. 503 of the Transport Regulations [1] have been met. 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 ageing management for packages intended to be used for shipment after storage (para. 503(e) of the Transport Regulations [1]) and the appropriate use of records and logbooks (as described in TS-G-1.4 [24]) if servicing and maintenance operations are performed at different locations.

4.64. For packages that are required to be approved by the competent authority, the user should record all safety related deviations from (and modifications to) the design specifications, as well as any significant damage noted during the use of the packages. The competent authority should be informed of any such deviations or modifications within a certain time period (e.g. 30 days) before the packages are returned to service, in accordance with the requirements of the competent authority. Corrective measures or modification proposals, including any plans for repairs, may 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 TRANSPORT OPERATIONS

4.65. 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. 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.

4.66. 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 carry out inspections. Users involved in all types and aspects of transport should be periodically inspected, in accordance with a graded approach.

4.67. 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 carry out an effective programme for compliance with the Transport Regulations [1]. 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 carrying out the programme for compliance with the Transport Regulations [1], and this training should be documented.
- (c) The consignor should use the proper packaging for the contents of packages.
- (d) The user should have all the documentation required by the Transport Regulations [1], including the relevant approval certificates of the competent authority and any associated instructions for handling, loading, stowage and use of packages, and for the maintenance of packagings. These instructions are usually in the form of an instruction manual.
- (e) The user should follow established procedures for the preparation and use of the packages, in accordance with the approval certificate, the instruction manual and related documents.
- (f) Procedures should be established and followed to properly mark and label packages in accordance with the Transport Regulations [1]. 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. 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 [1].

4.68. When preparing for inspections of transport operations, the competent authority should consider the requirements that apply to industrial packages in the Transport Regulations [1] that incorporate the provisions of international conventions and standards (see Refs [13, 14, 17]).

4.69. The requirements for notification of the competent authority regarding certain packages and shipments are established in paras 557–560 of the Transport Regulations [1]. 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.

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

INSPECTION OF CONSIGNORS

4.71. The consignor may be the owner or manufacturer of the package, or the user or operator of a package owned by a third party. The consignor may delegate some of the actions needed to achieve this compliance but is required to retain overall responsibility for these actions and for their completion. The declaration on the transport documents signed by the consignor attests to this responsibility.

4.72. The competent authority should assure that the consignor's responsibilities, as defined in paras 545–561 of the Transport Regulations [1], are followed. An example of a checklist that could be used for inspections of consignors is provided in Annex V. 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 carry out 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; it could also involve verifying that other specified parameters are correct.
- (d) The consignor should use the appropriate packaging for which there is a valid approval certificate 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 approval certificate is required to cover the entire radioactive contents permitted to be carried; the consignor is required to have the correct certificate for the contents being transported.
- (e) The consignor should have the relevant packing instructions for the package; copies of these instructions are required to be available at the location where the package is prepared for transport. The packing instructions provide detailed information and instructions on the loading configuration of the contents, the closure methods 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 the specifications indicated on the approval certificate and the packaging is in an acceptable condition based on written procedures. For new packagings, the consignor should have evidence, such as certificates of conformity or inspection reports, that the packagings conform to the specifications quoted on the approval certificate. In the case of reusable packagings, the consignor should have evidence, in the form of inspection reports, release notes, certificates of conformity, etc., that all necessary and specified servicing and maintenance work has been 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 and specified servicing and 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 knowledge and monitoring instruments to carry out the necessary measurements and checks for radioactive contamination associated with the transport of radioactive material. For example, the consignor should be able to satisfy the competent authority that it is capable of carrying out valid, calibrated measurements of the dose rate and radioactive contamination, to ensure radiation protection and transport safety.
- (i) The consignor should have the necessary licences or other permissions, granted by the competent authority or by other 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. Multiple approvals may be necessary for transport of radioactive material where considerations of security and considerations for the accounting and control of nuclear material apply.
- (j) The consignor is required to complete the required transport documents, giving the appropriate information specified in paras 546–555 of the Transport Regulations [1]. 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 (Para. 555 of

the Transport Regulations [1]). 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 [1]. 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. 4.73).
- (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 [1]. Through its inspections of consignors and its liaison with other competent authorities, the responsible competent authority should verify that the required notifications are being made.
- (m) The consignor should present a package or consignment for transport in compliance with the Transport Regulations [1]. 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 [1].
- (o) The consignor is required to establish a radiation protection programme that meets the requirements of para. 302 of the Transport Regulations [1]. Further recommendations on radiation protection programmes are provided in paras 4.83–4.85.

INSPECTION OF CARRIERS

4.73. Although the Transport Regulations [1] do not identify specific responsibilities for carriers, they contribute to the safe transport of radioactive material. The competent authority should conduct inspections [see para. 4.66] to verify the following:

- (a) The carrier should have an appropriate management system that 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 [1] and implement a procedure 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 should have appropriate arrangements for an emergency involving 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 should follow the requirements established in paras 562–563 of the Transport Regulations [1] 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 respond in accordance with the requirements of para. 309 of the Transport Regulations [1].
- (i) The carrier should establish a radiation protection programme that meets the requirements of para. 302 of the Transport Regulations [1]. Further recommendations on radiation protection programmes are provided in paras 4.83–4.85 of this Safety Guide.

INSPECTION OF CONSIGNEES

4.74. During inspection of the transport operations of the consignee, the competent authority should consider verifying that:

- (a) A management system covering all applicable activities is established and implemented.
- (b) A radiation protection programme has been established and implemented that meets the requirements of para. 302 of the Transport Regulations [1]. Further recommendations on radiation protection programmes are provided in paras 4.83–4.85 of this Safety Guide.
- (c) Workers receive appropriate training commensurate with their duties.
- (d) Appropriate actions are taken in cases of non-compliance in accordance with the requirements of para. 309 of the Transport Regulations [1].

ENFORCEMENT ACTIONS AND INVESTIGATIONS OF INCIDENTS

4.75. The compliance assurance programme should include provisions for enforcement consistent with GSR Part 1 (Rev. 1) [6], especially para. 4.55, and GSG-13 [4].

4.76. 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.

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

“The [competent authority] 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.”

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

“Enforcement actions by the [competent authority] 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.”

4.79. 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].

4.80. 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.

4.81. Users should be required to report to the competent authority all significant incidents, including accidents or significant non-compliance with the Transport Regulations [1]. 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.

4.82. Section 2 of this Safety Guide recommends that the competent authority arrange periodic meetings of all governmental bodies involved in the transport of radioactive material. One of the aims of such meetings is to ensure the consistent application of enforcement measures relating to compliance assurance.

RADIATION PROTECTION

4.83. Paragraphs 301–303 of the Transport Regulations [1] 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 TS-G-1.3 [25], which includes items to be reviewed to evaluate the contents and effectiveness of radiation protection programmes.

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

4.85. The competent authority is required to arrange for periodic assessments to evaluate the radiation doses to workers and to members of the public due to the transport of radioactive material (para. 308 of the Transport Regulations [1]). 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.

CONTENTS OF PACKAGES WITH OTHER DANGEROUS PROPERTIES

4.86. The Transport Regulations [1] require that, 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 addressed through compliance with the relevant transport regulations for dangerous goods (see para. 507 of SSR-6 (Rev.1) [1]). 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

4.87. Requirements for emergency preparedness and response are established in GSR Part 7 [26]. Detailed recommendations on emergency preparedness and response in the transport of radioactive material are provided in TS-G-1.2 [9] (DS469).

4.88. International cooperation may be necessary when States are affected by accidents that occur during the transport of radioactive material. Certain types of transport accidents are covered by the Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency [27].

TRAINING AND DISTRIBUTION OF INFORMATION

4.89. The competent authority should, as appropriate, specify and participate in the training of persons involved in the transport of radioactive material, including its own staff. Furthermore, 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 [1]. The training programme for an individual may be adjusted based on the relevant experience and responsibilities of the person.

4.90. In some States, the holders of certain posts within the competent authority and the organizations of the consignor, the carrier and/or the consignee have to be authorized or certified before they are allowed to perform their duties. In such cases, each organization should maintain adequate records of the training provided, the performance of individual trainees and the authorizations or certificates issued. Also, records should be maintained in accordance with the management system, and these 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.

4.91. Training material applicable to personnel involved in the transport of radioactive material is provided in Ref. [28].

4.92. 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 and interpretation of the Transport Regulations [1]. 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 [1]. 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 [29].

MAINTENANCE OF REGULATIONS AND FEEDBACK TO THE COMPETENT AUTHORITY

4.93. 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 of this Safety Guide.

5. MULTILATERAL APPROVALS

5.1. Under the Transport Regulations [1], multilateral approval of a design or shipment may be effected by either of the following:

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

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

5.2. 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 certification or validation — will be issued for which type of design or shipment). The competent authority's policy may be based on criteria such as the risk associated with the use of the package on its territory.

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

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

5.5. 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 may 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 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 authorities of the States 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). For vessels, the competent authority of any State where the shipment is to be transported through or into, should take part in any chain of multilateral approvals by competent authorities.

5.8. Multilateral approvals should not be issued before the approval certificate is issued by the competent authority of the State of origin of the design or shipment. 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. Such shipments will often occur without the knowledge of the national competent authority; nevertheless, each such instance of transport should comply with regulatory requirements.

6.2. To ensure compliance with the Transport Regulations [1] 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.

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

6.3. Operations associated with foreign packages and shipments may also 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 approval certificate 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 approval certificate, will contribute to ensuring that the necessary compliance assurance is provided.

6.4. 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.

6.5. 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 in para. 833(b) of the Transport Regulations [1], is legibly and durably marked on the packaging.

6.6. 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 as are also required, in accordance with paras 557–559 of the Transport Regulations [1].

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

6.7. Transport of radioactive material that does not require competent authorities to be notified, particularly packages and shipments of foreign origin, may nevertheless be subject to inspections by the competent authority. 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.

6.8. The competent authority may receive only the notifications required under paras 557 and 558 of the Transport Regulations [1]. 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 [1]. The competent authority should check this information as part of its compliance assurance programme.

6.9. In some States, information arising from legal requirements associated with, for example, the shipment of certain radioactive 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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- [27] INTERNATIONAL ATOMIC ENERGY AGENCY, Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, Legal Series No. 14, IAEA, Vienna (1987).
- [28] INTERNATIONAL ATOMIC ENERGY AGENCY, Safe Transport of Radioactive Material, Fourth Edition, Training Course Series No. 1, IAEA, Vienna (2006).
- [29] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. GSG-6, IAEA, Vienna (2017).

NOTE ON THE ANNEXES

The annexes provide examples of guidance, templates, procedures and checklists that may be used by a competent authority in carrying out 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 according to 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 section titled “Information to be Included in Applications for Approval of 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 Material¹. The checklists in Annexes V – VIII 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 1².

¹ US NUCLEAR REGULATORY COMMISSION, Regulatory Guide 7.10, Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material, Revision 2, March 2005, Washington, DC (2005).

² EUROPEAN ASSOCIATION OF COMPETENT AUTHORITIES, Technical Guide: Compliance Inspections by the European Competent Authorities on the Transport of Radioactive Material, Issue 1 (2015).

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 approvals of:

- (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 (PDSR) 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 guidance for the safety report of package designs has been issued by the European Association of Competent Authorities: Technical Guide “Package Design Safety Reports for the Transport of Radioactive Material” (PDSR Guide) [I-2]. It covers all types of packages and assists in the preparation of the PDSR 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 PDSR (see Fig. I-1). 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, guidance is 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].

I-4. Guidance on the formatting and contents of such a PDSR can be found in Ref. [I-2]

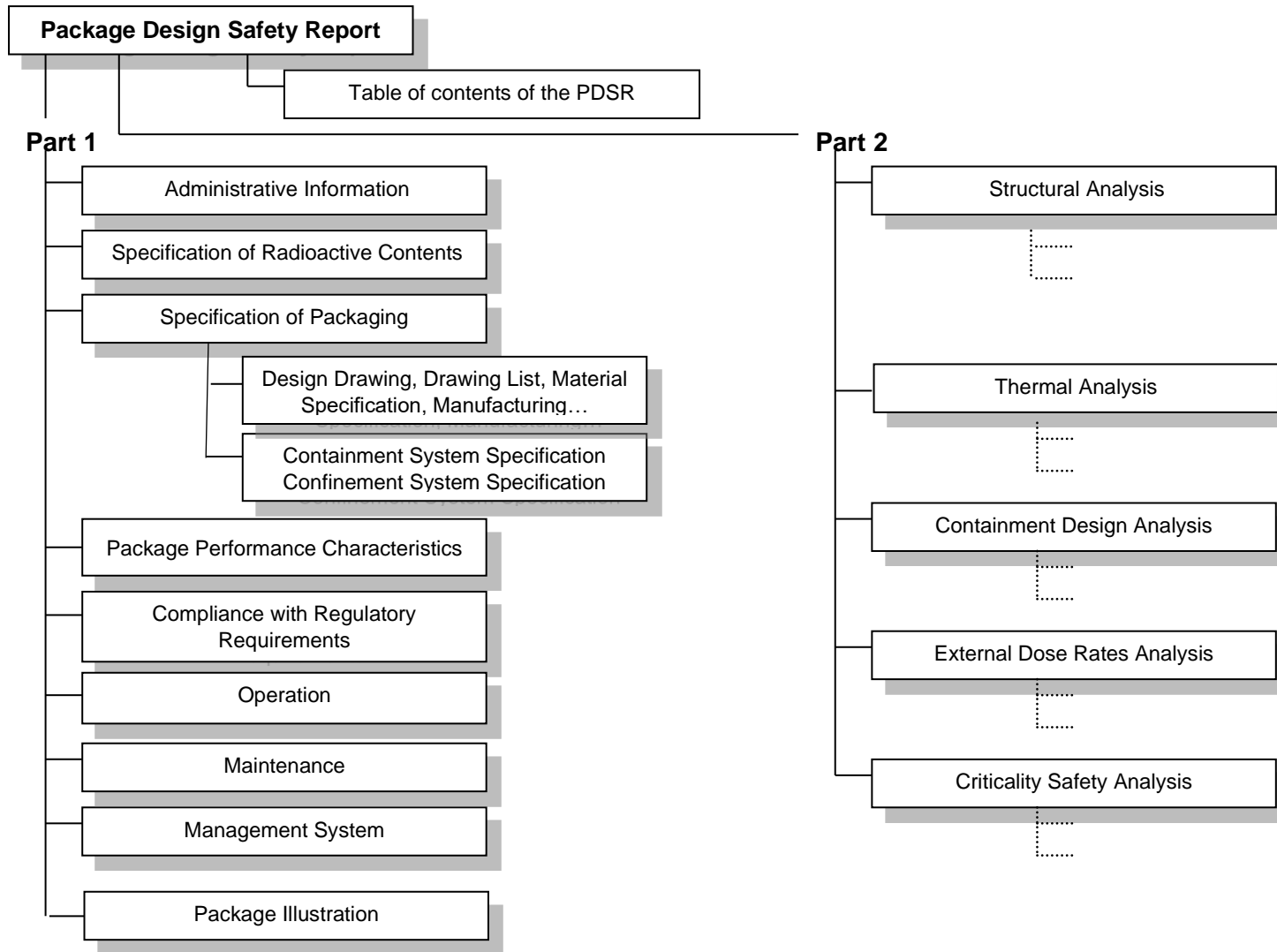


Fig. I-1.: Structure of Package Design Safety Report

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

General information

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

- Name, address and telephone number of the applicant
- Name, address and telephone number of the designer
- Name, address and telephone number of the manufacturer
- Type of approval required (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]

- A detailed description of the radioactive material or, if a capsule, the contents which includes the following:
 - Radionuclides present
 - Total activity
 - Nature of emitted radiation
 - Heat output
 - Physical and chemical state
 - Overall dimension and mass.
- A detailed statement of the design of any capsule to be used.
- 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].
- A specification of the applicable management system, as required by para. 306 of the Transport Regulations [I-1].
- 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

- 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.
- Number of shipments.
- List of applicable national and international regulations and specifying the edition of the Transport Regulations [I-1] under which competent authority approval is sought.
- Specification of the applicable management system, radiation protection programme and emergency response procedure.
- Radiation protection programme in case of shipments by special use vessels in accordance with para. 576(a) of the Transport Regulations [I-1].
- Applicable package design approval certificates (Type B(M) packages or packages containing fissile material).

Administrative information

- Name, address and telephone number of the applicant
- Name, address and telephone number of the consignor
- Name, address and telephone number of the consignee
- Name, address and telephone number 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
- General transport arrangement drawing number
- Date of application
- Date by which approval is desired

Specific information as required by paras 827 and 827A of the Transport Regulations [I-1]

For approval of shipments as specified in para. 825(a)–(c) of the Transport Regulations [I-1]:

- The period of time, related to the shipment, for which the approval is sought.
- 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.
- The modes of transport.
- The type of conveyance and the probable or proposed route.
- 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.

For approval of SCO-III shipments:

- The period of time, related to the shipment, for which the approval is sought.

- The actual radioactive contents, the expected modes of transport, the type of conveyance and the probable or proposed route.
- A statement of the respects in which, and of the reasons why, the consignment is considered SCO-III.
- 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.
- A detailed description of the proposed radioactive contents with reference to their physical and chemical states and the nature of the radiation emitted.
- A detailed statement of the design of the SCO-III, including complete engineering drawings and schedules of materials and methods of manufacture.
- 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.
- A transport plan.
- 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

- 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.
- Number of shipments.
- List of applicable national and international regulations and specifying the edition of the Transport Regulations [I-1] under which competent authority approval is sought.
- Specification of the applicable management system, radiation protection programme and emergency response procedure.

Administrative information

- Name, address and telephone number of the applicant
- Name, address and telephone number of the consignor
- Name, address and telephone number of the consignee
- Name, address and telephone number of the carrier
- Identification mark of the competent authority, if previously allocated
- General transport arrangement drawing number
- Date of application
- Date by which approval is desired.

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

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.

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

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVAL OF MANAGEMENT SYSTEMS

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. An application for approval of the management system should address all relevant transport activities of the organization concerned.

Although this annex focuses on packagings used in transport of radioactive material, it provides comprehensive information that can be adapted to any of the transport activities mentioned above.

Applications for approval of management systems might include the following information in accordance with international, national or other standards acceptable to the competent authority:

Management System Organization:

- Documentation of the formal structure of the organization by organization charts that identify each organizational element that functions under the management system.
- 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:

- 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.
- 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 management system user 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:

- 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:

- A description of measures to control the preparation, review, concurrence, and approval of all procurement documents

Instructions, Procedures, and Drawings:

- 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:

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

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

Identification and Control of Materials, Parts, and Components:

- 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 Processes¹:

- 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:

- 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.

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.

- 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.
- 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:

- 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:

- 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:

- 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:

- 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:

- 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 Action:

- 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:

- 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. As 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:

- 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, 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] EUROPEAN ASSOCIATION OF COMPETENT AUTHORITIES (EACA) Technical Guide: Package Design Safety Reports for the Transport of Radioactive Material European PDSR Guide, Issue 3 (2014).

http://www.euraca.eu/doc_documents/PDSRGuide_Package%20Design%20Safety%20Reports%20for%20the%20Transport%20of%20Radioactive%20Material_Issue3_December2014.pdf

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]
<p>4. This is to certify that the design of the package described in the following meets the applicable requirements for [Type B(U), B(M), Type C package] [Type ... package containing fissile material] in the IAEA Regulations for the Safe Transport of Radioactive Material, 2018 Edition, SSR-6 (Rev. 1) [hereafter referred to as ‘SSR-6 (Rev. 1)’], and in the regulations listed in Section 17.</p> <p>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.</p>	
Issue Date	
[Signature of the certifying official(s)]	
Address, telephone number and email address of the competent authority	
<p>5. Package identification</p> <p>(a) Reproducible illustration not larger than 21 cm × 30 cm showing the make-up of the package</p> <p>(b) Packaging</p> <p style="padding-left: 20px;">(i) Model name or number</p> <p style="padding-left: 20px;">(ii) Description (use, dimensions, materials, closures, penetrations, gross mass, etc.)</p> <p style="padding-left: 20px;">(iii) Reference to drawings or specification of design</p> <p style="padding-left: 20px;">(iv) Description of the containment system</p> <p>(c) Radioactive contents (non-fissile):</p> <p style="padding-left: 20px;">(i) Radioisotopes</p> <p style="padding-left: 20px;">(ii) Physical and chemical form (including special form radioactive material or low dispersible radioactive material, if applicable) and the mass in grams</p> <p style="padding-left: 20px;">(iii) Maximum activity per package (including activities of the various isotopes)</p> <p style="padding-left: 20px;">(iv) Any other restrictions on the radioactive contents that might not be obvious from the nature of the packaging</p> <p>(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):</p> <p style="padding-left: 20px;">(i) Type and form of fissile material</p> <p style="padding-left: 20px;">(ii) The maximum total mass of fissile nuclides or the mass for each fissile nuclide, when appropriate.</p> <p style="padding-left: 20px;">(iii) Description of the confinement system</p> <p style="padding-left: 20px;">(iv) Criticality safety index</p> <p style="padding-left: 20px;">(v) Reference to the documentation that demonstrates the criticality safety of the package</p> <p style="padding-left: 20px;">(vi) Special features on the basis of which the absence of water from certain void spaces has been assumed in the criticality assessment</p> <p style="padding-left: 20px;">(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</p> <p style="padding-left: 20px;">(viii) The ambient temperature for which the package design has been approved</p>	
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 may 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
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 approval certificate

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/number)	
5. Radioactive material (radionuclide(s), physical and chemical forms)	6. Maximum activity
7. Design specifications (reference to drawings)	8. Reference to the applicable management system
9. Specific actions to be taken prior to shipment	
10. This is to certify that the design of the special form radioactive material (or low dispersible radioactive material) described above meets the applicable requirements in the IAEA Regulations for the Safe Transport of Radioactive Material 2018 Edition, SSR-6 (Rev. 1), and in the regulations listed in Section 11.	
Issue Date	
[Signature of certifying official(s)]	
Address, telephone number and email address of the competent authority	
11. Applicable regulations concerning the transport of radioactive material	
(a) Road:	
(b) Rail:	
(c) Sea:	
(d) Inland waterways:	
(e) Air:	
(f) International:	
(g) Other:	
12. Table summarizing past and current revisions of the approval certificate	

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]
<p>4. This is to certify that the shipment of the radioactive material described in the following is designed to meet the applicable requirements for the shipment of the radioactive material in the IAEA Regulations for the Safe Transport of Radioactive Material, 2018 Edition, SSR-6 (Rev. 1) [hereafter referred to as ‘SSR-6 (Rev. 1)’] and in the regulations listed in Section 12.</p> <p>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.</p>	
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	
<p>6. Specification of actual radioactive contents, including:</p> <p>(a) Radioisotopes (including fissile material)</p> <p>(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]</p> <p>(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</p> <p>(d) Total amount in grams of fissile material (or for each fissile nuclide, when appropriate) per package and per conveyance</p> <p>(e) Any restrictions on the radioactive contents that might not be obvious from the nature of the packaging</p>	
7. Restrictions on the modes of transport, type of conveyance and/or freight container, and routing 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	
<p>12. Applicable regulations concerning the transport of radioactive material</p> <p>(a) Road:</p> <p>(b) Rail:</p> <p>(c) Sea:</p> <p>(d) Inland waterways:</p> <p>(e) Air:</p> <p>(f) International:</p> <p>(g) Other:</p>	
13. Table summarizing past and current revisions of the approval certificate	

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]
<p>4. This is to certify that the shipment of the radioactive material described in the following is designed to meet the applicable requirements for the shipment of the radioactive material under special arrangement in the IAEA Regulations for the Safe Transport of Radioactive Material, 2018 Edition, SSR-6 (Rev. 1) [hereafter referred to as ‘SSR-6 (Rev. 1)’] and in the regulations listed in Section 16.</p> <p>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.</p>	
Issue Date	
[Signature of the certifying official(s)]	
Address, telephone number and email address of the competent authority	
<p>5. Package identification</p> <p>(a) Reproducible illustration not larger than 21 cm × 30 cm showing the make-up of the package</p> <p>(b) Packaging:</p> <ul style="list-style-type: none"> (i) Model name or number (ii) Description (use, general external dimensions and appearance, materials of manufacture, closures, penetrations, gross mass, etc.) (iii) Reference to drawings or a specification of the design (iv) Description of the containment system <p>(c) Radioactive contents (non-fissile):</p> <ul style="list-style-type: none"> (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 <p>(d) Additionally, for packages containing fissile material:</p> <ul style="list-style-type: none"> (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. 667(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 routing 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
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 approval certificate

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 may direct its attention during inspections to ensure the following:

The management of the organization has provided the necessary personnel and resources to carry out 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.

- (a) The management has provided proper training to the persons who are responsible for carrying out 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.
- (b) Established procedures are followed for the design and fabrication or for the selection and procurement of packagings.
- (c) The consignor is using the proper packaging for the specific contents of packages. The competent authority may carry out direct examination of packages being prepared for shipment.
- (d) The organization has in its possession all the required documentation, including the relevant competent authority certificates and any associated instructions for handling, loading, storage, use and maintenance of the packaging (often given in the form of an instruction manual for the packaging).
- (e) Established procedures are followed for the preparation and use of the package, in accordance with the approval certificate, the instruction manual and related documents.
- (f) 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.
- (g) Established procedures are followed, and appropriate and properly calibrated instruments are provided, to monitor packages for both radiation and contamination.
- (h) 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.
- (i) 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.
- (j) 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.
- (k) 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.
- (l) The organization has developed and continues to maintain appropriate emergency response provisions, and such provisions are exercised periodically.

III-2. Examples of procedures and checklists that may be used by competent authorities for their inspection activities are given in Annexes IV-VIII. These checklists are not comprehensive and may be used as a starting point for a competent authority to develop its own checklists in accordance with the size and complexity of the industry and operations being inspected.

REFERENCES 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 AND CHECKLIST FOR INSPECTING A MANAGEMENT SYSTEM

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

1. PURPOSE

1.1. 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].

2. SCOPE

2.1. 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, extra inspection activities may be arranged if this is requested by other organizational units of the competent authority.

Inspection activities include, but are not limited to:

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

3. DEFINITIONS

3.1. Inspection checklist

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

3.2. Inspection matrix

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

3.3. Inspection plan

A timetable of inspecting activities.

3.5. Inspector(s)

The person(s) responsible for undertaking the inspection.

3.6. Inspection

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

3.7. Corrective actions

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

3.8. Non-compliance

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

3.9. Observation

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

3.10 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.

3.11 Inspection report

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.

3.12. 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.

4. RESPONSIBILITIES

4.1. 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.

4.2. 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.

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

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

5. PROCEDURE

5.1. Inspection preparation

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

5.1.2. 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 formal training in appropriate inspection techniques.

5.1.3. 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.

5.1.4. 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.

5.1.5. 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.

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

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

- (a) The date(s) and time(s) 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.

5.1.8. 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.

5.2. Performance of the inspection

5.2.1. 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:

- (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 and attendance.

5.2.2. 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.

5.2.3. 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.

5.2.4. Evidence and details of non-compliance regarding the standards or procedures on which the inspection is based are recorded. The record of noncompliance 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 may still be considered to be admissible if the team leader so decides.

5.2.5. The team leader regularly reviews the progress of the inspection, discussing noncompliance, 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.)

5.3. Closing meeting

5.3.1. 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.

5.3.2. 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.

5.4. Inspection report

5.4.1. The inspector(s) prepare(s) 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.

5.4.2. 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.

5.4.3. The progress of corrective actions is monitored by the team leader, using a statement of inspection completion. 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 required 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.

6. RECORDS

6.1. 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.

7. DECLARATION

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

EXAMPLE OF A CHECKLIST FOR INSPECTING A MANAGEMENT SYSTEM

MANAGEMENT SYSTEM AND STRATEGIC PLANNING

1. Is there an established and appropriately documented management system?
2. Is the organization's policy and statement of authority with respect to the management system documented?
3. Does the management system fully identify those processes and activities covered by the management system and provide for their effective control?
4. Is involvement in and commitment to the management system and its objectives evident on the part of senior management?
5. Does the management system fully cover the activities undertaken by the organization (these activities may include the design, manufacture, maintenance and repair of packagings, and the preparation, consigning, loading, carriage (including in-transit storage), unloading and receipt at the final destination of loads of radioactive material and packages)?
6. Is there a defined organizational structure and management responsibilities consistent with the size and complexity of the organization and its functions?
7. Are the functional responsibilities and levels of authority clearly defined at all levels within the organization?
8. How does the organization manage organizational changes to ensure that it remains effective and that quality and compliance remain unaffected?
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)?
10. Is the management system subject to review and evaluation, and, if so, how frequently?
11. Who is responsible for reviewing the management system?
12. Does the management system review process provide for an appropriate scope and include all necessary inputs?
13. Does the review process include a confirmation that the management system demonstrates compliance with the Transport Regulations [IV-1] relating to the transport of radioactive material by the modes of transport used by the organization?
14. Does a radiation protection programme exist within the organization?
15. What processes are used to encourage and manage a safety culture within the organization?
16. Do the strategic plans of the organization include the development of its policies, objectives and processes?

DOCUMENTATION AND CONTROL OF RECORDS

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

19. Do the procedures cover the preparation, approval and issuing of such documentation?
20. Has a system for the release, distribution and withdrawal of documents been established?
21. How are personnel made aware of changes to documents?
22. How are suppliers made aware of changes to documents?
23. Are applicable codes, standards and regulations updated as amendments are issued?
24. How are essential personnel made aware that amendments to documents, including codes and standards, have been issued?
25. Are copies of redundant or out of date documents suitably marked, withdrawn or destroyed?
26. Are superseded or redundant documents retained, and if so, how are they controlled to prevent their accidental use?
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?
28. How are incoming and/or external documents controlled?
29. Are records of changes to documentation retained?
30. Does the system cover the maintenance of essential records of the management system?
31. Does the system cover the identification, collection, indexing, filing, storage, maintenance and disposal of records?
32. Are records readily retrievable and maintained in a suitable environment?
33. Are retention periods for records defined?
34. Are records and/or logbooks available for each package and/or packaging?
35. Do logbooks contain the necessary information such as movement or transport records, authorized modifications to the package, and operating and maintenance instructions?
36. Are records available for servicing or for maintenance performed at other locations?

MANAGEMENT RESPONSIBILITY

37. Has a management representative been appointed and given appropriate authority to manage, monitor, evaluate and coordinate the management system?
38. Are measurable objectives of the management system established at relevant functions and levels within the organization?

SATISFACTION OF INTERESTED PARTIES

39. Are the interested parties (stakeholders) clearly identified?
40. Are the needs and expectations of interested parties identified?
41. What processes exist within the organization to monitor and measure the satisfaction of interested parties?

RESOURCE MANAGEMENT

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 needs?
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

44. How does the organization encourage the involvement and development of its personnel?
45. How is this measured?
46. Does the organization provide an appropriate training programme for all personnel involved in the transport of radioactive material?
47. How are training needs identified?
48. How are training records maintained?

INFORMATION AND KNOWLEDGE MANAGEMENT

49. How does the organization characterize, monitor and manage information and knowledge?
50. Is the procedure developed for information and knowledge management appropriate for the organization's transportation related activities and is it being followed?

COMMUNICATION AND INTERFACES

51. Does the organization provide for the effective communication of its policies, needs of customers and regulatory needs to all personnel within the organization?
52. Are internal and external lines of communication established and defined in processes and/or procedures?
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

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

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

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

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

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

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

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 require 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 require design verification to be accomplished by:
 - (i) Calculations; or
 - (ii) (ii) Computer codes?

Grade 3

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

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

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?

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

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

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?

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?

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?

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

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

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

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

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

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?

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

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?
74. Do the procurement documents specify that design and quality requirements be passed on to sub-suppliers?
75. Do the procurement documents specify that material traceability be maintained throughout fabrication and assembly as necessary?
76. Are suppliers selected and evaluated for their ability to supply products in accordance with specific criteria?
77. Who carries out this evaluation, and is it recorded?
78. How is the past performance of suppliers recorded?
79. How often is a supplier assessed?
80. Are audits of supplier management systems conducted as part of the evaluation process?
81. Are supplier audits planned and documented?
82. Do purchasing documents provide for adequate access by the purchaser and the competent authority to the plants of the suppliers and sub-suppliers?
83. What controls are established to ensure that purchased items conform to the specifications of procurement documents?
84. Are such controls documented?
85. Are suitable arrangements provided for the care and control of customer supplied materials or items?

IDENTIFICATION, TRACEABILITY AND PRESERVATION OF MATERIALS

86. Are suitable arrangements in place to determine when identification and traceability of materials, items and software, are necessary?
87. Are the necessary identification and traceability of such items being achieved?
88. Are measures established to control the handling, storage and shipping of materials both at initial delivery and during use in transport operations?
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

90. Have all relevant processes, including those necessary for the management system, been identified and their control provided for (e.g., design, procurement, manufacturing, and delivery processes and transport operations)?
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?
92. Are documents such as quality plans produced to support process control? Are such plans available?
93. Are any design, production or other processes performed by sub-suppliers controlled, and how is this done?

94. How are process control arrangements and procedures reviewed, controlled and issued?
95. Do sub-suppliers use their own process control procedures or those of the purchasing organization (e.g. process procedures and work instructions)?
96. Are inspections or other process control checks performed at defined points during the process (e.g. manufacturing, servicing)?
97. Are special processes controlled (e.g. welding or non-destructive testing)?
98. How are these special processes controlled and monitored?
99. Are only suitably qualified and experienced people used to control or perform special processes?
100. Are all necessary controls or supporting processes available for controlling special processes (e.g. heat treatment)?

CONTROL OF INSPECTIONS, MEASUREMENTS AND TESTS

Inspection

101. Have programmes for inspection of items and services been established?
102. Do the procurement documents require suppliers to establish inspection programmes?
103. Have programmes for in-service inspections been established?
104. Who authorizes inspection programmes?
105. Are such inspections conducted by qualified personnel other than those persons performing the activities?
106. Have inspection procedures been established?
107. What processes ensure that non-conforming in-service items are removed from use until the situation is rectified?
108. Are inspection hold points defined?
109. How is it ensured that work does not proceed beyond a hold point?

Measurement and monitoring

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

Testing

112. Have test programmes (e.g. prototype qualification, production, proof, and operational tests) been established?
113. How is it ensured that the test programme(s) demonstrate(s) the adequacy of the specification(s) and that all parts will perform satisfactorily in service?
114. Is testing conducted against written test procedures, and are the acceptance criteria specified?
115. Who evaluates the test results?

116. Does testing cover normal and accident conditions of transport?
117. Does the management system cover calibration and control of the measuring and test equipment?
118. Are calibration records available, and can they be traced back to a national standard?
119. Are measuring and test equipment calibrated, adjusted and maintained at prescribed intervals or prior to use?
120. Are measuring and test equipment labelled or tagged to indicate calibration status?
121. If equipment is found to be non-compliant, how is acceptance of the items reassessed?
122. Are controls established for the handling, storage and use of equipment?
123. How is inspection and test status identified, and is it maintained throughout the manufacture and use of an item?

SERVICING

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

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

INDEPENDENT ASSESSMENT

127. Is there a programme for internal and external audits?
128. Is the audit programme documented?
129. Are audits conducted by qualified persons who have not been involved in the activity being audited?
130. Are effective corrective and preventive actions taken when the system is found to be incorrect?
131. Are internal audit reports used for management system reviews?
132. Is the organization subjected to independent assessment by any of its interested parties?
133. How do the findings of any independent assessments compare with the findings made by internal auditing?

NON-CONFORMANCE, AND CORRECTIVE AND PREVENTIVE ACTIONS

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

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

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

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

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

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

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

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

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

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

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

IMPROVEMENT

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

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

REFERENCES 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 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 SFRM design	
Package manufacturing	
Radioactive material classification	
Selection of package type and of package design	
Preparation/handling of packages; loading/unloading/stowage of packages on conveyance	

Transport	
Maintenance/repairing of packaging	
Does the consignor subcontract above activities associated with the transport of RAM? (Identify what activities are subcontracted)	

Subject/Inspection aspect	Provision in SSR-6 (Rev.1), 2018 Edition	Compliance			Comments
		YES	NO	NA	
Company details and organisation					
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)				
Has the consignor 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 licenses? (e.g., carrier's registration or authorisation, laboratory's authorisations.)	(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?	545-561 (306)				

(Whenever possible, check the fulfilment of the procedures)					
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)				
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 packages 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 RAM 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, has the consignor procedures for this activity? (note reference(s))	(306)				

<p>If not, does the consignor conduct any control over the classification process?</p> <p>(Identify the procedure and the way the consignor does this control: Verification, inspection, calculation validation.)</p>	(306)				
<p>In case of special form radioactive material, or low dispersible radioactive material, are the approval certificates available? Are they still valid?</p>	561, 556				
<p>Is the radioactive material transported as “fissile excepted”?</p> <p>(identify the criteria used and the procedures applied by the consignor to confirm the criteria fulfilment)</p>	Table 1, footnote “b”, 417, 546j				
Packages:					
<p>Has the consignor procedures for selecting the packaging depending on the RAM to be transported?</p> <p>(Identify the package designs, the number of packagings of each design used and their suppliers)</p>	(306) 401, 408-434				
<p>For package designs subject to approval, are the approval certificates in force in possession of the consignor? Are they still valid?</p>	561, 556 802				
<p>Has the consignor implemented a procedure to be informed about changes of approval certificates?</p>	(306)				
<p>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?</p> <p>(Identify the documentation presented)</p> <p>Is this documentation still valid? (i.e.no design change)</p>	801				
<p>Is the general state of the packagings adequate?</p>	502, 503				
<p>Are the different components of the packagings in good state?</p>	502, 503				
<p>Are the packagings and their components in accordance with the package design?</p>	502, 503				
<p>Is the marking method of packages adequate?</p>	531-537, 545, 547				
<p>Is the labelling method of packages adequate?</p>	538-542, 545, 547				
<p>Are the radiological measures conducted on the packages according to regulations?</p>	508, 509, 516, 523- 524A, 526- 529				
Package maintenance/repair (Use Annex VIII)					

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 carry out the predefined inspection requirements before each shipment?	502, 503				
Does the consignor carry out 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 according to the Transport Regulations?	531-537				
Is the methodology for the determination of transport index clearly defined and according to the Transport Regulations?	523-524				
Whenever is 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)	554a				
Does the consignor provide restriction on the mode of transport or conveyance and any necessary routing instructions? (if necessary)	554b				
Does the consignor provide instructions on the mixed loading prohibition?	506, 507				
Does the consignor provide emergency arrangements appropriate to the consignment?	554c				

Is the documentation language used according to the Transport Regulations?	554				
Does the consigner fulfil the notification requirements?	557, 558				
Radiation protection requirements					
Does the consignor have a Radiation Protection Programme (RPP)? (identify and take 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 he/she responsible for ensuring the following? (if not, identify the responsible individual)					
Training	311				
Implementation of work procedures	306				
Assessment of workers' exposures	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 there exposed workers' categories? (identify the different categories used and the personnel included in)	301, 303				
Has radiological surveillance been undertaken? (if yes, describe)	303				
Are the results of radiological surveillance recorded? (check records)	303				
Are contamination checks performed? (describe method)	301, 508 509, 512				
Does the Company know the applicable limits for radiation levels or contamination?	508-514 526-529				
Are contamination check records kept?	306				
Is there a protocol in case of noncompliance with the above limits for radiation levels or 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 shielded areas used in the storage?	301, 562				
Is shielding used on the conveyances?	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 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)	314				
Are the radiation monitoring devices appropriate for the measurements to be taken?	(306)				
Are radiation monitoring devices periodically verified and calibrated? Is a calibration certificate available?	(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? (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 may 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)					
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Training					
Does the consignor provide an appropriate training programme for all personnel involved in the transport of RAM?	311-315				
Does the consignor maintain records of the training and competence?	314				
Management system (Use Annex IV)					

Annex VI. 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

Company details and organization:

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

Subject/Inspection aspect	Provision in SSR-6 (Rev.1), 2018 Edition	Compliance			Comments
		YES	NO	NA	
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 up-dated? (Document system?)	306				
Radiation Protection Requirements					
Has the carrier a Radiation Protection Programme (RPP)? If yes, identify and take 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 of the company 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 to minimize doses? (Identify the procedures implemented)	301, 302				
Is there a structured and systematic approach to dose assessment? (check workers' dose records)	301, 303				
Have dose assessments been undertaken? (Identify the procedure applied for the assessments)	301-303				
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, 513				
Are contamination check records kept?	306				

Does the Company know the applicable limits for radiation levels or contamination?	508-514 526-528, 566				
Is there a protocol in case of non-compliance with the above limits for radiation levels or 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 transport vehicle?	566				
Is segregation used on the conveyances?	566-569				
Does the company know the applicable conveyance activity limits for LSA and SCO	522, Table 6				
Are loading and unloading operations of conveyances (e.g. dose rates) optimized in accordance with the RPP?	301-302				
Is there a documented evidence of training? (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? (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 response procedures tested?	306				
Driver/ Company Requirements					
Is the vehicle crew supplied with written instructions regarding emergency response procedures?	554				
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 radiation levels, TI and CSI?	566, Table 10, 569, Table 11					
Is the mixed loading prohibition verified?	506, 507					
Training						
Does the company provide an appropriate training programme for all personnel involved in the transport of RAM?	311-315					
Does the company maintain records of the training and competence?	314					
Does the driver have any necessary documents to confirm his proficiency in handling radioactive material according to 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 require the consignor to make available copies of package and / or material approval certificates?						
Shipment Approval Certificates						
Is a procedure in place to meet shipment approval requirements, if necessary?	852, 829					
Are there shipment approval certificates in place? If yes, Certificate/Authorization Number:	825, 829					
Vehicles - Placarding, Fire Extinguishers, Miscellaneous Equipment and Stowage						
For road and rail: are the vehicles correctly placarded?	571, 572					
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				
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 Annex IV)					

Annex VII. 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	Provision in SSR-6 (Rev. 1), 2018 Edition	Compliance			Comments
		YES	NO	NA	
Management System (Use Annex IV)					
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 realised 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 CA approved packages: Are the fabrication and test plan organised with hold-points, quality checks, and are they sufficiently documented? Only for non-CA 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 according to 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 CA 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				
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Annex VIII. EXAMPLE OF A CHECKLIST FOR INSPECTING MAINTENANCE AND SERVICE 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	Provision in SSR-6 (Rev. 1), 2018 Edition	Compliance			Comments
		YES	NO	NA	
Management System (Use Annex IV)					
Instructions for maintenance and service operations					
Are there instructions, procedures, plans or drawings for maintenance and service 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 approval certificate 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 organisation and personnel involved in the transport of RAM 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/facility have necessary permits/licenses for use or maintenance operations of packages/packaging?	National regulations				

Have the maintenance and service operations been undertaken in accordance with the packages/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 approval certificate 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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