Compliance Assurance for the Safe Transport of Radioactive Material
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COMPLIANCE ASSURANCE FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL

A Safety Practice

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 1994
FOREWORD

The 1985 Edition of the IAEA’s Regulations for the Safe Transport of Radioactive Material reinforced the requirement placed on competent authorities to establish compliance assurance programmes that aim at ensuring that the Regulations are met in practice. A number of Member States have requested help from the IAEA in fulfilling this requirement. In response, the IAEA has prepared this book to provide further guidance on developing and implementing compliance assurance programmes. Furthermore, the IAEA has set up a work plan to increase its assistance to Member States wishing to implement these Regulations more fully.

This book is intended to be used by competent authorities that are establishing programmes to ensure compliance with the regulations governing the safe transport of radioactive material. The advice provided should also be useful to those competent authorities with established programmes seeking greater harmony in the international implementation of the Regulations. Additionally, the book should assist the users of the Regulations in their interaction with competent authorities.

It is expected that competent authorities will need to make use of the measures taken in the frame of quality assurance in implementing compliance assurance programmes. Indeed, competent authority auditing of quality assurance programmes established by the industry as a regulatory requirement is one of the most effective methods available for monitoring compliance. This close linkage has led the IAEA to prepare a companion Safety Practice on Quality Assurance for the Safe Transport of Radioactive Material.

The IAEA is grateful to all persons who have contributed to the production of the Safety Practices for Compliance Assurance and Quality Assurance for the Safe Transport of Radioactive Material. In particular, it acknowledges the work of C.J. Pecover of the United Kingdom Department of Transport who prepared the initial drafts of both publications.
This publication is no longer valid
Please see http://www-ns.iaea.org/standards/
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Section I
INTRODUCTION

PURPOSE AND SCOPE

101. The transport of radioactive material involves a potential radiological hazard. To ensure the safety of people, property and the environment, appropriate regulations, both domestic and international, are necessary. Governmental authorities regulate the transport of radioactive material through national regulations, in which the relevant international regulations and recommendations are usually taken into account. This book discusses the principles and objects that should be recognized and achieved in order to ensure that the transport of radioactive material, both domestic and international, is carried out in compliance with the IAEA Regulations for the Safe Transport of Radioactive Material (Safety Series No. 6 [1]).

102. The purpose of this book is to assist competent authorities in the development and maintenance of compliance assurance programmes in connection with the transport of radioactive material, and to assist applicants, licensees and organizations in their interactions with competent authorities. In order to increase co-operation between competent authorities and to promote uniform application of international regulations and recommendations it is desirable to adopt a common approach to regulatory activities. This book is intended to assist in accomplishing such uniform application by laying down most of the actions that competent authorities need to provide for in their programmes for ensuring regulatory compliance.

103. This book concerns specifically the radiation safety aspects of the transport of radioactive material, i.e. the subjects that are covered by the Regulations. Radioactive material, however, may also have other dangerous properties (such as explosiveness, flammability, pyrophoricity, chemical toxicity and corrosiveness); these must be taken into account in the regulatory control of the package design and transport (see, for example, paras 105, 208 and 407 of the Regulations).

104. Physical protection and safeguards control of nuclear material as well as aspects of third party liability are also mentioned in this book (paras 203, 214, 215, 312 and 313). These subjects are not within the scope of the Regulations, but they are included here because they have to be taken into account in the overall regulatory control of transport, especially when the regulatory framework is established.

105. According to para. 117 of the Regulations, “Compliance assurance shall mean a systematic programme of measures applied by a competent authority which is aimed at ensuring that the provisions of these Regulations are met in practice”.

Please see http://www-ns.iaea.org/standards/
Paragraph 210 states: "The competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, and the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the provisions of these Regulations are being met in practice."

106. While competent authorities are responsible for assuring compliance with the Regulations (which must include oversight and enforcement of all regulations), the prime responsibility for ensuring safety in transport rests with consignors and carriers, who must take account of all relevant safety regulations. Thus, consignors, carriers and any other users of the Regulations must comply with the actual regulations, and the competent authority should assure compliance with these regulations. The competent authority itself should comply with the IAEA Regulations, for example in such matters as issuance of approvals and the allocation of design identification marks for packagings.

107. A country whose radioactive material transport industry is not yet fully established may develop its own compliance assurance programme in stages, depending on the size of that transport industry. For example, initially the competent authority may only need to deal with the movement of packages that have been assessed and approved originally by authorities of other Member States. Later, that competent authority may have to monitor the quality of packages (approved or not) designed, built and used within its own jurisdiction. Then, the compliance assurance programme of the competent authority can develop accordingly.

108. An effective programme for compliance assurance by a competent authority should take into account all users of the Regulations, i.e. persons or organizations which, at one time or another, may be subject to the requirements of the Regulations, such as:

- consignors
- carriers
- suppliers/manufacturers of packagings
- multiple regulatory organizations (shared responsibilities).

109. A compliance assurance programme should include two major elements: Firstly, the competent authority should review and approve certain activities in advance of the activity in question. Secondly, the competent authority should ensure through a regulatory inspection and enforcement programme that all the regulatory requirements are correctly fulfilled in practice. The competent authority needs to be provided with adequate resources to perform these review, inspection and enforcement activities. Compliance assurance should also cover emergency response activities.
110. Through a compliance assurance programme the competent authority should obtain assurance that all transport requirements are being met in practice by the users of the Regulations. Monitoring of the effectiveness of compliance is generally performed by routine, periodic inspections (announced or unannounced) of the user’s activities. For consignors, these inspections are generally examinations of the procedures before, during or after the transport has actually taken place. For carriers, the inspections are generally performed during or after the transport itself. The frequency of inspection is established by taking into account the scope and potential safety importance of the user’s activities.

DEFINITIONS FOR THE PURPOSE OF THIS PUBLICATION

Applicant

111. Applicant shall mean any person or organization who applies to a competent authority for the issue of an approval in accordance with the Regulations.

Approval certificate

112. Approval certificate shall mean a certificate signifying compliance with the necessary regulatory requirements, resulting from the independent assessment, carried out by a competent authority or by another authorized body, of material submitted by an applicant.

Audit

113. Audit shall mean a documented activity performed to determine by investigation, examination and evaluation of objective evidence the adequacy of, and adherence to, established procedures, instructions, specifications, codes, standards, administrative or operational programmes and other applicable documents, and the effectiveness of implementation.

Carrier

114. Carrier shall mean any individual, organization or government undertaking the carriage of radioactive material by any means of transport. The term includes both carriers for hire or reward (known as common or contract carriers in some countries) and carriers on their own account (known as private carriers in some countries).

Competent authority

115. Competent authority shall mean any national or international authority designated or otherwise recognized as such for any purpose in connection with the Regulations.
Compliance assurance

116. Compliance assurance shall mean a systematic programme of measures applied by a competent authority which is aimed at ensuring that the provisions of Regulations are met in practice.

Consignor

117. Consignor shall mean any individual, organization or government which presents a consignment for transport and is named as consignor in the transport documents.

Design

118. Design shall mean the description of special form radioactive material, package or packaging which enables such an item to be fully identified. The description may include specifications, engineering drawings, reports demonstrating compliance with regulatory requirements, and other relevant documentation.

Licensee

119. Licensee shall mean the holder of a licence for the transport of radioactive material under the national regulations of countries. (In some countries the term is equivalent to applicant.)

Manufacturer

120. Manufacturer shall mean the person or organization who controls, partially or wholly, the fabrication, assembly or similar activity associated with the construction of a packaging to be used for the transport of radioactive material or the production of special form radioactive material.

Multilateral approval

121. Multilateral approval shall mean approval by the relevant competent authority, both of the country of origin of the design or shipment and of each country through which or into which the consignment is to be transported.

Nuclear material

122. Nuclear material shall mean radioactive material subject to further controls for the purpose of non-proliferation.

1 More specifically defined in the IAEA Legal Series No. 12 [14].
Package

123. Package shall mean the packaging with its radioactive contents as presented for transport.

Packaging

124. Packaging shall mean the assembly of components necessary to enclose the radioactive contents completely.

Quality assurance

125. Quality assurance shall mean a systematic programme of controls and inspections applied by any organization or body involved in the transport of radioactive material; this programme is aimed at providing adequate confidence that the standard of safety prescribed in the Regulations is achieved in practice.

Quality assurance programme

126. Quality assurance programme shall mean a documented set of activities, resources and events serving to implement the quality system of an organization.

Radioactive material

127. Radioactive material shall mean any material having a specific activity greater than 70 kBq/kg (2 nCi/g).

Regulations


Transport

129. Transport shall comprise all operations and conditions associated with and involved in the movement of radioactive material; these include the design, fabrication and maintenance of packagings, and the preparation, consigning, handling, carriage, storage in transit and receipt at the final destination of packages. Transport includes normal and accident conditions encountered in the carriage of radioactive material and in its storage during transport.

User

130. User shall mean a person or organization who designs, tests, assesses, manufactures, services, maintains, consigns, carries or otherwise uses a package in connection with the transport of radioactive material.
Unilateral approval

131. Unilateral approval shall mean the approval of a design which is required to be given only by the competent authority of the country of origin of the design.

Validation

132. Validation shall mean the process of endorsement by a competent authority of the original approval certificate issued by another competent authority.

Section II

RESPONSIBILITIES AND FUNCTIONS OF THE COMPETENT AUTHORITY

INTRODUCTION

201. The primary role of competent authorities in transportation is to ensure the safety of people, property and the environment against possible hazards involved in the transport of radioactive material.

LEGAL BASIS

202. The responsibilities and duties of a competent authority should be defined within the national legal framework of a country. These responsibilities should include:

(a) Development and implementation of all aspects of the Regulations;

(b) Activities in connection with exercising these responsibilities for the safe transport of radioactive material, such as:
   — guidance to applicants
   — safety review and assessment
   — issue of approvals
   — inspection and enforcement
   — provision for reporting of accidents and incidents
   — emergency response
   — co-ordination of research and development activities;

(c) Promotion and/or organization of training courses and seminars concerning the safe transport of radioactive material.
INTERLINKED RESPONSIBILITIES

203. More than one organization may be responsible for the regulatory control of transport in a country, depending on the existing regulations, as well as the mode of transport and the type of radioactive material (e.g. mode dependent package design, fissile or non-fissile materials). Usually, at least radiation protection bodies and government transport offices are involved in the control activities. Where there are several responsible authorities, close co-operation between them is essential, and there should be formal agreements covering the responsibilities of each authority. Each competent authority should establish and maintain liaison with the other governmental and non-governmental organizations having related responsibilities. The competent authority may also be responsible for physical protection and safeguards control of radioactive material. However, these functions may be carried out also by other authorities in accordance with the legal framework of a particular country.

DIVISION OF RESPONSIBILITIES OF THE COMPETENT AUTHORITY

204. There is no ideal or universal organizational model for the competent authority. Its organization depends mainly on the area of responsibility in question and on the general organizational approach in the country concerned. However, to avoid conflicts of interest, it is essential that the competent authority should not be involved in the activities it regulates.

GUIDANCE AND TRAINING

205. The competent authority should provide information and guidance on the safe transport of radioactive material. In particular, specific guidance regarding the presentation of applications for approval may be necessary. In addition, the competent authority may need to ensure that adequate training information and programmes are available so that the staff of users can acquire appropriate levels of knowledge of the regulatory requirements. In order to achieve the aim of full compliance with the regulations, there should be provisions for appropriate training. The competent authority should also sponsor seminars and conferences for the parties involved in the transport of radioactive material. Specifically, the competent authority should provide to the general public adequate information concerning the authority’s safety and regulatory philosophy, organization, procedures and decisions. More information on training is given in Section IV.
INDEPENDENT ASSESSMENT

206. The competent authority shall be able to independently assess and verify the technical and test data submitted by an applicant. This assessment may include nuclear criticality control, heat transfer, radiation protection, structural analysis and risk studies, and all related quality assurance measures.

207. The competent authority may not be entirely self-sufficient in all technical areas. It may delegate some of its specific activities to organizations having the necessary technical abilities. The competent authority may also engage consultants, as necessary. These organizations and consultants shall be independent of the organizations whose work they are evaluating. However, the responsibility for these activities remains with the competent authority, which must evaluate the results of delegated work. Suitable subjects for consultancy are, for example, inspections and material tests, and verification analysis of safety reports.

RESOURCES

208. The competent authority should be provided with adequate resources for carrying out the activities outlined in para. 202. For these activities, the competent authority must have access to expertise in many different fields. The resources and the numbers of staff depend on the nature and extent of the transport operations. Depending on the types of packages that exist or that are expected to be developed within a country, the expertise should specifically include some or all of the following points:

- criticality safety
- radiation safety
- thermal analysis
- structural analysis
- materials and mechanical engineering
- quality assurance and quality control
- emergency preparedness
- transport operations
- inspection and enforcement.

TRAINING OF EMPLOYEES

209. The competent authority should establish and maintain a programme for training of its own employees. Sufficient training to achieve consistency in the
application of the Regulations should be provided. Early in the development of a radioactive material transport industry, training in countries that have such an established industry is of special value. International seminars and conferences are also important for the education and training of employees of the competent authority.

EMERGENCY RESPONSE

210. The competent authority should be provided with adequate resources to respond to transport accidents. This means that the competent authority may have sufficient resources to enable it to completely direct transport emergency response or, alternatively, to act as a co-ordinator/adviser for other agencies.

LIST OF NATIONAL COMPETENT AUTHORITIES

211. A booklet on National Competent Authorities Responsible for Approvals and Authorizations in Respect of the Transport of Radioactive Material is published annually by the IAEA. Competent authorities should ensure that the information given in this booklet is correct and that it is checked annually.

LIAISON OF COMPETENT AUTHORITIES WITH OTHER GOVERNMENT AGENCIES

Liaison concerning the IAEA Regulations

212. As mentioned in paras 203 and 204, the competent authority may consist of an interlinked group of bodies. For example, persons and agencies that may be linked directly with the competent authority for the purpose of transport safety are:

- transportation executives
- dangerous goods executives
- health and safety executives
- radiation protection executives
- justice and police executives
- customs officials
- general post offices
- national research and material testing institutes
- institutions providing training and education.
213. The competent authority should arrange regular meetings for all parties within this potentially complex network in order to ensure:

- An exchange of information regarding the existing regulations, as well as provisions for changes to national laws and regulations, and changes to the IAEA Regulations in the appropriate revision process;
- A complete programme of training at all levels;
- Consistent application of inspection and enforcement relating to compliance assurance;
- A regular review of all emergency response measures, including those of the competent authority, the industry and other relevant agencies;
- A suitable forum for the discussion and solution of problem areas associated with the Regulations and with compliance assurance.

**Liaison concerning other regulations**

214. Clearly, there will be many occasions where the competent authority should have formal agreements with agencies responsible for national regulations that are only indirectly linked with the IAEA Regulations. Examples of such agencies are:

- other technical regulatory authorities
- national agencies involved in safeguards and physical protection of nuclear materials
- customs executives
- environmental agencies
- poisonous waste agencies
- emergency planning agencies.

215. In the case of offices responsible for safeguards and physical protection, the requirements in some countries necessitate total control over all transit, import, export and inland shipments relating to nuclear material. Therefore, some applications in connection with the transfer of nuclear material must be checked by the competent authority in advance to confirm that all packages and proposed shipments are in compliance with the Regulations. These checks are often required whether or not the proposed shipment or package needs approval under the Regulations. In these cases the required liaison between the two supervising authorities is extremely close.

216. Liaison between competent authorities and customs executives can usually be restricted to occasional meetings at which each party is informed of current developments. Particular attention should be paid to the exchange of information when new versions of regulations come into operation. The competent authority should also be prepared to provide telephone consultations for customs officers who are uncertain...
when they are confronted with the complex collection of papers that accompany radioactive material shipments at national customs points.

217. Liaison with environmental offices will normally be arranged on demand. The competent authority should keep such offices generally informed, in order to provide adequate information to the general public, as described in para. 205. In practice, the competent authority is most likely to come into contact with environmental offices when it has to provide written answers to questions relating to specific shipments or incidents, or when it develops emergency plans.

218. The competent authority needs to have a very close liaison with bodies for emergency planning. However, in practice, the plans of such bodies usually concern either the response to dangerous goods accidents in general or the response to emergencies involving nuclear plants, or both. It should not be difficult for the competent authority to agree to an adaptation of the emergency procedures of such bodies in the particular case of accidents during transport of radioactive material. Although the solution to these problems may be relatively simple, it is of utmost importance that the competent authority agrees to the procedures for emergency response and that it initiates a system of periodical review of any such procedures.

Section III
REGULATIONS AND GUIDES

GENERAL

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

NATIONAL REGULATIONS AND GUIDES

302. The authority responsible for promulgating regulations for the transport of radioactive material and the designation of the competent authority should be clearly established in each IAEA Member State.
303. National documents for regulating the transport of radioactive material can in principle be grouped into three main categories, namely:

- legislation and regulation documents
- approval and other mandatory documents
- guides, standards and other advisory documents.

304. National regulations made by the government of a country or by a competent authority on behalf of the government must be based on the appropriate legislation. Mandatory requirements that are not directly covered by the legislation should be given in the regulations. These regulations should define the approval procedures and the essential safety requirements.

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

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

307. In the preparation of national regulations, guides and standards for the transport of radioactive material, all relevant international agreements, regulations and recommendations should be taken into account. The appropriate language should be used in the preparation of such documents 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 nationally accepted language(s), and the accuracy of the translations should be verified.

INTERNATIONAL REGULATIONS AND GUIDELINES

308. The provisions of the IAEA Regulations govern the worldwide transport of radioactive material. The last comprehensive revision of the Regulations led to the publication of the 1985 Edition of Safety Series No. 6; the latest amended issue was
published in 1990. Many supporting documents [2–5] were also published by the IAEA.

309. International bodies have published many general and modal regulations and recommendations on the safe transport of dangerous goods. As far as the transport of radioactive material is concerned, these documents are based on the IAEA Regulations. International regulations and recommendations are given, for example, by the International Civil Aviation Organization [6], the International Maritime Organization [7] and the Universal Postal Union [8]. These regulations and recommendations are updated periodically.

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

— The European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), published by the United Nations Economic Commission of Europe [9];
— The Convention relative aux transports internationaux ferroviaires (COTIF), published by the Central Office for the International Transport by Rail [10];

These agreements and conventions are compatible with the IAEA Regulations.

311. It is important that all international transport operations are conducted under the same regulations. However, a country may need to deviate from, or add to, the provisions of the IAEA Regulations or of other international regulations and guidelines. In this case, the competent authority should communicate these differences to its industry, to other competent authorities with whom its industry is engaged in international transport, and to the IAEA. Such communications should assist in the efficient movement of radioactive material between countries and should minimize any delays or misunderstandings.

312. Peaceful uses of nuclear material are normally assured by the application of the IAEA safeguards, which are based on several international agreements. An introduction to the IAEA safeguards is given in various IAEA documents, for example in Ref. [12].

313. Guidelines for protecting nuclear material during transport against sabotage and theft are given in the IAEA report on Physical Protection of Nuclear Material [13] and in the Convention on the Physical Protection of Nuclear Material [14]. The Convention concerns specifically the international transport of nuclear material and is in conformity with the provisions of Ref. [13].
314. International co-operation is essential when countries are affected by transport accidents. Such accidents or incidents occurring in international waters or airspace will naturally attract international interest and debate, but accidents/incidents happening within a national boundary can also have implications for a neighbouring country, and close co-operation between countries/authorities is invaluable in such circumstances. Some of these accidents are covered by the following conventions:

- Convention on Early Notification of a Nuclear Accident [15]
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency [16].

Section IV
COMPLIANCE ASSURANCE

GENERAL

401. The following guidance will be of assistance specifically to competent authorities which are still developing their compliance assurance programmes; however, competent authorities which have established programmes may also benefit from this guidance. It should assist in the uniform application and interpretation of the international regulations and recommendations.

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

- Review and assessment activities, including the issue of approval certificates;
- Inspection and enforcement;
- Emergency response.

PROVIDING FOR COMPLIANCE ASSURANCE

403. The development and implementation of a compliance assurance programme in a country requires that a number of actions be taken before such a programme
can be considered to operate and, consequently, that reasonable assurance (and evidence) of compliance be provided. In order for a competent authority to provide assurance of compliance it should:

- Create a legal environment in which it can function effectively;
- Organize itself so as to be independent;
- Have an appropriate size and expertise for the activities in connection with radioactive material transport for which it is responsible;
- Issue or revise regulations appropriate to the activities for which it is responsible;
- Develop its own compliance assurance programme and work to it;
- Produce evidence that compliance assurance is being achieved.

404. When a compliance assurance programme has been developed and introduced, it should not be considered to be completed. Instead, the compliance assurance programme should be reviewed periodically by the competent authority in the light of regulatory changes and taking into account experience with the users' performance since the programme was established. While the programme should be updated in a timely fashion when any specific change takes place, it is also desirable that the programme be reviewed periodically in order to ensure that it meets the goals it was designed to achieve. In some cases such reviews may be performed by external groups.

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

406. Compliance assurance programmes may be relatively simple and straightforward or they may be progressively complex and wide ranging, depending on the size and variety of the industry for which the competent authority has responsibility. A simple compliance assurance programme for a State whose radioactive material industry involves, for example, only medical isotope transport activities needs, as a minimum, to take account of:

- Material classification;
- Import/export operations;
- All relevant modes of transport;
- All package types and associated certificates;
- A low volume of movements;
- End disposal of packaging.
407. A more complex compliance assurance programme will be needed for a State whose radioactive material industry involves all types of radioactive material movements. Such a programme would need to take additional account of:

- Package design, manufacture and maintenance;
- A high volume of movements.

408. Irrespective of the size or complexity of the competent authority or its industry, the three fundamental activities mentioned in para. 402 must be addressed in the compliance assurance programme according to the complexity and variety of the particular responsibilities of the competent authority.

METHODS OF ASSURANCE AND INSPECTION

409. Assurance of regulatory compliance and the associated inspections can be carried out in a variety of ways, examples of which are listed below:

- Issue of competent authority approvals;
- Assessment of package designs;
- Assessment and approval of quality assurance programmes;
- Witnessing/inspection of testing arrangements;
- Observation of manufacture;
- Examination of maintenance and servicing arrangements;
- Inspection/observation of transport operations;
- Inspection/observation of emergency arrangements;
- Distribution of information (communication with industry);
- Application of enforcement measures, such as
  - written notices
  - suspensions
  - prosecutions;
- Interdepartmental liaison/co-operation;
- Review of regulations (national and international);
- Review of the compliance assurance programme of the competent authority.

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

ISSUE OF COMPETENT AUTHORITY APPROVALS

410. The Regulations distinguish between cases where the transport of radioactive material can be made without competent authority approval and cases where some
kind of approval is required. In both cases the Regulations place the primary responsibility for compliance on the consignor. In the second case an independent assessment by the competent authority is required, as appropriate, in respect of special form radioactive material, packages containing fissile materials, Type B packages, special arrangements, certain shipments, radiation protection programmes for special use vessels, and the calculation of unlisted $A_1$ and $A_2$ values. As described in Section VII of the Regulations, certain shipments and items are subject to the specific approval of a competent authority or of several competent authorities.

411. Within the provisions of the national legislation or regulations, approval for the transport of radioactive material should be given directly by the competent authority in the cases referred to in para. 410.

412. The respective responsibilities and the relationship between the competent authority and the applicant or licensee need to be clearly understood. It is the responsibility of the applicant/licensee to demonstrate compliance with the regulations in force, and it is the responsibility of the competent authority to review and assess compliance. This should not discourage or prohibit the competent authority from giving informal advice, without commitment, as to what is likely to be an acceptable way of demonstrating compliance. However, independence and objectivity must be maintained by the competent authority.

413. Upon receipt of an application for approval, the competent authority should evaluate whether or not all relevant requirements are fulfilled and whether the applicant and other organizations involved are competent and capable to meet in practice the regulatory requirements. A competent authority may also be interested in the safety of a shipment, within or through its country, for which its approval is not required according to the Regulations. If this is the case, all necessary documents must be available to that competent authority.

414. When shipment approval by the competent authority is required, that approval should be considered on the basis of the assessment of the application sent to the competent authority. The application should include the items described in Annex II.

415. For each application, the competent authority should evaluate compliance with the regulatory requirements. On the basis of the results of the evaluation, the shipment or shipments should be accepted or rejected. The competent authority should give an approval certificate (see Section VII of the Regulations and Annex III of this book).
416. Consistent with the requirements of para. 209 of the Regulations, quality assurance programmes are necessary for transport and in-transit operations. The competent authority should verify that such programmes provide for compliance with the Regulations and that they are consistent with the number, complexity and radiological significance of the actual transport movements.

417. The competent authority should verify that applicants and subsequently consignors and carriers have adequate emergency planning provisions.

418. When considering applications for approvals of special arrangements the competent authority should assess the applicant's demonstration that the overall level of safety provided by the package design 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 are discussed, for example, in Ref. [3] (para. A-712).

419. The types of approval certificate are discussed in greater detail in Section V, and specific information to be included in applications for approvals is given in Annex II. It is essential that the competent authority complies with the Regulations when it considers applications for approval and that it issues appropriate certificates of approval giving all the required information. Appropriate records should be maintained by the competent authority to demonstrate that correct and due consideration was given to each application before the necessary approval was issued.

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

SPECIAL FORM RADIOACTIVE MATERIAL

421. The Regulations require unilateral approvals in respect of special form radioactive material (SFRM) to be issued by the competent authority of the country in which the SFRM was designed. There are, however, some options or variations in the testing of SFRM, and the competent authority should ensure that the methods used are in compliance with para. 611 of the Regulations.

422. The competent authority should satisfy itself that the quality assurance arrangements for the design, testing and manufacture of SFRM are appropriate and adequate, having due regard to the nature of the material and the numbers/quantities that are likely to be produced.
423. The competent authority may inspect the test facilities and arrangements before actual testing is carried out, especially the specimens, the target and the measuring system. The competent authority may also witness the tests, and the applicant must point out any deviation from the testing plan and present the testing results, for example evidence of leakage, distortion or other damage.

424. The final application for approval of the design of SFRM should be sent to the competent authority. The application should include, among other subjects as described in Annex II, the final test programme and the testing results, which need to be evaluated by the applicant. The application should specify the requirements for the individual SFRM and demonstrate that the regulatory requirements for SFRM are met.

425. The competent authority should give consideration to the design life, the working life and the necessary identifications of SFRM, as well as the in-service inspections and safety checks to be made in order to assure the continued integrity of SFRM.

426. When the competent authority has verified that the design of SFRM meets all the valid regulations, it will issue an approval certificate. Examples of certificates are given in Annex III.

427. During the manufacture of SFRM the competent authority should carry out random inspections to ensure that all the requirements have been correctly implemented.

PACKAGES REQUIRING COMPETENT AUTHORITY APPROVAL AND PACKAGE DESIGN ASSESSMENT

428. The competent authority may discuss the development and the proposed tests of a package with the applicant on the basis of preliminary information. The preliminary information may cover the topics described in Annex II. Specifically, it may include the testing plan of the package, stating clearly the model scale, the requirements and specifications of the model, the number of tests proposed, the drop attitudes of packages, the essential measuring and recording equipment to be used and the nature of the target. The information may also cover the quality assurance requirements for design and testing. If there is no need for further testing, the final application should be sent to the competent authority for approval (see para. 432).

429. The competent authority should pay attention to the special features of the package design, as well as to the testing plan. If it is proposed to use a scale model
specimen, it should be ensured that all relevant features are adequately scaled and represented, including materials, contents and internal structures. The adequacy of the means proposed to establish compliance with the acceptance limits should be reviewed. Account should be taken of instrumentation for the measurement of local accelerations, strains, internal pressure transients, etc.

430. The competent authority should verify that the manufacture of the models or prototypes is carried out in a controlled and quality assured manner so that they are representative of the proposed package design. Special attention should be given to materials, welding and inspections, as well as quality control results. Any deviations from the requirements and specifications should be noted.

431. Before the commencement of tests by the applicant, the competent authority should inspect the testing arrangements, especially the specimen, the target and the measuring system. The competent authority may also witness the tests. The applicant should inform the competent authority of all deviations from the test plan, as well as the testing results, for example evidence of leakage, distortion or any other damage.

432. The final application for approval of the package design should be sent to the competent authority. The application should include, among other subjects as described in Annex II, the final test programme and the testing results, after they have been evaluated. The application should specify in particular the requirements for the series production of packages and their proper maintenance and use. Specifically, the applicant should demonstrate that the requirements for the package type in question are met. The following aspects should be included, if appropriate, and should be verified by analyses (in normal and accident conditions):

- criticality safety
- heat transfer
- radiation safety (including shielding)
- structural integrity.

According to the Regulations, compliance with the specific test requirements may also be demonstrated by analyses if suitable criteria or established data already exist.

433. When assessing safety the competent authority should, as appropriate, make independent assessments to verify the results presented in the application. In making such assessments, the competent authority should ensure that proper codes and models have been used, that they have been adequately verified by appropriate experiments and that all input data have been defined conservatively. Depending on the package type, expertise in different areas is needed. The evaluation should also cover specifically the applicant’s or designer’s provisions for manufacture, servicing, maintenance and use of the package.
434. When assessing package design applications the competent authority should ensure that full and proper provision is made for the application, legibility and durability of identification marks and serial numbers, as well as for the proper notification of the competent authority regarding serial numbers of packages. This is particularly important in cases where multiple or interchangeable packaging components are used.

435. In the case of applications for full approval with regard to the current Regulations concerning designs previously approved under the 1967, 1973 and 1973 (As Amended) Regulations, the competent authority should fully evaluate the design against all appropriate aspects of the current Regulations. This may involve an in-depth ‘design review’ of the materials and manufacturing methods, as well as of the testing and quality assurance applied to the original design of packages. Similarly, when changes as described in paras 713 and 714 of the Regulations are made, the competent authority should ensure that all appropriate aspects of the design and of the manufactured packaging are evaluated against the requirements of the current Regulations.

436. The design of the package type in question should be accepted, or rejected, on the basis of the evaluation results. An approval certificate should be issued by the competent authority. More detailed guidelines on certification are given in Section V and in Annex III.

APPROVAL OF SPECIAL ARRANGEMENTS

437. The Regulations prescribe that when a consignment does not satisfy the applicable requirements, it may be transported under a special arrangement. In this case the competent authority issues a special arrangement approval certificate, as prescribed in para. 722 of the Regulations. Moreover, for international shipments of this type, multilateral approval is required.

438. For a special arrangement the applicant should be able to demonstrate to the competent authority that if the proposed provisions for transport and storage in transit are fulfilled, there is an acceptable degree of confidence that a level of safety equivalent to that required by the Regulations shall be achieved.

439. The competent authority should carefully evaluate the provisions for design and operation control submitted to it by the applicant for approval, but it should not take part in such control activities in order to maintain its objectivity.
440. The information submitted by the applicant for approval of a special arrangement should include, as appropriate:

- The necessary information related to the particular package design;
- The applicable requirements of the Regulations that the consignment does not comply with;
- The reasons why the consignment cannot be made in full accordance with the applicable requirements of the Regulations;
- The design, operational, administrative or special provisions to be employed during transport and storage in transit to compensate for the inability to meet the applicable requirements of the Regulations.

PACKAGES NOT REQUIRING COMPETENT AUTHORITY APPROVAL

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

442. Despite the reduced involvement of the competent authority in respect of packages not requiring certification, the following subjects should be considered in a compliance assurance programme:

- quality assurance programme
- design and internal approval process
- manufacturing control
- maintenance programme (in the case of reusable packagings).

IDENTIFICATION OF PACKAGES AND SERIAL NUMBERS OF PACKAGINGS

443. For the safe transport of radioactive material it is of fundamental importance that, once packagings have been correctly designed, assessed and manufactured, they are correctly identified throughout their working life. The Regulations specify the competent authority identification marks, serial numbers of packagings and markings of the package types that should be present during transport; Safety Series No. 37 [3] gives further advice on the legibility, durability and positioning of such markings. During its compliance assurance activities the competent authority should take every opportunity to verify that all required markings, serial numbers and identification marks are correctly, durably and appropriately applied.

444. The scheduled inspection and maintenance programme required for packagings should include provisions for inspecting and, if necessary, correcting all
permanent markings and for repairing any damage or defects. Such inspections will show whether durability has been achieved in practice.

445. The competent authority should control the allocation of the required identification marks and advise its applicants of the allocation process. These identification marks can be assigned readily by the competent authority during the preliminary design assessment or evaluation phase. Such an arrangement should prevent that two or more different designs of packages entering service have the same identification marks. The competent authority should also communicate to its transport industry recommendations for the self-allocation/determination of identification/design numbers for package designs not subject to competent authority approval, to avoid confusion in transport and in emergency situations.

446. The packaging serial number should uniquely identify each packaging manufactured. For packagings manufactured to an approved Type B(U) or Type B(M) package design, or for fissile material package design, the appropriate competent authority should be informed of the serial number. In this case, the term ‘appropriate’ has a broad interpretation and could pertain to any of the following:

— the competent authority of the country where the packaging design originated
— the competent authority of the country where the packaging was manufactured
— the competent authority of the country or countries where the packaging is used.

In the case of packagings approved for continued use under paras 713 and 714 of the Regulations, all competent authorities involved in the multilateral approval process should receive and maintain information on packaging serial numbers.

447. An approved package design may be such that different internal components are used with a single outermost component, or that the internal components of the packaging are interchangeable between more than one outermost component. In these cases, each outermost component of the packaging with a unique serial number will identify the packaging as an assembly of components; this satisfies the requirements of para. 438(b) of the Regulations, provided that the assembly of components is in accordance with the design approved by the competent authorities. In such cases, the correct identification and use of these components should be ensured by the quality assurance programme established by the consignor.

RADIATION PROTECTION

448. Paragraphs 201 to 205 of the Regulations prescribe the general principles for radiation protection in transport of radioactive material. Through its compliance
assurance programme the competent authority should ensure that the provisions are met.

449. Appropriate radiation monitoring equipment needs to be used, as well as appropriate equipment and containers for samples of radioactive material to be analysed. The equipment should be calibrated and maintained, and the staff using it should be adequately trained and qualified. Where necessary, information on radiation protection programmes should be required to be included in the applications for approval. Further, the places where radioactive material is handled/stored must be segregated sufficiently from places occupied by transport workers and members of the public (see para. 205 of the Regulations). The competent authority should ensure that the parameters for calculating the segregation distances are properly determined. The competent authority should ensure through inspections that the requirements for all modes of transport are met in practice.

450. The radiation protection principles of the Regulations require that radiation exposures from the handling, storage and transport of radioactive material shall be kept as low as reasonably achievable, with economic and social factors being taken into account (optimization of radiation protection). The competent authority should ensure through a compliance assurance programme that this requirement is met. More guidance on the optimization of radiation protection during transport of radioactive material is given in Ref. [17].

451. The competent authority is required to arrange periodic assessments to evaluate the radiation doses to workers and to members of the public due to the transport of radioactive material (para. 203 of the Regulations). In these assessments the competent authority could use the data from those consignors and carriers who need to assess the doses arising from their transport operations. The competent authority should independently verify the data received from the consignors and carriers. Questionnaires, analyses, site visits and measurements may be used to assess the doses.

RADIOACTIVE MATERIAL HAVING OTHER DANGEROUS PROPERTIES

452. In addition to posing radiological hazards, radioactive material may have other dangerous properties that may pose additional hazards, for example chemical toxicity and corrosiveness. These properties are known as 'subsidiary hazards' in international regulations and recommendations for the transport of dangerous goods (see Refs [6-11] and Ref. [18]).
453. The Regulations stipulate provisions against radiological and criticality hazards of radioactive material; in addition, they require that national regulations and international requirements for the transport of dangerous goods also apply for radioactive material having other dangerous properties. The competent authority should ensure that adequate national regulations exist for the transport of dangerous goods and that they are also followed in practice during the transport of radioactive material posing subsidiary hazards. This may involve liaison and co-operation between the competent authority and any other government or federal departments being responsible in such matters, to ensure that all primary and subsidiary hazards are properly recognized and provided for, and also that in the various inspections carried out by different departments or inspectors a true perspective of the relative importance of the hazard is maintained.

QUALITY ASSURANCE IN SUPPORT OF COMPLIANCE ASSURANCE

454. It is expected that competent authorities will need to make increasing use of quality assurance in assuring compliance with the Regulations (see, for example, Annex IV). Paragraph 209 of the Regulations, which requires that quality assurance programmes shall be established for all packages and all aspects of transport, has considerable significance. Where approval for package design and use is needed, the competent authority is required (para. 209) to consider the appropriate quality assurance programme(s). Therefore, in a compliance assurance programme the competent authority has to make considerable efforts to assess the user’s application of quality assurance in the design, procurement, manufacture, testing, inspection, use and maintenance of packages and packagings.

455. It is recognized that quality assurance plays an important part in the efforts of the competent authority to achieve full assurance of compliance with the Regulations because:

(a) For all aspects of radioactive material transport, appropriate quality assurance programmes are needed;
(b) Quality assurance is a management tool or management control system;
(c) Quality assurance can be used to demonstrate compliance;
(d) Quality assurance can assist in self-correction or self-improvement;
(e) Quality assurance techniques can be used by the competent authority;
(f) The application and use of quality assurance can promote public confidence in radioactive material transport operations.

456. The competent authority should use the quality assurance practiced by the industry in support of its own compliance assurance efforts. When applications for
approval are received by the competent authority, the existing quality assurance programme(s) should be examined and verified. This may involve a relatively straightforward quality assurance programme; it may also involve more complex interacting programmes if design, testing, manufacture, use, servicing and maintenance are carried out by different organizations, each with their own, separate quality assurance arrangements. Matters can be further complicated if one organization’s individual quality assurance programme applies to the design, testing, manufacture, etc., of a range of packages, but with individual quality plans being applicable to each separate package design or type. The competent authority may confirm the adequacy of the quality assurance arrangements not only by examining the actual written programmes and plans but also by auditing the arrangements in order to verify their correct functioning. When the competent authority has confirmed the existence of satisfactory quality assurance arrangements, it can issue an approval certificate, which specifies the quality assurance programme(s) concerned. The interest in quality assurance does not end with the issue of a certificate; further action should be taken to ensure that the packages concerned continue to comply with the approved specification. It is considered most important that the original design and its approval not be compromised in subsequent use. The competent authority should therefore further examine or audit the quality assurance programmes applied to all post-manufacturing transport operations, such as servicing, maintenance, modification and use.

457. The competent authority should have an auditing programme to determine that the quality assurance programmes are implemented and followed correctly. The quality assurance programmes used by designers and manufacturers, and by users of Type B packages and packages containing fissile materials will be of particular interest to the competent authority. However, the competent authority should also ensure by periodic audits that suitable quality assurance programmes are implemented in the transport of other types of packages. In determining the auditing programme the continuity of the activity in question should also be taken into account, i.e. the programme may be different for the manufacture of a single package and for the continuous manufacture of packages.

458. The auditing programme may cover all aspects identified in Appendix IV of Safety Series No. 37 [3]. Further detailed information on the auditing of quality assurance programmes is given in Annex V of this book. The competent authority should place special emphasis on quality assurance activities before the manufacture of packagings begins.

459. Irrespective of the size of the organization concerned or of its scale of activities, the competent authority should verify through audits that, consistent with the recommendations given in Appendices IV and V of Safety Series No. 37 [3], the
quality assurance programme of the applicant, designer, manufacturer and/or user is based on:

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

460. The extent of the quality assurance programmes will depend on the type of transport activities being considered, ranging from minor requirements for infrequent transport of packages excepted from approval by the competent authority to extensive detailed requirements for regular transport of packages subject to such approval. Appendix V of Safety Series No. 37 [3] gives guidance on how to address each aspect of quality assurance; this is presented in the form of a chart. Each quality assurance programme should be available for review and audit by the respective competent authority or by another relevant authority.

461. In verifying the effectiveness of the quality assurance arrangements of a user, the competent authority will inspect procedures, records and facilities, especially those in which designers and manufacturers perform their operations. The purpose of this verification is to ascertain that:

(a) The design of a package is unequivocally described by engineering drawings, material specifications and records of the methods of construction. (Note: For package designs requiring competent authority approval, this information is a necessary part of the application for the approval certificate. For other package designs the information should be provided by the user upon request by the competent authority.)
(b) The packagings are manufactured in complete accordance with the design. (Note: For package designs requiring competent authority approval, changes in the packaging construction methods, the materials of construction, etc., are subject to the approval of the competent authority. For other package designs, such changes should be documented and made available to the competent authority upon request. This applies equally to new package designs and to packagings in service.)
(c) Test and manufacturing equipment is properly controlled, suitable for its purpose, calibrated, and used and maintained in accordance with written procedures and schedules, with all results completely documented.
(d) The packages are being correctly prepared, packed and transported. This includes all necessary servicing, maintenance and other administrative procedures, as well as appropriate radiological protection measures.

(e) All non-conformances are correctly documented and reviewed, and accepted or rejected.

TRANSPORT INSPECTIONS

462. A major feature of any competent authority's compliance assurance programme will be the performance of inspections of the transport operations, since these inspections can be used to monitor both the adequacy of the various regulations and the degree of compliance with those regulations by the user, as well as to produce evidence of compliance. Such inspections can be carried out during any phase of the transport or during storage in transit and can be announced or unannounced. They should, however, be planned (as far as possible), and their frequency should be determined by the scope and activities of the organization being inspected, as well as by their complexity and radiological significance. Examples of check lists that could be used for this type of inspection are given in Annexes VI and VII.

463. Transport inspections should be carried out by the competent authority or by its nominated agent. In some countries such inspections are carried out on a modal basis, by examining all types of dangerous goods, with the aviation authority inspecting air shipments, the maritime department inspecting marine shipments, etc. The competent authority acts as an adviser and co-ordinator. It is important that all types and aspects of transport, consistent with the size of the radioactive material transport industry within a country, are periodically inspected.

464. During inspections of the user's activities the competent authority or its agent will usually direct specific attention to assuring that:

(a) The user's management has provided the necessary personnel and resources to carry out an effective programme for compliance with the Regulations. For this programme, which may also be the quality assurance programme, those persons who are responsible for fulfilling the various specific requirements and who are capable of doing this should be clearly identified. Clear delegation of authority by the management to those responsible persons is essential.

(b) The user's management has provided the proper training of those persons who are responsible for carrying out the programme for compliance with the Regulations. Documentation of the training that has been provided should be submitted to the competent authority upon request.
(c) The consignor is using the proper packaging for the specific contents of packages. The packages being prepared for shipment should be examined by the competent authority, where practicable.

(d) The user has in his possession all of the required documentation, including the relevant competent authority certificates and any associated instructions for handling, loading, stowage and use of packages, and for maintenance of packagings. These instructions are most often in the form of an instruction manual.

(e) The user follows established procedures for the preparation and use of the packages, in accordance with the approval certificate, the instruction manual and related documents.

(f) Procedures are established and followed to properly mark and label packages in accordance with the Regulations. This includes the proper determination and application of the correct transport index. When practicable, the competent authority should observe these actions by the user.

(g) Procedures are established and followed, and appropriate and properly calibrated instruments are provided to monitor both the radiation and contamination of packages.

(h) Procedures are established and followed for correct preparation and control of all relevant shipping documents, as well as for provision of the correct placarding of the carrier's vehicles, of the required documentation for carriers, and of any required notification of the competent authorities of each country into which or through which the consignment is transported.

(i) During transport, carriers are performing the required actions relating to placarding, stowage and separation of packages, etc., particularly any administrative controls relating to exclusive use shipments or to supplementary operational controls as specified in the competent authority approval certificate.

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

466. Within its compliance assurance programme and the associated inspections of transport operations, the competent authority should also consider the occasionally different requirements that apply to freight containers and tanks. Other international conventions and standards concerning these types of packages should also be taken into account (see, for example, Refs [7, 9, 19]). The guidance given in this book is equally applicable to transport operations involving freight containers and tanks.

467. The specific provisions for notification are prescribed in paras 455-458 of the Regulations. The competent authority may request additional notification before a
package is shipped or after it has been received so that plans can be made for certain inspections. The need for further notification should be determined by the package types and the number of shipments.

468. The competent authority should analyse the reports of all relevant inspections as well as their findings. This analysis will help the competent authority to decide whether the performance of the user and the compliance with the Regulations are satisfactory. It will also assist in detecting unsatisfactory performance or trends and enable the competent authority to take whatever action it considers appropriate to restore a satisfactory situation, thereby continuing to assure compliance. All inspection reports should be retained by the competent authority for an appropriate time, because they constitute part of the evidence of compliance as required by para. 210 of the Regulations.

469. If, as a result of transport inspection or of any other actions, an unsatisfactory situation or a case of non-compliance comes to the attention of the competent authority or its agent, it is essential to follow up on the matter, to determine the real cause of the problem and to initiate suitable action to prevent its recurrence. Certain enforcement actions (discussed in paras 4114–4119) may be necessary if non-compliance is discovered. On the other hand, a more informal educational approach by the competent authority may be more appropriate.

RESPONSIBILITIES AND ACTIONS OF CONSIGNORS

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

471. The competent authority should be provided with the legal means that enable it to determine that the consignor’s responsibilities, as defined in paras 446–459 of the Regulations, are clearly understood and followed by all consignors of radioactive material. The competent authority should be able to verify that:

(a) The consignor has an appropriate and functioning quality assurance programme covering all aspects of his transport management responsibilities and activities.
(For example, if a consignor consigns only one type of package infrequently, he may control and carry out all activities directly. Another consignor, who produces or reuses a large number of different package types, may use different contractors for different parts of the work, but their activities must be provided for and controlled by the consignor's quality assurance programme.)

(b) The consignor has an appropriate and clear understanding of the radioactive material to be consigned, including its nature, form and activity. (For example, the consignor often prepares the material for loading/filling and carries out that operation; for some materials, such as uranium hexafluoride or spent nuclear fuel, this is done in accordance with detailed procedures. For the preparation of radiopharmaceutical and industrial radioactive sources prior to transport, relevant knowledge and procedures are also needed.)

(c) The consignor has filled or loaded the material into the packaging for transport in a correct way. (For example, this could involve verifying that the contents of the package have been positioned correctly within the packaging to maximize the shielding protection afforded by the packaging; it could also involve verifying that the specified quantities, pressures and densities within the package are correct.)

(d) The consignor has correctly identified and used a suitable packaging for which there is an appropriate valid approval certificate. (For example, package design approvals should be valid for the duration of the complete journey and should not expire in the course of a long international transport. Also, the approval certificate or the series of certificates should cover the whole radioactive contents permitted to be carried; the consignor must have available the particular certificate for the contents being transported.)

(e) The consignor has the relevant packing instructions for the package (when applicable); copies of these instructions must be available at the location where the package is prepared for transport. (For example, packing instructions are very often specified in competent authority approval certificates; usually, these give detailed information and instruction on the loading configuration of the contents, the closure methods and the tightening torques of fasteners, etc. Such packing instructions must be complied with, so that transport safety is preserved and the competent authority approval is not invalidated.)

(f) The consignor has procedures in operation which ensure that the packaging used for transport conforms (or does not conform) to the specification indicated on the approval certificate and is in an acceptable condition. (For example, in the case of new packagings the consignor should have evidence, such as certificates of conformity, inspection reports, etc., that the
packagings conform to the specification quoted on the approval certificate. In the case of reusable packagings the consignor should have evidence, in the form of inspection reports, release notes, certificates of conformity, etc., that all necessary and specified servicing and maintenance work has been carried out and that the package is suitable for the next complete transport operation or programme of movements. The consignor’s procedures should prevent use of a package that does not comply with the approved specifications or that has not been subjected to the required and specified servicing and maintenance.)

(g) The consignor is able to determine, complete and apply the correct labels for packages and he also understands what other markings should be featured on the package when it is presented for transport. (For example, the consignor should be able to demonstrate to the competent authority that he knows the appropriate ways to determine the transport index and has correctly functioning and calibrated monitoring instruments for measuring the radiation levels of the package, the overpack, the freight container, etc. The consignor should also know what other kinds of markings, such as competent authority identification marks, should appear on the package, how they are derived and how durable they should be.)

(h) The consignor has appropriate knowledge and instruments to carry out the necessary relevant measurements and contamination checks associated with the transport of radioactive material. (For example, the consignor or the person (organization) under the consignor’s control should be able to satisfy the competent authority that he (it) is capable of carrying out valid, calibrated measurements of radiation and contamination levels to ensure radiation and transport safety.)

(i) The consignor has the necessary licences or other permissions, granted by the competent authority or by other federal/government departments, to function as a consignor of radioactive material. Also, the competent authority should be satisfied that the consignor is able to determine the applicable current transport approvals. (For example, in some countries it is necessary for the consignor to obtain appropriate permissions or licences from the responsible organization(s) to be able to legally consign or transport radioactive material; this is particularly important for the movement of radioactive material in cases where safeguards and physical protection considerations apply. The consignor should also have available the relevant package design approval of the competent authority and other approvals for inspection by another competent authority, if necessary.)

(j) The consignor is able to obtain and complete the necessary transport documents, giving the appropriate information as required in paras 447–451 of the Regulations. The consignor should also provide the necessary transport docu-
ments to enable the subsequent carrier(s) to meet any other applicable national or international modal regulations; he should maintain records of consignments for an agreed time period.

(For example, during competent authority inspections it should be verified that pertinent and accurate information is given in the transport documents, which are sometimes called shipper's certificates or consignment notes. These documents are provided by the consignor, who should have suitable evidence/records from his quality assurance programme to substantiate the declared details. These transport documents should also take account of any variations imposed by national or international modal regulations, and the consignor should be able to demonstrate his understanding of these regulations to the competent authority. It should also be verified that the transport documents cover the whole journey of the package(s) and are not consigned to an airport or a port of entry/exit.)

(k) The consignor provides sufficient information and documents to the carrier(s) to enable the package(s) to be carried safely and in compliance with the Regulations.

(For example, the provision of essential information/documents to carriers can be verified by the competent authority during its inspections of both the consignor and the carrier. It is particularly important that all applicable transport or in-transit operational requirements, all restrictions on the mode of transport or conveyance, all necessary routing restrictions, or the appropriate arrangements in the event of an emergency or mishap are clearly understood and can be put into effect without misunderstanding.)

(l) The consignor is able to determine when it is necessary to notify the competent authorities of transport movements and understands the importance of such notifications.

(For example, through its inspections of consignors and its liaison with other competent authorities the responsible competent authority should verify that the required notifications are being made.)

(m) The consignor has dispatched or is capable of dispatching a package or consignment in compliance with the Regulations.

(For example, the competent authority should verify that the consignor's quality assurance programme provides evidence that all necessary pre-dispatch activities have been identified and completed, and that the declaration and signature of the final consignor is valid and meaningful.)

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ACTIONS AND OPERATIONS OF CARRIERS

472. According to the Regulations, the consignor has the primary responsibility for transport safety; he has to ensure safety through his package selection and preparation procedures. The carrier(s) (there may be several carriers for one international transport operation) should ensure that his (their) contribution to transport safety is complementary to the efforts of the consignor and that overall transport safety is not compromised as a result of the carriage operations.

473. Although the Regulations do not identify specific responsibilities for carriers, it should be ensured, for example by contract, that:

(a) The carrier has an appropriate and functioning quality assurance programme, covering all relevant aspects of his transport management responsibilities and activities.
   (For example, a carrier who carries only one type of package occasionally, using one mode of transport within national boundaries, may have a relatively simple quality assurance programme, whereas a national or international carrier who carries large numbers of packages frequently and operates a multi-modal carriage and distribution service will need a more comprehensive quality assurance programme to control his activities and provide the necessary assurances.)

(b) The carrier has sufficient knowledge of national and international regulations to be aware of the information and documents that he should receive from the consignor.
   (For example, the carrier should be able to demonstrate his knowledge and understanding of the applicable Regulations and his way of checking the validity and accuracy of the transport documents.)

(c) The carrier has the ability and resources to respond to any additional specified requirements concerning loading, stowage, transport, handling and unloading of packages, as well as the ability to recognize and comply with any restrictions on routing, conveyance or mode of transport.
   (For example, the carrier should be able to demonstrate that the means of conveyance used, such as trucks and railway wagons, have the necessary facilities/equipment for achieving secure tie-down arrangements and that, if additional speed limits are specified, they are complied with. Also, if escort vehicles and personnel are required by the transport approval or other regulations, the carrier should satisfy the competent authority that he can provide them.)

(d) The carrier is able to recognize damaged or ill prepared packages, is familiar with all appropriate placards, package labels and markings, understands their
meaning and purpose, and can relate the information displayed to the details given in the transport documents.

(For example, the carrier should have appropriate procedures and the necessary understanding to ensure that any damaged, ill 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 are conducted.)

(e) The carrier operates 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 transport index limitations, etc.; also, the placards or labels on the packages must have the appropriate number, type and size.

(f) The carrier has appropriate emergency arrangements for the types of radioactive material he is carrying and the type of conveyance being used.

(For example, the carrier may have his own emergency arrangements; alternatively, he may participate in or use the consignor's emergency arrangements or other national emergency schemes/arrangements. Whatever emergency arrangements apply, the carrier should be able to demonstrate suitable familiarity and understanding in such matters, and all personnel involved should have received the necessary training.)

(g) The carrier has provided for appropriate control of operations in connection with storage in transit, with particular regard to the safety of workers and the public, and has also provided for the control of radiation exposure and the necessary segregation of the radioactive material from other dangerous goods.

(For example, the carrier should not allow radioactive material to be stored during transit in places occupied by workers or other persons or in places where photographic film is stored. The carrier should be able to demonstrate that he knows and controls the number of category II–Yellow and category III–Yellow packages, etc., that may be stored in certain areas.)

474. The examples given in paras 464, 471 and 473 should not be considered to be exhaustive, and other examples can be added in the light of knowledge and experience.

DESIGN ASSESSMENTS

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

476. Section V of the Regulations specifies requirements for all packagings, packages, special form radioactive material and low specific activity (LSA) material; the resultant designs can be assessed in respect of their compliance with the regulatory requirements. In the case of designs specified in paras 701(a), (b) and (c) of the Regulations, competent authority approval is necessary and hence the design must be assessed by the competent authority or its agent.

477. It is the responsibility of the competent authority to determine that the designs of packages are assessed against all the relevant parts of the Regulations. Therefore, the competent authority or its agent should not only conduct assessments of ‘designs’, if appropriate, but it should also ensure that similar assessments of package designs which do not require competent authority approval (such as Type A packages or industrial packages) are carried out by the appropriate organizations and that the necessary evidence of such assessments is available to the competent authority, if requested.

478. Irrespective of who is carrying out the design assessment, the assessor must be aware of the basic aims of the Regulations and must very carefully consider any aspect of the design, however remote, that could adversely affect:

- effective containment of the radioactive material
- effective control of radiation emitted from the package
- maintenance of a subcritical condition for any fissile material
- adequate dissipation of heat generated within the package.

479. The applicant (or designer) seeking approval should give the assessor all necessary information, including the documents demonstrating that the design meets all regulatory requirements. The assessor should be clearly independent of the applicant and should not be expected ‘to make the case’ for the applicant. However, the assessor should encourage early contact with the applicant/designer, even in the preliminary design feasibility stages (i.e. before formal application for approval is made), to discuss the application and implementation of any novel and other relevant design features or principles, so avoiding unnecessary or wasted effort by both parties involved.
480. Assessments by competent authorities of package designs requiring approval are usually more demanding with regard to the resources, skills and expertise to be employed. These can be considered separately as follows:

(a) The assessor should have a thorough knowledge of the Regulations pertinent to the design under assessment.

(b) The assessor should examine in detail the shielding features and radiation safety aspects of the design; he should satisfy himself that with regard to the maximum proposed radioactive contents the design of the finished package will provide sufficient radiological shielding in all dimensional planes to comply with the relevant Regulations and the ALARA philosophy. The assessor should satisfy himself that the material used for shielding is physically and chemically stable and is not likely to move or deteriorate during transport, since this would decrease the degree of shielding provided by the packagings. Particular care should be taken to verify the absence of any ‘shine paths’ through package closures and ports used for package testing. The need to decontaminate the packagings in use should also be considered, and the creation of contamination traps or the use of materials that are difficult to decontaminate should be avoided in the design.

(c) The assessor should thoroughly examine the thermal aspects of the package design; he should consider both the dissipation of heat in normal transport conditions and the absorption of heat in thermal test conditions. Thermal stresses should be analysed to ensure that leaktightness or mechanical properties of the package are not unduly compromised in normal transport or in thermal test conditions. Any computer codes or other calculational techniques used should be verified by the assessor and confirmed to be appropriate, valid and quality assured.

(d) The assessor should thoroughly examine all aspects of containment provided by the package. He should also consider those features of the design which provide for containment and should investigate how they might be adversely affected by normal transport operations, by the prescribed servicing/maintenance periods and instructions, as well as by the effects of accident conditions and related testing.

(e) The assessor should thoroughly examine the design and supporting documents to ensure that all factors pertinent to nuclear safety of the design have been identified and addressed, and that the design is safe under normal and accident conditions. The assessor should also confirm that computer codes or other calculational methods used by the applicant are appropriate, valid and quality assured.

(f) The assessor should examine all physical and mechanical aspects of the package design in order to confirm that the package will be physically able to safely carry the specified radioactive material under both normal and accident
conditions (this includes tie-down points, trunnions, etc.). The assessor should be able to analyse the package’s structural attributes and should confirm that any impact or other damage which the package may sustain in normal or accident conditions will not compromise its ability to meet the post-accident condition requirements of the Regulations.

(g) The assessor should examine all materials intended for use in the package design, with regard to their correct specification and condition, their ability to perform satisfactorily under all expected and specified environmental conditions (temperature, pressure, irradiation, humidity, etc.) and their compatibility with other materials used.

(h) The assessor should examine the in-service handling, inspection, maintenance and servicing instructions in sufficient depth to confirm that all such instructions/specifications are accurate and adequate, and that they will allow the original designer’s intentions for the package to be upheld and not to be compromised. These ‘in-service’ instructions/specifications should also provide for authorized repairs/modifications of the packaging, and the repair/ modification procedures must be agreed to or approved by the competent authority’s assessor. (The assessor should also bear in mind that such package instructions may well have to be followed by persons and organizations who, as consignees, may be unfamiliar with the package and its design principles.)

(i) When scale modelling is used in testing to support an application for approval, the assessor should confirm that all scaling factors are taken into account, with all pertinent package design features being accurately represented.

(j) At the commencement of the design assessment the assessor should be satisfied that appropriate levels of quality assurance have been applied throughout the design process, and appropriate evidence of this should be made available to the assessor.

481. Where a number of very similar package designs exists, the assessor may make comparisons related to final acceptability, but only after the detailed differences have been identified and accepted as being of minor or known significance.

TESTING

482. It is often necessary to test packages and scale models or representative examples of package features and materials (including SFRM) to prove compliance of a design with the regulatory requirements. Testing may be carried out by the designer, the applicant, a third party testing organization, the competent authority or its nominated independent agent. Irrespective of who actually does the test work, it should be carried out to the satisfaction of the competent authority and in a quality
assured manner. The following points need to be considered when seeking to determine compliance with the regulatory test requirements:

(a) There should be an appropriate quality assurance programme for the test to be done in support of demonstrating that the finished package will meet the regulatory requirements. This quality assurance programme should address all aspects of the testing and should cover not only the manufacture of the specimens to be tested but also all the relevant management, preparation, measuring, testing, recording, analysing and reporting activities associated with the particular test or series of tests to be carried out.

(b) The actual test programmes should satisfy the approving body (the competent authority or another appropriate organization), and the number of tests and specimens, the drop sequences, drop attitudes, measurement techniques and analysis methods should be clearly established. The outcome of the test work is inevitably uncertain; therefore, some variation in the programme may be necessary in the course of testing, and allowance should be made for this fact when preparing test specimens, scheduling tests and using test facilities. The approving authority, particularly the competent authority, should reserve the right to vary the test programmes while testing is performed in the light of the experience gained.

(c) The objects and parameters of the test(s) should be clearly established, i.e. it should be made clear whether the sole object of the test(s) is a straightforward proof that a package meets all of the regulatory requirements or only a part of them, or whether the designer wants different or more stringent test criteria to be applied, or whether he wants additional information from the test(s) to improve his knowledge of the design principles, safety margins, performance, etc.

(d) It should be clearly established that the test facilities comply with the regulatory requirements, particularly in the case of the targets used in drop and penetration tests, where the weight of the test specimen must not exceed the capacity of the test facility.

(e) All measuring and monitoring equipment used before, during and after the test(s) to confirm and record the state of the test specimen and any forces imposed upon it as a result of the test(s) should be operated within the accepted limits for the particular piece of equipment. It should be proven that this equipment works accurately, within accepted or declared limits. This is usually achieved by using properly calibrated test equipment, such as pressure and leak test equipment, accelerometers, strain gauges and thermal measuring apparatus.

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

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

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

CONTROL OF MANUFACTURE

485. It is of fundamental importance that packagings are manufactured in a controlled manner and in accordance with the design specifications and the quality assurance programme. In order to confirm this, the competent authority may request sufficient information to carry out such inspections of manufacture as it deems necessary to assure compliance. An example check list for this type of inspection is given in Annex VIII.

486. Manufacturing facilities and subcontractors may be subject to inspections by the competent authority. The frequency and extent of inspections should be determined by the established levels of confidence in the manufacture and by the safety related importance of the package features concerned.

487. The manufacturing and quality assurance arrangements may be audited by the competent authority before commencement of manufacture of a packaging. The purpose of such audits is to ensure that the manufacturer’s quality assurance methods are suitable to achieve and demonstrate compliance with the approved specifications and that qualified methods are used. In the case of continuous manufacture of packagings, additional audits of the quality assurance arrangements may be carried out periodically. However, significant changes in the manufacturing and quality assurance arrangements should be agreed to before they are put into effect.

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

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

490. The competent authority needs to ensure that before the first use of a packaging the manufacturer has fulfilled the requirements of para. 401 of the Regulations. On the basis of the quality control results, reports on deviations and other quality assurance measures, the manufacturer should also be required to determine that the packaging has been manufactured in compliance with the Regulations. The competent authority may confirm the manufacturer’s determination by direct inspections.

491. Following the manufacturer’s determination, the responsible organization should legibly and durably mark the packaging in accordance with the requirements of paras 436–439 of the Regulations and in accordance with any other identification requirements by the competent authority. For packages approved by it, the competent authority shall be informed of the serial number of each accepted packaging, according to para. 715 of the Regulations.

MAINTENANCE AND SERVICING ARRANGEMENTS

492. The competent authority needs to be assured that the user has determined before each use of a packaging that the requirements of para. 402 of the Regulations have been met. Inspections and maintenance as required by the original designer or the competent authority should have been systematically carried out. An example check list for this type of inspection is given in Annex IX.

493. The person or organization carrying out the maintenance and servicing operations must have an appropriate quality assurance programme and work to it. For the required maintenance and servicing tasks and the way in which they are carried out, the current relevant instructions covering maintenance and servicing of packagings need to be available. (This can present certain difficulties when a packaging has to
be maintained or serviced in a place or country away from that of the owner/user of the packaging or the original approving competent authority.)

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

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

496. The competent authority should witness the maintenance and servicing operations carried out by the user (this should be planned but perhaps not announced). During the life of the packaging the user will have to maintain sufficient quality assurance records to demonstrate that the requirements of para. 402 of the Regulations are met. The user must make available such records to the competent authority and permit it to inspect the records, the packaging and the facility. Appropriate use of records and log-books (as described in Appendix IV of Safety Series No. 37 [3]) should be made when servicing and maintenance operations are carried out at different locations.

497. For packages approved by the competent authority, the user should be requested to record all safety related deviations from the specifications as well as other significant damage noted during the use of the packages. The competent authority must be informed of these deviations within a certain time period (for example 30 days). Corrective measures, including the plan for repairs, should be subject to the agreement of the competent authority.

ACCIDENT AND EMERGENCY RESPONSE

498. The competent authority should periodically assess the consequences and risks of potential transport accidents. Emergency planning by the competent
authority and other responsible authorities, usually the public health and safety organizations, should be based on these and other relevant assessments.


4100. International co-operation may be needed in cases of transport accidents, as discussed in paras 314 and 610. More guidance in this area is provided in the IAEA documents INFCIRC/310 [20] and INFCIRC/321 [21].

DISTRIBUTION OF INFORMATION

4101. Preparation and issuance of information and guidance by the competent authority are needed for the implementation and functioning of a compliance assurance programme. This 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 the users in the application and interpretation of the Regulations. Finally, it may involve the development and sponsoring of seminars, conferences, courses, etc., for personnel of regulatory bodies, consignors, carriers and other groups, to explain the correct application of the Regulations.

TRAINING AND JOB RELATED SKILLS

4102. Only appropriately trained persons should be engaged in the transport of radioactive material. The jobs and the associated duties and responsibilities should be clearly indicated in the descriptions of the organizations of the consignor, the carrier and the consignee. For other personnel, such as employees of the competent authority, independent inspectors and emergency personnel, it is also appropriate to specify their duties and responsibilities so that the necessary training can be determined and accomplished.

4103. In addition to providing for the training of its own personnel, the competent authority should, as appropriate, specify and participate in the training of other persons involved in the transport of radioactive material. Furthermore, the competent authority should ensure through its compliance assurance programme and its monitoring of quality assurance programmes that all training needs of the organizations involved in transport are recognized and implemented. The training programme of an individual may be varied slightly or considerably, depending on the relevant experience of that person.
4104. In some IAEA Member States, certain persons 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 this case, measures for authorization and training must be designed and organized.

4105. Each organization should maintain adequate records of the training plans, the performance of the individual trainees and the authorizations issued. Also, records should be maintained according to the applicable quality assurance requirements and should be examined or inspected periodically by the competent authority. The main purposes of these records are:

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

4106. Further guidance and information on training of all personnel involved in the transport of radioactive material is given in the IAEA Training Course Series No. 1 on the Safe Transport of Radioactive Material [22].

MAINTENANCE OF REGULATIONS AND REGULATORY BODY FEEDBACK

4107. National and international regulations and conventions are discussed in Section III. The maintenance and further development of the existing regulations is considered to be an important aspect of compliance assurance. The regulations should be regularly reviewed and revised to take account of developments in all areas of the radioactive material transport industry as well as developments in comparable activities and industries.

4108. The IAEA has recognized the value of a continuous review of its Regulations and has implemented such a review process after the publication of the original edition (1985) of the Regulations. It is only by such a review process that specific and more general needs and developments in the safe transport of radioactive material can be recognized and provided for in a timely manner. If regulations are allowed to remain in place for long periods of time without appropriate revision and amendment, they become out of date soon, are increasingly ignored or difficult to enforce, and their credibility and levels of confidence are reduced.
4109. Also, the competent authority should periodically review the regulations to be implemented by it and should make the necessary changes to those regulations. (This can be difficult or time consuming in some countries where the competent authority has to obtain formal permission from its government for making changes to those regulations or where it has to refer to the legislative process.)

4110. The competent authority should, through its compliance assurance programme, accumulate evidence of compliance and non-compliance. This evidence, which may consist of reports on inspections and enforcement actions, audit reports, communications with the industry, etc., should help the competent authority to determine the degree of effectiveness and adequacy of the regulations that it has to implement. Users of the regulations should draw the attention of the competent authority to problems of understanding, interpretation, ambiguity, inaccuracy, impracticality, etc.

4111. The competent authority should carefully evaluate all reported and perceived problems and developments, as well as proposals for regulatory changes; then it should consider all aspects and implications of any proposed changes, and consult the relevant users of national regulations and acknowledged experts.

4112. The competent authority should exercise great care when it considers changes to national regulations in order to prevent disharmony or conflict with the requirements of accepted international regulations and conventions or the requirements of other applicable national regulations.

4113. Any change to regulations should be carefully monitored by the competent authority after implementation to confirm that the change has been effective and that the object or the desired result has been achieved without compromising safety and without adversely affecting other parts of the radioactive material transport industry.

ENFORCEMENT ACTIONS AND INVESTIGATIONS OF INCIDENTS

4114. Any system for compliance assurance should include provisions for enforcement. In this context, enforcement means any formal actions by the competent authority against the user of the regulations when cases of violation or non-compliance by that user have been observed. These observations are most often made during routine inspections of the competent authority. A range of enforcement actions may be applied, depending on the safety implications of the circumstances of the non-compliance. Enforcement sanctions should be applied in an appropriate
manner and within the legal framework of the individual state. These sanctions could include, for example, the following measures:

(a) **Written notice.** A written notice from the competent authority to the user should set out the non-compliance that has been observed or reported. The user would be required to provide a written reply explaining the causes of the non-compliance and the corrective actions taken to prevent a recurrence.

(b) **Suspension.** This could involve a written notice of non-compliance, accompanied by a statement of intent to suspend or revoke or modify a user’s authorization unless or until the user gives a good reason why the suspension should not be applied. The user would be obliged to demonstrate that the non-compliance has ceased or that steps to prevent recurrence had been taken. In applying this type of sanction the competent authority should take into account the safety significance of the non-compliance, the prior enforcement history of the user and the financial impact of the suspension on the user.

(c) **Prosecution.** In circumstances where non-compliance has occurred and where the above measures are considered inappropriate or have failed to prevent the user from continuing with the non-compliance, the competent authority may wish to initiate legal action against the user; this would be a higher form of sanction. In some nations prosecution may include a monetary and/or criminal penalty. Prosecution may be appropriate in cases where:

- the user has refused to rectify a non-compliance,
- the user has failed to discontinue an unsafe practice,
- there is evidence of deliberate negligence, or
- there is evidence of criminal action.

4115. Suitable guidelines for the use of these sanctions should be provided by the appropriate authorities in individual Member States to ensure fair and uniform application of the sanctions.

4116. The inspection and enforcement programmes of the competent authority should apply to all activities that are important to safety (design, testing, manufacture and maintenance of packagings, preparing and carrying out transport and quality assurance), irrespective of whether a competent authority approval certificate is required.

4117. A system of reporting of all significant incidents, accidents or deviations should be developed, and the competent authority or its agents should investigate these reported occurrences. Such investigations may reveal where:

- clear breaches of regulations have occurred,
- individual or collective procedures are in need of improvement,
— individual or collective work practices are in need of improvement,
— closer supervision of personnel is necessary,
— improved training is needed,
— misunderstanding of regulatory requirements has occurred,
— unwelcome trends in transport operations are developing, or
— apparent inadequacies of the regulations exist.

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

4118. Section II covers interdepartmental or interagency liaison in general and suggests that the competent authority should arrange periodic meetings of all government departments or agencies involved in the transport of radioactive material. One of the aims of these meetings is to ensure consistent application of inspection and enforcement relating to compliance assurance. It may often be the case that the control of safe transport of radioactive material, for example inspection of aviation safety, is only a small part of the work of inspecting departments or agencies. It is of considerable importance that the regulations and inspection criteria for radioactive material transport are understood and applied by inspectors of such agencies in a manner similar to that in which other inspections are applied, such as inspections of maritime safety or road traffic.

4119. Liaison with other groups concerning enforcement is also necessary for the competent authority in order to obtain a clear understanding of the respective responsibilities and operating methods of each of the departments or agencies involved. When the competent authority has such an understanding, it can consider the completeness of the inspection and enforcement arrangements and identify any areas of overlap between the arrangements of different agencies or, more importantly, it can identify where gaps exist between the operations of one agency and those of another agency. At meetings for liaison purposes, enforcement levels and criteria can be discussed, compared and subsequently standardized, wherever possible, and it can be ensured that the interfaces between the liaising departments/agencies are well defined and are functioning correctly.
Section V
APPROVALS AND APPROVAL CERTIFICATES

APPLICATIONS FOR APPROVALS

501. It is one of the responsibilities of the competent authority to issue approvals. The decision to give an approval is based upon the competent authority's evaluation of the applicant's demonstration of compliance with the relevant regulations. As described in Section IV, the competent authority should complete and record these safety evaluations, which provide the basis for the issue of approvals.

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

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

504. In some countries it has been found to be advantageous to provide a guidance document, such as a check list, to assist applicants for approvals of special form radioactive material, packages, special arrangements and shipments in submitting the necessary information in a convenient form. Such a guidance document is also of value to the competent authority in evaluating the completeness and accuracy of submissions. An example of the contents of such a guide is shown in Annex II. The guide is not intended to be a substitute for the Regulations; therefore it is not necessary to print the text of a regulatory provision in the guide, but the applicant should
be referred to the Regulations by quoting the relevant paragraph numbers, for example:

Show what the maximum normal operating pressure will be within each successive enclosure of the containment system:
- before shipment (para. 402(c));
- during normal transport (paras 132, 554);
- during and subsequent to tests for demonstrating the ability to withstand accident conditions in transport (paras 553, 619–624 and 626–629).

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

506. It is desirable to divide the guide into parts, each of which refers to a particular aspect or type of approval. This ensures that the applicant uses only that part of the guide which is relevant to the type of approval required. Convenient divisions are:

I — General information
II — Administrative information
III — Specification of radioactive contents
IV — Specification of packaging
V — Package analyses and tests
VI — Shipment
VII — Special arrangement transport operation
VIII — Special form radioactive material
IX — Quality assurance
X — Modification procedure.

507. In general, Parts I, II and IX always have to be provided by the applicant. In the case of an application for a special arrangement, the applicant should provide the information denoted in Parts III, IV and V (as applicable) in addition to that in Part VII, since a necessary prerequisite of establishing compensatory measures is the identification of deficiencies of the package. An example of the contents list of an applicant’s guide is provided in Annex II.
TYPES OF APPROVAL

508. In accordance with para. 701 of the Regulations, competent authority approval is required for the following:

— Special form radioactive material,
— All packages containing fissile material,
— Type B(U) and Type B(M) packages,
— Special arrangements,
— Certain shipments,
— Radiation protection programme for special use vessels,
— Calculation of unlisted $A_1$ and $A_2$ values.

509. According to paras 702 and 704 of the Regulations, unilateral approval by the competent authority is specifically required for:

— The design of special form radioactive material;
— Type B(U) package design, except the package design for fissile material.

510. According to paras 704, 707, 710, 713, 714, 716 and 720 of the Regulations, multilateral approval by the competent authority is specifically required for:

— The package design for fissile material;
— Type B(M) package design;
— The packagings manufactured to a design approved by the competent authority under the provisions of the 1967 Edition of the Regulations;
— The packagings manufactured to a design approved by the competent authority under the provisions of the 1973 Edition and the 1973 Edition (As Amended) of the Regulations (after 31 December 1992);
— The shipment of Type B(M) packages designed to allow controlled intermittent venting, or Type B(M) packages containing radioactive material with an activity greater than $3 \times 10^3$ $A_1$ or $3 \times 10^3$ $A_2$ (as appropriate) or 1000 TBq, whichever is the lower;
— The shipment of packages containing fissile materials, if the sum of the transport indexes of the individual packages exceeds 50;
— Radiation protection programmes for shipments by special use vessels;
— Each consignment shipped under special arrangement.

511. Whenever possible, standard formats should be utilized for each type of certificate. Models for certificates are shown in Annex III.

512. Certificates for international carriage of certain packages, provided by national competent authorities to the IAEA, are listed in an IAEA report [23] that is updated annually.
MULTILATERAL APPROVAL

513. Under the Regulations, multilateral approval of a design or shipment may be effected

— either by independent certification as part of a chain of multilateral competent authority approvals
— or by validation of the approval certificate issued by the original competent authority.

514. The essential difference between independent certification and validation is that the latter does not specify the design or shipment, since this specification is already contained in the original certificate. Instead, the applicant should refer to the original certificate for this information.

515. A safety assessment should always be made in the case of multilateral approval. If it is necessary in the course of the assessment for multilateral approval to require modification of any of the essential detailed provisions of the certificate of the original competent authority, subsequent independent assessment and certification should be carried out.

516. Validation eliminates the possibility of confusion of certificates issued by different competent authorities that cover the same case. Validation may apply to the original certificate in its entirety, or to the appropriate part(s) of it if there are other parts which constitute a unilateral approval or which are otherwise inappropriate for multilateral approval.

517. When a ship is used for transport, the competent authority of the flagstate of the vessel has to take part in any chain of multilateral approvals by competent authorities, even if the ship is not destined to enter a port on the territory of that competent authority.

518. When a competent authority is requested to give its approval as part of a chain of multilateral approvals, the safety assessment should be carried out only on receipt of a copy of the certificate of approval issued by the original competent authority.
Section VI

INTERNATIONAL CO-OPERATION BETWEEN COMPETENT AUTHORITIES CONCERNING PACKAGES AND SHIPMENTS ON FOREIGN TERRITORY

NEED FOR INTERNATIONAL CO-OPERATION RELATING TO COMPLIANCE ASSURANCE

601. National competent authorities meet regularly under the auspices of the IAEA in order to develop the Regulations and their associated advisory and explanatory guides for the safe transport of radioactive material. The common aim of these meetings is related to the uniformity of the application of the Regulations in all Member States. International co-operation in the field of compliance assurance is clearly a powerful tool that can help to achieve that aim.

602. In many countries the competent authority has a clear responsibility regarding compliance assurance for all activities related to the transport of radioactive material within national boundaries. However, a large number of movements involve packages of foreign origin. These movements will often occur without the national competent authority knowing, but, nevertheless, each such transport should be in compliance with the regulatory requirements.

603. For a competent authority attempting to confirm compliance with regulations in the case of packages and shipments of foreign origin, it is essential to co-operate with all competent authorities concerned. Radioactive material and packages of foreign origin, coming within the jurisdiction of a national competent authority, belong to two categories:

- Packages and shipments (and radiation protection programmes) that are subject to multilateral approval;
- Packages and shipments that do not require national approval.

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

604. Operations associated with foreign packages and shipments (see para. 510) may also require multilateral approval by and/or notification of competent authorities, as stated in paras 455–458 of the Regulations. For these cases, the validating competent authority can justifiably require to be informed of the details relating to
quality assurance programmes before it issues a certificate of validation. Through co-
operation between the validating and originating competent authorities the necessary
compliance guarantees can be provided.

605. In cases where there is doubt about a specific quality assurance programme,
the validating competent authority should contact the competent authority of the
country of origin and should request the relevant details of inspections and audits.
Where important shipments or large scale operations are concerned, this inter-
national co-operation may justify visits between competent authorities and joint visits
of the respective organizations for detailed discussion of the quality assurance
programme. The purpose of such visits is to gain confidence in the standards used
in the foreign country and to reach agreement on the approach concerning
differences in standards.

606. Where multilateral approval is effected by the issue of independent certifi-
cates by successive countries, a further useful measure is to require that the user be
responsible for ensuring that the validating mark is indelibly printed on the packag-
ing, in accordance with para. 725(b) of the Regulations. In the case of multiple-use
packagings, the date of the next maintenance inspection should also be noted on each
package; this measure can help avoid accidental use of packages after the date when
maintenance is due.

PACKAGES AND SHIPMENTS OF FOREIGN ORIGIN
THAT DO NOT REQUIRE NATIONAL APPROVAL

607. Packages and shipments of foreign origin that do not require national
approval present a compliance assurance problem to the national competent
authority. A system of international co-operation between competent authorities is
needed because this problem cannot be solved by regulation alone.

608. For competent authorities the only information concerning these transports or
packages will be the notifications required under paras 455 and 456(a) of the
Regulations. In practice, this information is inadequate to form the basis of a compli-
ance assurance programme for these activities. Further, the required notifications
give no information concerning the scale of such operations or the current condition
of the packages.

609. A solution of these problems can therefore only be found on the basis of
controls other than those required by the transport Regulations. For example, some
of these controls can be performed by the authorities responsible for the control of
nuclear material under a country’s nuclear laws and under its legislation for port
authorities. Also, information from controlling activities associated with national radiation protection laws or with import and export controls of radioactive material, could be used. Such information, together with international co-operation between the competent authorities responsible for the transport of radioactive material, could then form the basis for a compliance assurance programme.

610. In any case, after accidents or incidents involving packages or shipments of foreign origin, or if there are deviations from the transport Regulations, international co-operation between competent authorities during any follow-up activities is essential.
ANNEXES

The annexes present sample documents and forms; they show how the procedures for organizing and implementing a compliance assurance programme for the safe transport of radioactive material can be documented and controlled. Most of the documents have been provided by one competent authority. The procedures applied by a competent authority must reflect its own working practices and methods that have been developed to meet the requirements of para. 210 of the Regulations.
Annex I

EXAMPLE OF THE ORGANIZATION OF A COMPLIANCE ASSURANCE PROGRAMME

Figures A-1 and A-2 illustrate the steps in the development of a compliance assurance programme and the compliance assurance circle.

1. Determination/confirmation of the size and state of the existing industry for radioactive material transport
2. Determination/confirmation of the existing powers/resources available to the competent authority
3. Establishment of liaison with government departments or organizations having a legitimate interest in or an interface with radioactive material transport
4. Provision of a sound legal framework for the competent authority to function effectively

5. Formal confirmation of the working relationships between other government departments/organizations
6. Gathering of further detailed information on the size of the industry for radioactive material transport, including information on package types and numbers of movements

7. Formal establishment of the size, structure and resources of the competent authority

8. Initial training of competent authority personnel and other enforcement personnel
9. Creation/adoption of national regulations for radioactive material transport (providing for all package types, transport operations and modes of transport)
10. Development of the initial compliance assurance programme (including activities of existing competent authorities, such as inspections and assessments)
11. Information of all parts of the industry regarding the competent authority's policy, regulations and plans for radioactive material transport
12. Implementation of the initial compliance assurance programme

13. Collection of initial evidence of compliance with the Regulations from the following activities:
   - Design assessment (of packages)
   - Witnessing of testing
   - Witnessing of manufacture
   - Examination of maintenance/servicing arrangements
   - Monitoring of transport operations
   - Auditing of quality assurance programmes
   - Interdepartmental liaison/co-operation
   - Information distribution
   - Enforcement actions and incident investigation
   - Regulatory review (adequacy, accuracy, etc.)
   - Emergency planning and exercises
   - Issuance of approvals

14. Accumulation and review of evidence of compliance on a continual basis
15. Conduct of periodic reviews of all aspects of the compliance assurance programme; adjustment of the competent authority input or effort deployed in addressing the various segments of the compliance assurance circle shown in Fig. A-2

FIG. A-1. Steps in the development of a compliance assurance programme.
FIG. A-2. The compliance assurance circle. The segments of this circle represent the essential features of a compliance assurance programme of a competent authority.
Annex II

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR APPROVALS

The competent authority should provide a guide that will help applicants to submit the necessary information for approvals in a convenient form. Items on which information should be required, as appropriate, are:

Parts

I — General information
II — Administrative information
III — Specification of radioactive contents
IV — Specification of packaging
V — Package analyses and tests
VI — Shipment
VII — Special arrangement transport operation
VIII — Special form radioactive material
IX — Quality assurance.

Part I — General information

Instructions on the provision of approval information;
Reference to related publications (IAEA Safety Series No. 6 and No. 37, National Standards, etc.);
List of transport regulations;
Designs not requiring competent authority approval (excepted, industrial or Type A packages), and procedures to be followed for these designs;
Information on the compliance assurance programme.

Part II — Administrative information

Name, address, telephone number of applicant;
Name, address, telephone number of designer;
Name, address, telephone number of manufacturer;
Type of approval required (e.g. Type B(U), Type B(M), packages containing fissile material);
Modes of transport;
Competent authority identification mark, if previously allocated;
Package title and general arrangement drawing number;
Date of application;
Date by which approval is required.
Part III — Specification of radioactive contents

General nature;
Radionuclide;
Physical state;
Chemical state;
Quantity, in mass units, and enrichment, where applicable (i.e. for packages containing fissile material);
Total activity/specific activity;
Calculation of $A_1/A_2$ values other than those listed in Safety Series No. 6;
Nature of emitted radiation;
Information on irradiated fuel, e.g. rating, irradiation, initial enrichment and cooling time;
Heat output;
Hazards other than radioactivity.

Part IV — Specification of packaging

Drawings (arrangement, assemblies, sub-assemblies and details);
Material specifications;
Types of closures (e.g. welding);
Overall dimensions and mass;
Handling facilities;
Tie-down system;
Radiation shielding;
Neutron absorbers;
Containment system;
Quality control programme for manufacturing;
Maintenance provisions;
Actions before shipment;
Actions during shipment;
Restrictions (including model restrictions);
Instructions for handling and stowage;
Emergency instructions.

Part V — Package analyses and tests

Behaviour of radioactive material;
Effects of radiolyses;
Structural evaluation;
Containment evaluation;
Radiation shielding evaluation;
Thermal evaluation, including surface heat flux;
Criticality evaluation;
Model tests;
Prototype tests;
Tests with real specimen.

Part VI — Shipment

Mode of transport;
Consignor;
Carrier;
Consignee;
Consignment details;
Exclusive use provisions;
Operational controls;
Storage in transit;
Stowing, handling and lifting;
Radiation protection programme;
Transport instructions;
Emergency instructions.

Part VII — Special arrangement transport operation

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

Part VIII — Special form radioactive material

Drawings;
Specifications of materials and closures;
Overall dimensions and mass;
Radionuclide;
Physical and chemical state;
Nature of emitted radiation;
Heat output;
Water concentration of contents;
Demonstration of compliance with tests;
Leakage tests and other quality assurance measures.
Part IX — Quality assurance

Description of the organizations involved;
Duties and responsibilities of different organizations;
Quality assurance programmes.
Annex III

EXAMPLES OF APPROVAL CERTIFICATES
ISSUED BY THE COMPETENT AUTHORITY

Included are examples of standard forms of approval certificates for:

— design of special form radioactive material
— package design
— shipment
— special arrangement.

These example certificates may be used as models by the competent authority.
III-1. DESIGN APPROVAL CERTIFICATE FOR
SPECIAL FORM RADIOACTIVE MATERIAL

1. Certificate issue date

2. Competent authority
   identification mark

   Expiry date

3. This certificate is issued on the basis of the application by

   [Name and address of the applicant]  [Title and identification of the application]

4. Radioactive material
   (radionuclide, chemical and
   physical form)

5. Maximum activity

6. Specification and drawing references

7. References to the quality assurance
   programme

8. This is to certify that the design of the radioactive material identified in items 4, 5, 6 above
   meets the requirements for special form radioactive material in the IAEA Regulations for
   the Safe Transport of Radioactive Material, Safety Series No. 6, 1985 Edition, and in the
   regulations [references] listed below.

   Date
   [Signature(s) of authorized official(s)]

   Address and telephone and telex numbers of the competent authority

Regulations concerning the transport of radioactive material

Road ...............................................................

Rail ...............................................................

Sea ...............................................................

Air ...............................................................

International ..................................................

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

1. Certificate issue date
2. Competent authority identification mark

Expiry date
Package identification number

3. This certificate is issued on the basis of the application by

[Name and address of the applicant] [Title and identification of the application]

4. This is to certify that the design of the package described below meets the applicable
requirements for [Type B(U) or B(M) packages] [Type ... packages containing fissile
material] in the IAEA Regulations for the Safe Transport of Radioactive Material, Safety
Series No. 6, 1985 Edition, and in the regulations [references] listed below, and is condi­
tional upon fulfilling the requirements specified on the following pages of this certificate.

This certificate does not release the consignor from compliance with any requirement of
the government of any country through or into which the package will be transported.

Date [Signature(s) of authorized official(s)]

Address and telephone and telex numbers of the competent authority

5. Package identification

(a) Packaging
   (i) Model No.
   (ii) Descriptions
       [Use, dimensions, materials, closures, penetrations, gross mass, etc.]
   (iii) Reference to drawings and specifications

(b) Radioactive contents (non-fissile)
   (i) Type and form
       [including special form radioactive material, if applicable]
   (ii) Maximum activity per package
       [including activities of the various isotopes]

(c) Packages for fissile material
   (i) Type and form of fissile material
   (ii) Maximum activity and quantity per package
   (iii) Transport index for nuclear criticality control
   (iv) Special features
       [On the basis of which the absence of water from certain void spaces has been
assumed in the criticality assessment]
   (v) Irradiated fissile material
       [Any determination on the basis of which decreased neutron multiplication has been
assumed in the criticality assessment as a result of actual irradiation experience]
III-2. (cont.)

6. References to certificates for alternative radioactive contents, other competent authority validation, or additional technical data or information

7. Restrictions on the modes of transport

8. Shipment approval required

9. Shipment authorization

10. Specification of quality assurance programme(s)

11. Operational controls
   [Conditions for operational controls for the preparation, loading, transport, storage, unloading and handling of the consignment, and storage provisions for dissipation of heat, as well as use of the packaging and specific actions prior to shipment]

12. [Ambient conditions if they are not in accordance with paras 545, 546 and 556, as applicable, of the Regulations]

13. [For Type-B(M) packages, the prescriptions of paras 550-556 of the Regulations with which the package design does not conform, as well as amplifying information]

14. [Other endorsements
   (a) Emergency arrangements
   (b) Others]
III-3. SHIPMENT APPROVAL CERTIFICATE

1. Certificate issue date
   Expiry date

2. Competent authority identification mark(s)

3. This certificate is issued on the basis of the application by

   [Name and address of the applicant]  [Title and identification of the application]

4. This is to certify that the shipment of the radioactive material described below 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, Safety Series No. 6, 1985 Edition, and in the regulations [references] listed below, and is conditional upon fulfilling the requirements specified on the following pages of this certificate.

   This certificate does not release the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

   Date  [Signature(s) of authorized official(s)]

   Address and telephone and telex numbers of the competent authority

5. Identification of the package design approval certificate(s)

6. Identification of radioactive material
   (i) Type and form
      [including fissile material and special form radioactive material]
   (ii) Maximum activity per package
        [including activities of the various isotopes]
   (iii) Maximum quantity of fissile material per package

7. Restrictions on the modes of transport, type of conveyance and/or freight container, and routing instructions

8. Specification of quality assurance programme(s)

9. Operational controls
   [Conditions for operational controls for the preparation, loading, transport, storage, unloading and handling of the consignment, and storage provisions for dissipation of heat, as well as specific actions prior to shipment]

10. [Other endorsements]
   (a) Emergency arrangements
   (b) Others

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III-4. SPECIAL ARRANGEMENT APPROVAL CERTIFICATE

1. Certificate issue date

2. Competent authority identification mark

Expire date

3. This certificate is issued on the basis of the application by

[Name and address of the applicant] [Title and identification of the application]

[In addition, name and address of the carrier]

4. This is to certify that the shipment of the radioactive material described below 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, Safety Series No. 6, 1985 Edition, and in the regulations [references] listed below, and is conditional upon fulfilling the requirements specified on the following pages of this certificate.

This certificate does not release the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

Date [Signature(s) of authorized official(s)]

Address and telephone and telex numbers of the competent authority

5. Package identification

(a) Packaging

(i) Model No.

(ii) Descriptions

[Use, dimensions, materials, closures, penetrations, gross mass, etc.]

(iii) Reference to drawings and specifications

(b) Radioactive contents (non-fissile)

(i) Type and form

[including special form radioactive material, if applicable]

(ii) Maximum activity per package

[including activities of the various isotopes]

(c) Packages for fissile material

(i) Type and form of fissile material

(ii) Maximum activity and quantity per package

(iii) Transport index for nuclear criticality control

(iv) Special features

[On the basis of which the absence of water from certain void spaces has been assumed in the criticality assessment]

(v) Irradiated fissile material

[Any determination on the basis of which decreased neutron multiplication has been assumed in the criticality assessment as a result of actual irradiation experience]
III-4. (cont.)

6. References to certificates for alternative radioactive contents, other competent authority validation, or additional technical data or information

7. Mode(s) of transport

8. Restrictions on the modes of transport, type of conveyance and/or freight container, and routing instructions

9. Specification of quality assurance programme(s)

10. Operational controls
   [Conditions for operational controls for the preparation, loading, transport, storage, unloading and handling of the consignment, and storage provisions for dissipation of heat, as well as use of the packaging and specific actions prior to shipment]

11. Reasons for special arrangement

12. Compensatory measures as a result of the shipment under special arrangement

13. [Ambient conditions if they are not in accordance with paras 545, 546 and 556, as applicable, of the Regulations]

14. [Other endorsements
   (a) Emergency arrangements
   (b) Others]
IV-1. COMPETENT AUTHORITY AUDITS AND INSPECTIONS

The following is a list of general items to which the competent authority should direct its attention during audits/inspections (inspections may also include measurements carried out by the competent authority) in order to ensure that:

— The management of the organization has provided the necessary personnel and resources to carry out an effective programme for compliance with the transport Regulations. This programme should clearly identify those persons who are responsible for fulfilling the various specific requirements. Clear delegations of authority by the management to those responsible persons are of extreme importance.

— The management has provided the proper training of those persons who are responsible for carrying out the programme for compliance with the Regulations. Documentation of the training that has been provided should be submitted to the competent authority upon request.

— Established procedures for the design and fabrication or for the selection and procurement of packagings are followed.

— The consignor is using the proper packaging for the specific contents of packages. Direct examination of packages being prepared for shipment should be made by the competent authority, when applicable.

— The organization has in its possession all of 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).

— Established procedures for the preparation and use of the package are followed, in accordance with the approval certificate, the instruction manual and related documents.

— Established procedures for the proper marking and labelling of packages, in accordance with the Regulations. This includes the proper determination and application of the correct transport index. When practicable, the competent authority should directly observe these actions.

— Established procedures are followed, and appropriate and properly calibrated instruments are provided, to monitor packages for both radiation and contamination.

— 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 of the competent authorities of each country into which or through which the consignment is transported.

— During transport, carriers are performing any required actions relating to placarding, storage and segregation of packages, etc., particularly any administrative controls relating to exclusive use shipments, or supplementary operational controls as specified in the competent authority certificate.

Examples of check lists used by competent authorities for their audit and inspection activities are given in Annexes VI, VII, VIII and IX.
IV-2. EXAMPLE OF A QUALITY AUDITING PROCEDURE

CONTENTS

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

1. PURPOSE

1.1. To define the method used by the Department of Transport (DT), Radioactive Materials Transport Division (RMTD), to perform quality and compliance audits [in support of the programme developed by the Department of Compliance Assurance in response to the requirements of the IAEA Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material (1985 Edition)].

2. SCOPE

2.1. The procedure covers the auditing activities of the RMTD and its agents in connection with a programme specified by the Principal Quality Engineer and agreed by the Head of Department. In addition to the planned programme of auditing, extra auditing activities can be arranged if this is requested by other sections.
IV-2. (cont.)

Auditing activities shall include, but may not be limited to:
— Establishing whether elements within the quality assurance programme are documented accordingly;
— Verifying through reviews and evaluation of documentary evidence that the quality assurance programme is being implemented;
— Evaluating the adequacy, effectiveness and efficiency of the quality system;
— On identification of non-compliance, requesting and verifying termination of actions.

3. DEFINITIONS

3.1. Audit check list
A listing of the enquiries to be raised by the audit team.

3.2. Audit matrix
A chart of activities audited and the quality assurance standard(s) against which the activities have been audited.

3.3. Audit plan
A time table of auditing activities.

3.4. Auditee
The department or organization which is the subject of the audit.

3.5. Auditor(s)
The person(s) responsible for undertaking the audit.

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

3.7. Corrective action
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 quality assurance standard or the prescribed quality assurance arrangements.

3.9. Observation
A reportable deviation from good working practice which may result in a quality problem occurring.

3.10. Quality audit
A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the objectives aimed at.
4. RESPONSIBILITIES

4.1. The Principal Quality Engineer shall be responsible to the Head of Division for the management of all quality and compliance auditing by the RMTD. The Principal Quality Engineer is responsible for appointing the audit team leader.

4.2. The team leader shall be responsible for planning, preparation, documentation and reporting of all quality audit activities. In undertaking quality audits the following shall be developed:
   — quality audit plan
   — quality audit check lists
   — audit matrix
   — quality audit report
   — audit completion statement.

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

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

5. PROCEDURE

5.1. Audit preparation

5.1.1. The Principal Quality Engineer or his designate shall prepare and issue an overall audit programme to the Division Head. The programme shall be reviewed and updated every six months.

5.1.2. The Principal Quality Engineer shall select the audit team and nominate a team leader. The team leader may delegate preparatory and follow-up activities to team members. Team members other than observers should have received formal training in quality assurance auditing.

5.1.3. The team leader shall open an audit file (all commercial information being confidential), allocate a sequential reference number and arrange initial contact with the auditee. If other government departments, e.g. the Nuclear Installations Inspectorate, have an interest in the audit they should be informed in accordance with any extant letters of understanding or similar interdepartmental agreements.

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

5.1.5. The team leader shall record the proposed audit activities on an audit plan. A questionnaire (audit check list) shall be used which covers the scope of the audit to be undertaken.

5.1.6. An audit matrix shall be completed, reflecting the criteria of the codes or standards against which the auditee will be audited.
IV-2. (cont.)

5.1.7. The agreed date(s) for the audit shall be confirmed by letter, telefax or telex sent to the auditee; other interested parties shall also be notified. In all instances the notification shall include the following points:
   — date and time of the planned audit
   — details of the audit plan
   — auditor(s)
   — agenda for the opening meeting.

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

5.2. Performance of the audit

5.2.1. The audit shall be opened by a meeting between the audit team and the representatives of the auditee. The topics covered at the meeting shall include:
   — introduction
   — purpose of the audit
   — audit plan and scope of the audit
   — interests of other government departments
   — closing meeting and attendance.

5.2.2. The audit shall be conducted objectively so as to establish whether the areas under examination have a satisfactory quality programme and whether the auditee is adhering to it.

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

5.2.4. Evidence and details of non-compliance regarding the standards or procedures on which the audit is based shall be recorded. The non-compliance record should indicate whether the necessary corrective action should be taken immediately or within a given time. This record should be signed by a representative of the auditee to confirm that it is factual and correct. However, if the representative of the auditee does not countersign the non-compliance record, it may still be considered to be admissible when the team leader so decides.

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

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

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

5.4. **Audit report**

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

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

5.4.3. The progress of corrective actions shall be monitored by the team leader, using a statement of audit completion. If problems in connection with these required actions are encountered, the Principal Quality Engineer and the Head of Division may also be involved in this process. Where required, follow-up reports are issued to inform the appropriate senior management of the auditee that a potential quality problem continues to exist. When the audit is complete, the team leader shall confirm this in a letter to the auditee. The team leader shall also check that all required documentation and records are filed and indexed. The completion of the audit is certified by a written statement of audit completion which is signed by the team leader.

6. **RECORDS**

6.1. The following audit records are retained by the Department of Transport:

- Audit programmes;
- Individual audit files, containing audit plans, audit matrixes, audit reports, follow-up letters, correspondence, audit completion statements.
- Index of completed audits.

7. **DECLARATION**

This procedure does not preclude the Department from any suitable enforcement action deemed necessary.
Annex V
EXAMPLE/MODEL OF A CHECK LIST FOR AUDITING A QUALITY ASSURANCE PROGRAMME

V-1. AUDIT CHECK LIST
Standard: IAEA Safety Series No. 37, Appendix IV

<table>
<thead>
<tr>
<th>QUALITY SYSTEM</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is there an established and documented quality assurance programme?</td>
<td></td>
</tr>
<tr>
<td>2. Are the quality assurance programme and the associated procedures subject to document control?</td>
<td></td>
</tr>
<tr>
<td>3. Is the quality assurance programme subject to review and, if so, how frequently?</td>
<td></td>
</tr>
<tr>
<td>4. Who is responsible for reviewing the quality assurance programme?</td>
<td></td>
</tr>
<tr>
<td>5. Is the organization's policy and statement of authority with respect to the quality assurance programme documented?</td>
<td></td>
</tr>
<tr>
<td>6. Is there a graded approach to quality assurance and, if so, is it defined?</td>
<td></td>
</tr>
<tr>
<td>7. Are the requirements of the quality assurance programme commensurate with the complexity of the packaging or its components and with the degree of hazard associated with the material being transported?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ORGANIZATION</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Is there a documented organization structure?</td>
<td></td>
</tr>
<tr>
<td>9. Are the functional responsibilities and levels of authority clearly defined?</td>
<td></td>
</tr>
<tr>
<td>10. Is the personnel responsible for performing the work also responsible for the attainment of quality?</td>
<td></td>
</tr>
<tr>
<td>11. Are the verification activities carried out by persons who do not have direct responsibility for performing the work?</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>12.</td>
<td>Are internal and external lines of communication established and documented?</td>
</tr>
<tr>
<td>13.</td>
<td>Are the interfaces between organizations defined? Are these interfaces regularly reviewed? Have the responsibilities of each organization been clearly defined?</td>
</tr>
<tr>
<td>DOCUMENT CONTROL</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Does the system require that documents essential to the performance and verification of the work are reviewed and approved?</td>
</tr>
<tr>
<td>15.</td>
<td>Do procedures define the individuals and organizations responsible for document preparation, review and approval?</td>
</tr>
<tr>
<td>16.</td>
<td>Do procedures, instructions, drawing, etc., include appropriate qualitative and quantitative acceptance criteria for determining that important activities have been satisfactorily accomplished?</td>
</tr>
<tr>
<td>17.</td>
<td>Has a document release and distribution system been established?</td>
</tr>
<tr>
<td>18.</td>
<td>How is the personnel made aware of document changes?</td>
</tr>
<tr>
<td>19.</td>
<td>How are suppliers made aware of document changes?</td>
</tr>
<tr>
<td>20.</td>
<td>Are codes and standards updated as amendments are issued?</td>
</tr>
<tr>
<td>21.</td>
<td>Is the personnel made aware that amendments to codes and standards have been issued?</td>
</tr>
<tr>
<td>22.</td>
<td>Are copies of out-of-date, redundant documents destroyed?</td>
</tr>
<tr>
<td>23.</td>
<td>Is the original of out-of-date, redundant documents retained? Are such documents retained in a manner preventing accidental use?</td>
</tr>
<tr>
<td>24.</td>
<td>Are changes to documents recorded and is written information on document revision and status promptly and timely distributed?</td>
</tr>
</tbody>
</table>
25. Are changes to documents subject to review and approval:
   - in accordance with documented procedures?
   - by designated persons or organizations having relevant background information, and knowledge and understanding of the original document?

26. Are incoming documents registered?

DESIGN CONTROL

27. Are design control procedures documented?

28. Are design office practices documented?

29. 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 system require design verification to be accomplished by:
       - design review and prototype testing or
       - calculations or
       - computer codes?

   Grade 2
   (a) Are the relevant regulations, industrial standards and codes defined?
   (b) Does the system require design verification to be accomplished by:
       - calculations or
       - computer codes?

   Grade 3
   (a) Design to follow accepted engineering or industrial practice.

30. Have provisions been made to ensure that the applicable regulatory and design basis requirements of standards and codes are included in design documents?
<table>
<thead>
<tr>
<th></th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>31.</td>
<td>Have provisions been made to ensure that the applicable quality standards, including quantitative and qualitative acceptance criteria, are specified and stated in design documents?</td>
</tr>
<tr>
<td>32.</td>
<td>Are the applicable standards and codes (including the issue status) referenced in design documents?</td>
</tr>
</tbody>
</table>
| 33. | Does the design system provide for control of changes/deviations/concessions regarding the design requirements?  
   (a) Are they documented?  
   (b) Is a register available?  
   (c) Do such documents require authorization by the person responsible for the design?  
   (d) Do such documents, after authorization, state the justification for acceptance of such changes/deviations? |
| 34. | What measures are established for the selection and for the review of suitability of application of any:  
   — materials  
   — equipment  
   — processes?  
   (a) Are such measures defined in procedures or instructions?  
   (b) Are such selections/reviews documented?  
   (c) Are such selections/reviews evaluated by technical personnel other than those performing the original design? |
| 35. | Is the design input documented in a way that permits adequate evaluation by technical personnel other than that performing the original design?  
   (a) Are such evaluations planned?  
   (b) Are such evaluations documented?  
   (c) Are such evaluations carried out before submitting design information to the competent authority and to suppliers or before commencing manufacture? |
| 36. | Are there formal procedures for controlling internal interfaces between design disciplines? |
37. Are formal procedures established for communicating design information, including changes, between:
   — departments
   — external interfaces?

38. Is the flow of design information to or from internal and external interfaces documented?

39. How are internal/external interfaces advised of changes to design documents?

40. Are design control measures established to verify the adequacy of the design?
   (a) Are design reviews conducted?
       Are they planned and systematic?
       Are they documented?
       Do they include technical personnel other than that performing the designs?
   (b) Are alternative calculational methods employed?
   (c) Is there a programme of testing in accordance with the requirements of the regulations?

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

42. (a) Are registers available for all design documents?
   (b) Do such registers include the revision status and the approval status?
   (c) Is the distribution of design documents recorded?
<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>PROCUREMENT CONTROL</td>
<td>COMMENTS</td>
</tr>
<tr>
<td>43. Have procurement control measures been documented?</td>
<td></td>
</tr>
<tr>
<td>44. Does the system ensure that the relevant design documents and regulatory requirements are included or referenced in procurement documents?</td>
<td></td>
</tr>
<tr>
<td>45. Does the system ensure that adequate vendor design documents and quality records are submitted by suppliers?</td>
<td></td>
</tr>
<tr>
<td>46. Do the procurement documents allow for adequate access by the purchaser and the competent authority to the plants of the suppliers and sub-suppliers?</td>
<td></td>
</tr>
<tr>
<td>47. Do the procurement documents require that design and quality requirements be passed on to sub-suppliers?</td>
<td></td>
</tr>
<tr>
<td>48. Is the selection of suppliers based on their evaluated and documented capability to provide similar items?</td>
<td></td>
</tr>
<tr>
<td>49. Who carries out this evaluation and is it documented?</td>
<td></td>
</tr>
<tr>
<td>50. Are supplier assessments conducted and by whom?</td>
<td></td>
</tr>
<tr>
<td>51. Are supplier assessments documented?</td>
<td></td>
</tr>
<tr>
<td>52. How is the past performance of suppliers recorded?</td>
<td></td>
</tr>
<tr>
<td>53. How often is a supplier assessed?</td>
<td></td>
</tr>
<tr>
<td>54. Are supplier audits conducted?</td>
<td></td>
</tr>
<tr>
<td>55. What are the criteria for selecting which suppliers to audit?</td>
<td></td>
</tr>
<tr>
<td>56. Are supplier audits planned and documented?</td>
<td></td>
</tr>
<tr>
<td>57. What controls are established to ensure that purchased items conform to the requirements of procurement documents?</td>
<td></td>
</tr>
<tr>
<td>58. Are such controls documented?</td>
<td></td>
</tr>
<tr>
<td>59. Are material control measures documented?</td>
<td></td>
</tr>
<tr>
<td>60. How is material traceability controlled?</td>
<td></td>
</tr>
</tbody>
</table>
61. Do the procurement documents require material traceability to be maintained throughout fabrication and assembly?

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

**PROCESS CONTROL**

63. Are all production processes controlled (e.g. by sub-contracts) and how is this done?

64. How are process procedures reviewed, controlled and issued?

65. Do sub-contractors use their procedures or the company’s procedures (e.g. process procedures and work instructions)?

66. Is inspection carried out at defined points in the manufacturing processes?

67. How are these processes controlled and monitored?

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

69. Are only suitably qualified people used to perform special processes?

70. Are processes available for controlling special processes (e.g. heat treatment)?

**INSPECTION AND TEST CONTROL**

71. Are programmes of inspection for items and services established?

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

73. Are programmes for in-service inspections established?

74. Who authorizes inspection programmes?

75. Are such inspections conducted by qualified personnel other than that performing the activities?

76. Have inspection procedures been established?
<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>77.</td>
<td>Do procedures require that in-service items found not to conform to specifications are removed from use until the situation is rectified?</td>
</tr>
<tr>
<td>78.</td>
<td>Are inspection hold points defined?</td>
</tr>
<tr>
<td>79.</td>
<td>How is it ensured that work does not proceed beyond a hold point?</td>
</tr>
<tr>
<td>80.</td>
<td>Are test programmes established?</td>
</tr>
<tr>
<td>81.</td>
<td>How is it ensured that the test programme demonstrates the adequacy of the specification and that all parts will perform satisfactorily in service?</td>
</tr>
<tr>
<td>82.</td>
<td>Is testing carried out against written test procedures and are the acceptance criteria specified?</td>
</tr>
<tr>
<td>83.</td>
<td>Who evaluates the test results?</td>
</tr>
<tr>
<td>84.</td>
<td>Does testing cover normal and accidental conditions of transport?</td>
</tr>
<tr>
<td>85.</td>
<td>Does the system cover calibration and control of measuring and test equipment?</td>
</tr>
<tr>
<td>86.</td>
<td>Are calibration records available and can they be traced back to a national standard?</td>
</tr>
<tr>
<td>87.</td>
<td>If equipment is found to be non-compliant, how is the acceptance of items reassessed?</td>
</tr>
<tr>
<td>88.</td>
<td>Are controls established for the handling, storage and use of equipment?</td>
</tr>
<tr>
<td>89.</td>
<td>How is the inspection status identified and is it maintained throughout manufacture and use of an item?</td>
</tr>
</tbody>
</table>

**CONTROL OF USE AND CARE OF PACKAGES**

90. Have systems for handling, labelling, dispatch, receipt, carriage and storage of packages been established?

91. Do procedures include controls for:
   - the contents
   - cleaning of packages
   - preserving
   - leaktightness
   - radiation and contamination levels?
<p>| | |</p>
<table>
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<tbody>
<tr>
<td>92.</td>
<td>Do procedures enable confirmation of compliance with the regulations?</td>
</tr>
<tr>
<td><strong>NON-CONFORMANCE</strong></td>
<td></td>
</tr>
<tr>
<td>93.</td>
<td>Is there an effective system for controlling non-conformance material?</td>
</tr>
<tr>
<td>94.</td>
<td>Are the procedures for rework and repair of non-conforming material documented and acceptable?</td>
</tr>
<tr>
<td>95.</td>
<td>Is the responsibility for the review and acceptance of non-conforming items defined?</td>
</tr>
<tr>
<td><strong>CORRECTIVE ACTION</strong></td>
<td></td>
</tr>
<tr>
<td>96.</td>
<td>Are accepted non-conformities reported to the purchaser and, if necessary, to the competent authority?</td>
</tr>
<tr>
<td>97.</td>
<td>Does the system provide for detection of inferior quality and for correction of its causes?</td>
</tr>
<tr>
<td>98.</td>
<td>Is adequate action taken to correct the causes of inferior quality (i.e. design faults, defective material)?</td>
</tr>
<tr>
<td>99.</td>
<td>Are analyses made to identify trends towards material non-conformance?</td>
</tr>
<tr>
<td>100.</td>
<td>Does corrective action extend to sub-contractor material?</td>
</tr>
<tr>
<td>101.</td>
<td>Are data analysis and material examination conducted on failed items to determine the extent and causes of defects?</td>
</tr>
<tr>
<td>102.</td>
<td>Is the effectiveness of corrective action reviewed and monitored?</td>
</tr>
<tr>
<td><strong>RECORDS</strong></td>
<td></td>
</tr>
<tr>
<td>103.</td>
<td>Does the system cover the maintenance of essential quality assurance records?</td>
</tr>
<tr>
<td>104.</td>
<td>Does the system cover the identification, collection, indexing, filing, storage, maintenance and disposal of records?</td>
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<tr>
<td><strong>105.</strong> Are records readily retrievable and maintained in a suitable environment?</td>
<td></td>
</tr>
<tr>
<td><strong>106.</strong> Are retention periods for records defined?</td>
<td></td>
</tr>
<tr>
<td><strong>107.</strong> Are records/log-books available for each package?</td>
<td></td>
</tr>
<tr>
<td><strong>108.</strong> Are they available for inspection?</td>
<td></td>
</tr>
<tr>
<td><strong>109.</strong> Do log-books contain the information required in para. AIV.13.2 of Safety Series No. 37?</td>
<td></td>
</tr>
<tr>
<td><strong>110.</strong> Are records available for services or for maintenance carried out at other locations?</td>
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</tbody>
</table>

**TRAINING**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>111.</strong> Who identifies training needs?</td>
<td></td>
</tr>
<tr>
<td><strong>112.</strong> Who maintains training records?</td>
<td></td>
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</tbody>
</table>

**AUDITS**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>113.</strong> Is there a programme for internal and external audits?</td>
<td></td>
</tr>
<tr>
<td><strong>114.</strong> Is the audit programme documented?</td>
<td></td>
</tr>
<tr>
<td><strong>115.</strong> Are audits conducted by qualified persons who have not been involved in the activity being audited?</td>
<td></td>
</tr>
<tr>
<td><strong>116.</strong> Are effective corrective actions taken when the system is found to be incorrect?</td>
<td></td>
</tr>
<tr>
<td><strong>117.</strong> Are internal audit reports used for systems review?</td>
<td></td>
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</table>
Annex VI
EXAMPLE/MODEL OF A CHECK LIST FOR INSPECTING TRANSPORT DOCUMENTATION

VI-1. COMPETENT AUTHORITY CHECK LIST FOR TRANSPORT DOCUMENTATION

<table>
<thead>
<tr>
<th>Company/organization:</th>
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</thead>
<tbody>
<tr>
<td>Location:</td>
<td></td>
</tr>
<tr>
<td>Quality assurance programme reference:</td>
<td></td>
</tr>
<tr>
<td>Report No.:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

1. Checks
The competent authority may decide to implement transport documentation checks at any stage of the operation, e.g.
- prior to dispatch
- during shipment
- during trans-shipment
- during storage in transit
- upon arrival at destination

2. Driver’s instructions/handbook
(a) Are drivers supplied with written instructions?
(b) Do these instructions contain emergency response procedures compiled by the consignor and/or the carrier?
(c) Do these instructions and/or procedures cover any trans-shipment or en-route storage requirements?
(d) Does the driver carry or have in his possession any necessary documents to confirm his proficiency in handling radioactive material (e.g. a training certificate)?

3. Consignment documentation (load manifest)
(a) Is the driver supplied with a completed load manifest?
(b) Does the manifest contain shipment details?
(c) Does the manifest contain load details, such as source types and activity, package types, category labelling of packages?
(d) Are the individual package transport indices correct and entered on the manifest?
(e) Is the total load transport index correct and entered on the manifest?
(f) Is the compliance statement made as required in Safety Series No. 6 and is it correct?
VI-1. (cont.)

4. **Particulars of consignment**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Have <em>all</em> of the regulatory aspects of the particular consignment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>have been complied with?</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>(b) Are competent authority certificates available?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>(c) Are special arrangement provisions and conditions being complied</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>with?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) Are <em>all</em> requisite documents, certificates, etc. correct, complete</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and authorized?</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

5. **Records**

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Are the necessary documents kept as records?</td>
</tr>
</tbody>
</table>
Annex VII

EXAMPLE/MODEL OF A CHECK LIST FOR INSPECTING TRANSPORT OPERATIONS

VII-1. COMPETENT AUTHORITY CHECK LIST FOR TRANSPORT OPERATIONS

<table>
<thead>
<tr>
<th>Company/organization:</th>
<th></th>
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<tbody>
<tr>
<td>Location:</td>
<td></td>
</tr>
<tr>
<td>Quality assurance programme reference:</td>
<td></td>
</tr>
<tr>
<td>Report No.:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

1. Company details

(a)Does the transporter require national licensing such as an operator or transport licence? 
(b) Is the licence authorized and valid? 

2. Modes of transport

(a) What modes of transport does the operator offer? 
   Land (road/rail) — sea — air 
(b) Is the operator familiar with these modes of transport? 
(c) Is the operator aware of the regulations related to the mode of transport?

3. Vehicles

(a) Are vehicles subject to a maintenance programme? 
(b) Are there records of vehicle maintenance? 
(c) Are the vehicles suitable for the transport of the particular consignments (e.g. weight limitations)? 
(d) Are all tie-down/anchorage points subject to testing and are records kept of the test results? 
(e) Are the vehicles correctly placarded? 
(f) How are the stowage conditions met? 
(g) How are the segregation requirements fulfilled?

4. Operators

(a) Does the operator provide an adequate training programme for all personnel? 
(b) Does the operator maintain records of the training and of the level obtained?
VII-1. (cont.)

5. Documentation

(a) Is all requisite documentation completed and recorded by designated personnel?
(b) Where certification is required, are copies of certificates kept and are the conditions stated in them being met?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

6. Regulations

(a) Is the operator aware of all necessary regulations (national, international) and does he comply with them?
(b) Are all necessary current certificates available?

7. Procedures

(a) Does the operator document his operations by written work programmes and instructions?

8. Emergency arrangements

(a) Are there adequate emergency response plans/procedures?
(b) Are the plans of the carrier and those of the consignor compatible?

9. Security arrangements

(a) Where considered necessary, are there appropriate security arrangements?
Annex VIII

EXAMPLE/MODEL OF A CHECK LIST FOR INSPECTING PACKAGE MANUFACTURE

VIII-1. COMPETENT AUTHORITY CHECK LIST FOR PACKAGE MANUFACTURE

<table>
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<tr>
<th>Company/organization:</th>
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<tbody>
<tr>
<td>Location:</td>
<td></td>
</tr>
<tr>
<td>Quality assurance programme reference:</td>
<td></td>
</tr>
<tr>
<td>Report No.:</td>
<td>Date:</td>
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</tbody>
</table>

1. Quality assurance programmes
   (a) Does the manufacturer have a quality assurance programme for manufacture?
   (b) Does the manufacturer apply appropriate levels or grades of quality assurance to his manufacturing and how are these grades obtained and designated?
   (c) Are the quality assurance programmes verified/audited by appropriate agencies?

2. Equipment
   (a) Does the manufacturer have sufficient production equipment (tools) and is it suitable?
   (b) Does the manufacturer have sufficient and adequate inspection and test equipment and is it suitable?

3. Personnel
   (a) Does the manufacturer have sufficient qualified and trained personnel?
   (b) Where qualification is required, how is this carried out (e.g. welder qualification by provision of certified test pieces; certifiable skills of inspectors in non-destructive testing) and what records are kept?

4. Documentation
   (a) Are documented procedures/plans available (e.g. written manufacturing, testing and inspection instructions; records of deviations/concessions and modifications)?
   (b) Are all drawings, specifications and records adequate, current and available?
   (c) Are all documents subject to control procedures?
### 4. Documentation (cont.)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tr>
<td>(d)</td>
<td>Do all drawings used conform to the numbers and the issue category stated on the relevant competent authority or other approval certificate?</td>
<td></td>
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<tr>
<td>(e)</td>
<td>Are all package serial numbers controlled and are they traceable to the competent authority certificate, and is the competent authority notified of the numbers?</td>
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### 5. Materials

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<tr>
<td>(a)</td>
<td>Does the manufacturer exercise sufficient control on all materials used in the manufacture of packages?</td>
<td></td>
</tr>
<tr>
<td>(b)</td>
<td>Does the manufacturer procure materials from sources verified against national or international standards?</td>
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<tr>
<td>(c)</td>
<td>Are the materials adequately stored and tested to assure conformance with specifications?</td>
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### 6. Regulations

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<td>(a)</td>
<td>Is the manufacturer aware of the regulatory requirements, and are these understood and being observed?</td>
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### 7. Records

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<tr>
<td>(a)</td>
<td>Does the manufacturer maintain adequate records of his operations (e.g. reports of manufacture, testing, materials specification, deviations/concessions)?</td>
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Annex IX

EXAMPLE/MODEL OF A CHECK LIST FOR INSPECTING MAINTENANCE AND SERVICING OPERATIONS

IX-1. COMPETENT AUTHORITY CHECK LIST FOR MAINTENANCE AND SERVICING OPERATIONS

| Company/organization: |  |
| Location: |  |
| Package design — competent authority certificate: |  |
| Package drawings references: |  |
| Number of packages inspected: |  |
| Quality assurance programme reference: |  |
| Report No.: | Date: |

1. Documentation

(a) Are maintenance/servicing instructions and schedules available and do they correspond to the requirements of the competent authority certificate?

(b) Do they specify disassembly and assembly procedures and maintenance frequency/periods?

(c) Are records kept of maintenance/servicing (e.g. package log-book)?

(d) Are these records or log-books correctly completed, verified or certified by authorized personnel?

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<th>Yes</th>
<th>No</th>
<th>N/A</th>
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2. Identification/designation of components/features

(a) Are package components or features identified or divided into categories (indicating major or minor importance to safety)?

(b) Are these categories consistent and are they correctly interpreted?

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3. Testing and inspection

(a) Is evidence available showing that specified tests and inspections have been performed? Examples are:

- functional/operational tests of components;
- visual inspection for condition, wear, damage, failure;
- dynamic testing;
- pressure tests;
- leak tests;
- non-destructive, radiographic, ultrasonic, dye penetrant testing.

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91
4. Components

(a) Are there specified procedures for the repair, reconditioning, refurbishment and disposal of components?

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<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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5. Equipment and tools

(a) Is the specified test equipment available?

(b) Is all required test and inspection equipment in good condition and is it calibrated?

(c) Is calibration carried out by a certified test house, and are the applied calibration standards and procedures traceable to recognized national or other acceptable standards?

(d) Is the specified/required special equipment available and does it conform to the specifications?

6. Training

(a) Does all personnel performing tasks receive appropriate training?

(b) Are the training programmes adequate for the required tasks?

(c) Are the training programmes effective in helping personnel to acquire the necessary skills and understanding?

7. Records

(a) Are records generated and appropriately maintained?
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