IAEA Safety Standards

for protecting people and the environment

The Management System for the Safe Transport of Radioactive Material

Safety Guide

No. TS-G-1.4

IAEA
International Atomic Energy Agency

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (i.e. all these areas of safety). The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Safety standards are coded according to their coverage: nuclear safety (NS), radiation safety (RS), transport safety (TS), waste safety (WS) and general safety (GS).

Information on the IAEA's safety standards programme is available at the IAEA Internet site

http://www-ns.iaea.org/standards/

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at P.O. Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to Official.Mail@iaea.org.

OTHER SAFETY RELATED PUBLICATIONS

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Reports on safety and protection in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

Other safety related IAEA publications are issued as **Radiological Assessment Reports**, the International Nuclear Safety Group's **INSAG Reports**, **Technical Reports** and **TECDOCs**. The IAEA also issues reports on radiological accidents, training manuals and practical manuals, and other special safety related publications. Security related publications are issued in the **IAEA Nuclear Security Series**.

THE MANAGEMENT SYSTEM FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL

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

IAEA SAFETY STANDARDS SERIES No. TS-G-1.4

THE MANAGEMENT SYSTEM FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL

SAFETY GUIDE

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FOREWORD

by Mohamed ElBaradei
Director General

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

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

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

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

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

THE IAEA SAFETY STANDARDS

BACKGROUND

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

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

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

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

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

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

THE IAEA SAFETY STANDARDS

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

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

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

Safety measures and security measures[1] have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

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

Safety Fundamentals

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

Safety Requirements

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

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

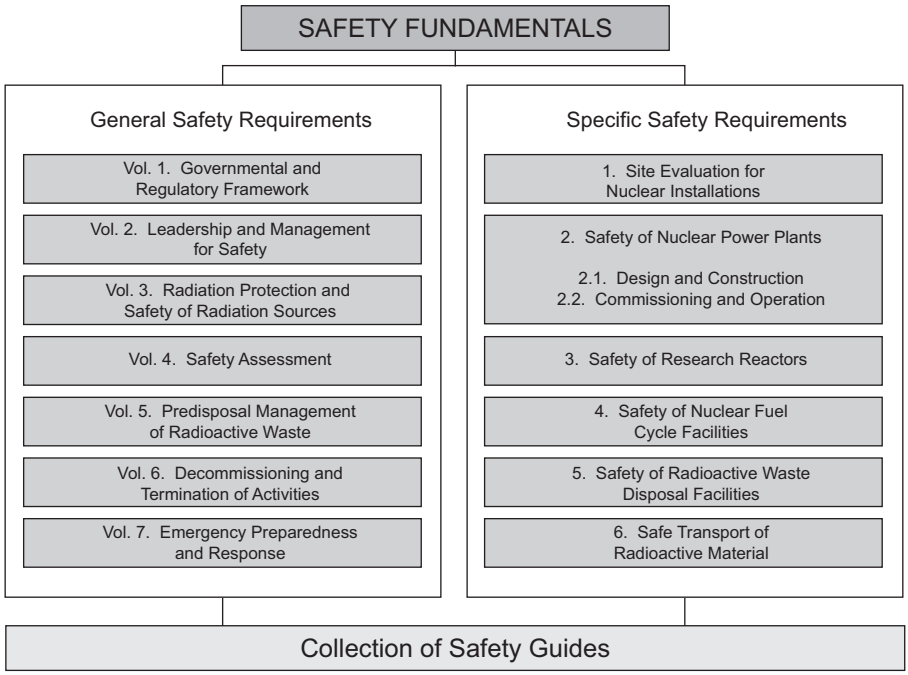

FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

Safety Guides

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

APPLICATION OF THE IAEA SAFETY STANDARDS

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

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

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

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

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

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

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

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

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

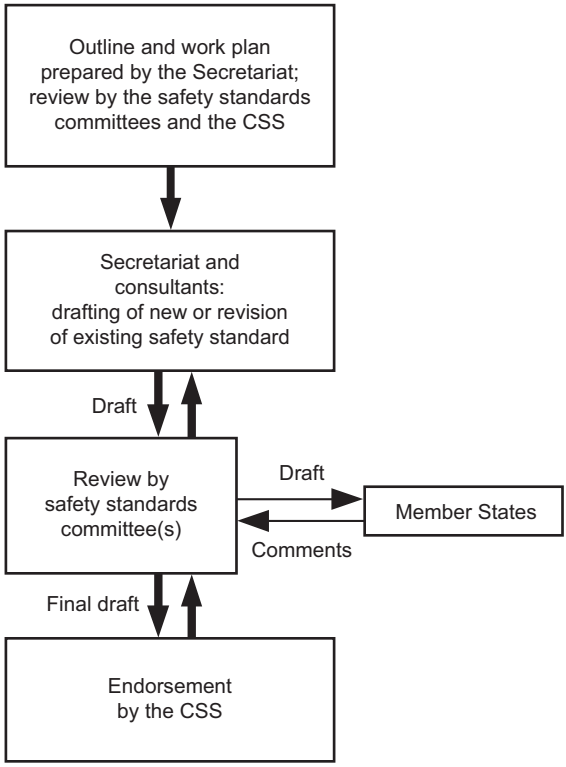

FIG. 2. The process for developing a new safety standard or revising an existing standard.

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

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

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

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

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

INTERPRETATION OF THE TEXT

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

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

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

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

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. The transport of radioactive material includes the carriage of radioisotopes for industrial, medical and research uses, and the shipment of radioactive waste and of consignments of nuclear fuel cycle material. A large number of organizations may be involved in a transport operation; for example, the movement of one package alone may involve a designer, a test facility, a packaging manufacturer, a consignor, shipping agents, carriers and a consignee. Transport comprises all operations and conditions associated with and involved in the movement of radioactive material; these include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage (including in-transit storage), unloading and receipt at the final destination of loads of radioactive material and packages.

1.2. The IAEA Regulations for the Safe Transport of Radioactive Material (the Transport Regulations) [1] apply to the transport of radioactive material by all modes on land or water, or in the air, including transport that is incidental to the use of the radioactive material. The Transport Regulations (para. 306) require the establishment and implementation of quality assurance programmes, based on international, national or other standards acceptable to the competent authority. Such programmes are required to encompass design, manufacture, testing, documentation, use, maintenance and inspection of all special form radioactive material, low dispersible radioactive material and packages, as well as transport and in-transit operations, as applicable.

1.3. The Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material [2] provides guidance to users[1] on how to comply with and demonstrate compliance with the requirements of the Transport Regulations [1]. This Safety Guide provides additional guidance to users on how to comply with the requirements in Ref. [1] on quality assurance programmes and with the requirements in Ref. [3] on the management system.

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

1.4. This Safety Guide uses the term 'management system' rather than 'quality assurance programme' (as used in Ref. [1]). The term management system reflects and includes the initial concept of 'quality control' (controlling the quality of products[2]) and its evolution through quality assurance (the system to ensure the quality of products) and 'quality management' (the system to manage quality). This Safety Guide supports the IAEA Safety Requirements publication on The Management System for Facilities and Activities [3], which defines requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements to ensure that safety is properly taken into account in all the activities of an organization. The management system is a set of interrelated or interacting elements that establishes policies and objectives, and that enables those objectives to be achieved in a safe, efficient and effective manner.

OBJECTIVE

1.5. The objective of this Safety Guide is to provide guidance on implementing the requirements in Ref. [3] for establishing, implementing, assessing and continually improving a management system for the transport of radioactive material. It also provides guidance on implementing the requirements established in Ref. [1] on quality assurance and quality assurance programmes within the management system for transport.

SCOPE

1.6. This Safety Guide applies to management systems for all activities relating to the transport of radioactive material, including, but not limited to, the design, fabrication, assembly, inspection, test, maintenance, repair, modification, use, procurement, handling, shipping, storage, cleaning and disposal of radioactive material packagings.

[2] A 'product' is the result or output of a process.

STRUCTURE

1.7. This Safety Guide follows the structure of Ref. [3]. Section 2 provides guidance on implementing the management system, including guidance relating to safety culture, grading and documentation. Section 3 provides guidance on the responsibilities of senior management for the development and implementation of a management system. Section 4 provides guidance on resource management, including guidance on human resources, infrastructure and the working environment. Section 5 provides guidance on how the processes of the transport organization can be identified and developed. Section 6 provides guidance on measuring, assessing and improving the management system. The appendix provides information on the graded approach in applying the management system to transport activities. The nine annexes provide illustrative examples of management systems and procedures.

2. THE MANAGEMENT SYSTEM

GENERAL

2.1. If a package or packaging is to be used in a safe manner and in compliance with the Transport Regulations [1] throughout its life, a management system should be applied to each phase of the life of the package or packaging so that the approved design work, intent and definition are not compromised, for example, by subsequent misuse or incorrect maintenance operations. Each organization concerned with transport of packages or packagings should have an individual management system covering its activities. Contractual arrangements between organizations should not relieve organizations of their responsibilities or diminish these responsibilities.

2.2. The extent of the management system will depend on the type of transport activities being performed, ranging from general requirements for infrequent consignors of excepted packages to extensive detailed requirements for regular consignors of packages that are subject to the approval of the competent authority.

2.3. The management system establishes an organization's objectives and working system for implementing and monitoring and improving work.

Reference [3] requires the adoption of a management system that integrates safety, human health, protection of the environment, security, product and service quality, and economic elements. The management system covers all activities and facets of the organization. The development of the management system of an organization involved in transport will be influenced, as applicable, by:

— Its organizational policies;
— Its defined objectives;
— Its size;
— The scope and complexity of its packaging and transport activities;
— Applicable management standards (e.g. Refs [3–5]);
— Relevant regulatory and statutory requirements of some States (e.g. NRC 10 CFR 71, Subpart H on "Quality Assurance" [6]);
— The requirements for the nuclear programme in each State, where applicable;
— Other IAEA Safety Requirements and Safety Guides, as relevant [7].

2.4. The design of the system should be such that, whenever an assessment of any type is performed, the results demonstrate that the management system is under control and that the procedures for executing the processes that are controlled under the management system are producing results that satisfy the specified requirements.

2.5. The management system should be developed to cover all aspects of the transport of radioactive material, irrespective of whether they are individual activities or composite activities.

2.6. The management system should be designed to ensure that the transport operations conform to all applicable requirements, respecting the principle of carrying out work properly the first time.

2.7. Senior management[3] should establish and plan its strategies for the organization. These strategies should include development of the organizational policies, objectives and management process.

[3] 'Senior management' means the person who, or the group of people that, directs, controls and assesses an organization at the highest level. This term is equivalent to 'top management' as defined in Ref. [4].

STRUCTURING THE MANAGEMENT SYSTEM

2.8. The management system for transport related activities should include the processes necessary to achieve the organization's overall objectives. It should also address the requirements mandated in applicable management standards and in national and international regulatory, transport and environmental statutes (see Annex II).

2.9. The defined management system should consist of, as a minimum:

(a) The description of the management system (e.g. the management system manual);
(b) Documents that describe the management system processes (e.g. procedures[4]);
(c) Detailed work control documents (e.g. instructions[5], checklists, process control cards and forms).

2.10. The management system manual for transport related activities should be subject to approval by senior management and should include:

— Organizational policies;
— Mission and business[6] management objectives that are based on the demands of customers, interested parties, business needs, governmental regulations and other applicable requirements (e.g. international modal transport regulations);
— The purpose and scope of the management system, including the standards and requirements that it meets;
— The organizational structure (a description or diagram);
— A description of key customers, interested parties and vendors, and interfaces with them;
— Management processes for achieving the organization's objectives;
— Identification of supporting procedures;

[4] Procedures may be documented or not, as appropriate.

[5] An instruction may be oral or written.

[6] In this context a 'business' means a commercial or government enterprise or establishment. The word may also be used to refer to the commercial, industrial or professional dealings that take place in a business.

— A description of the graded approach for selectively applying the management system processes to packaging and transport related activities;
— The roles and responsibilities of managers and individuals responsible for implementing the management system;
— A matrix that maps the management processes to higher level requirements;
— Definitions of terms commonly used in the management documents;
— References utilized to develop and maintain the management system manual.

2.11. Two examples of management systems are included in Annex I.

2.12. The organizational structure pertaining to planning, implementing and monitoring and improving the management system should be clearly established within the description of the management system. General and specific responsibilities should be specified. Responsibilities for providing training in the management system should be established. The lines of authority and communication should be defined. While senior management leads in the development and integration of the management system at all levels, individuals at all levels should be given responsibility for quality and safety while carrying out the work that is assigned to them. Managers should be held responsible for ensuring that individuals working under their supervision have been provided with the necessary training, resources and directions (see Ref. [7], para. 3.4). These and other recommendations on management commitment are also discussed in paras 3.1–3.7.

2.13. Responsibility and authority to stop work when conditions or the product or service are unsafe or of unacceptable quality should be assigned in such a manner that planning, scheduling and other considerations do not override established requirements.

SAFETY CULTURE

2.14. The management system should provide structure and direction to the organization in a way that permits and promotes the development of a strong safety culture together with the achievement of high levels of safety performance, regardless of the type, scale, complexity, duration and evolution of the transport activities (see Ref. [7], para. 2.32). The controls established in

the management system should reflect the safety culture at all levels of the organization and at all stages of transport operations.

GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

2.15. Due allowance may be made in the management system for the application of control measures to packagings and/or packages in ways that such measures are sufficiently stringent to ensure adequate control without being excessively severe.

2.16. The degree to which the management system requirements are applied to a product or activity should reflect the importance of the product or activity to safety, health, environmental, security, quality and economic expectations, the complexity of the product or activity, and the possible consequences if the product fails or if the activity is carried out incorrectly (see Ref. [7], para. 2.38).

2.17. Grading the application of management system requirements should enable valuable resources and attention to be targeted at the products or activities of more safety significance. This can result in minimizing total costs while improving safety (see Ref. [7], para. 2.39).

2.18. All products and processes should have various controls and checks, consistent with the graded approach, built in to ensure that they perform correctly.

2.19. Applying controls necessitates resources. Care in the allocation of resources should be exercised to avoid unnecessary overcontrol and overchecking in some areas, which can be detrimental to the overall process.

2.20. Organizations typically use the graded approach and qualitative expressions of risk to assess the consequences of failure of the structures, systems and components (SSCs) of the packaging as well as other transport operations and services.

2.21. See the Appendix to this Safety Guide for a detailed discussion of the graded approach and examples of the application of the graded approach to transport activities.

DOCUMENTATION AND CONTROL OF DOCUMENTS

2.22. Transport activities can vary greatly in size and complexity, and may involve multiple organizations. Particular attention should be paid to ensuring that documents used to control work processes remain relevant to the diverse organizations and situations in which they are used. They should be reviewed periodically and updated as equipment, information technology, industrial practices, terminology, the typical educational level of users, the knowledge base, risks and regulatory requirements change.

2.23. Cost effective paper based or computer based procedures should be developed for the preparation, issue and control of documents needed to perform transport related activities. Procedures should be consistent with the size and complexity of the organization and its management system. If electronic data management systems (EDMSs) are used, it should be ensured that the EDMS software is qualified for its intended use.

2.24. The preparation, issue and control of documents should be such as to limit documentation to a minimum consistent with the degree to which work processes need to be controlled. Documentation may be in any form or any type of medium (e.g. hard copies or electronic documents).

2.25. Document control measures should include the unique identification of each document, an indication of the revision number or issue status of each document, and identification of the individuals or organizations that have the authority for:

— Preparation of documents;
— Review of documents;
— Approval of documents;
— Revision of documents;
— Issue and distribution of documents.

2.26. Document control should be applied to the following, as a minimum:

— Manuals and manufacturing documents (e.g. quality plans[7], manufacturing drawings);

[7] See para. 5.73.

— Design documents (e.g. drawings, specifications, design change requests and computer codes);
— Procurement documents;
— Operating, maintenance and modification procedures;
— Inspection and test procedures;
— Non-conformance reports and corrective action reports;
— Transport forms and documents;
— Internal audit reports.

2.27. Control of the release and distribution of documents should be in accordance with the appropriate procedure, using up to date distribution lists. The procedure used should ensure that persons needing the documents are made aware of, and use, the appropriate and correct documents.

2.28. Modifications to documents should be subject to review and approval as described in a documented procedure. The organizations reviewing the document should have access to appropriate background information and should possess an adequate understanding of the requirements of the original document. A modification to one document may affect other documents, and affected documents should be revised accordingly. Changes to documents should be reviewed and approved by the original review and approval organization or, alternatively, by a qualified organization that has been specifically designated for this purpose.

2.29. Information on the revision and status of documents should be given to all persons affected by the changes made. Arrangements should be made to prevent the use of outdated and inappropriate documents.

CONTROL OF RECORDS[8]

2.30. The management system for organizations involved in transport should include documented procedures for identifying, storing, protecting, retaining, maintaining, retrieving and disposing of pertinent documentation and records. Records required from suppliers and records provided to customers should be identified and made available as agreed.

[8] In this context, a ‘record’ is a document stating results achieved or providing evidence of activities performed.

2.31. The records should be able to demonstrate adequately the achievement of the required objectives of the product or service. Records should also be maintained for demonstrating the effective operation of the management system. All necessary records should be legible, dated (including revision dates), clean, readily identifiable, authenticated, and maintained in a good condition and in an orderly manner, so as to be readily retrievable. Records may be in the form of hard copy or as data stored electronically or in other acceptable media.

2.32. The following are examples of types of records that may require control:

— Inspection, measuring and test reports;
— Test data;
— Process qualification[9] reports;
— Process validation reports;
— Internal audit reports (and external audit reports, where appropriate);
— Material certification[10] and related data;
— Calibration data for inspection, measurement and test equipment[11];
— Manufacturing and fabrication records;
— Non-conformance and corrective action reports;
— Servicing and maintenance records;
— Consignment documents;
— Training and personal qualification[12] records;
— Radiation monitoring reports;
— Package approval certificates;
— Management review reports;
— Contract review records;

[9] In this context, 'process qualification' means the characteristics that are measured against established requirements, standards or tests in order to qualify a process or component to perform a stated function.

[10] In this context, 'certification' refers to the act of determining, verifying and attesting in writing to the qualifications of personnel, processes, procedures or items in accordance with specified requirements.

[11] In this context, 'measurement and test equipment' means devices or systems used to calibrate, measure, gauge, test or inspect in order to control or to acquire data to verify conformance with a specified requirement, or to establish characteristics or values not previously known.

[12] In this context, 'qualification' means the abilities gained through education, training or experience that are measured against established requirements, standards or tests to qualify an individual to perform a stated function.

— Purchasing data and records;
— Supplier evaluation records.

2.33. Records should be retained, and their retention period should be defined. Record retention periods may vary according to the importance of the records and the future need for reference to them. For example, manufacturing and modification records for a packaging should be retained for the lifetime of the packaging, whereas it may be appropriate to keep records of individual transport movements for shorter periods. Retention periods and the means of disposing of records should be included in appropriate procedures. It may be necessary to require similar records from suppliers and subcontractors for demonstrating overall product or service quality.

2.34. The owner and/or user of packagings should establish and maintain appropriate servicing and maintenance records for each packaging. The records for each individual packaging should be maintained and appropriately listed in a document such as a log book, which should be available for inspection. The log book should contain appropriate references to the following information and records:

(a) Competent authority approval of the package design and the individual packaging serial number (package design number and packaging serial number);
(b) Operating and maintenance document (document reference number);
(c) Certificate of conformance or commissioning certificate, including a summary of the applied test procedures (certificate number);
(d) Test procedure for re-inspection tests (procedure reference number);
(e) Certificates of re-inspection tests (certificate number);
(f) Movement or transport record of the package (actual record);
(g) Authorized modifications to the packaging (modification numbers or certificates);
(h) Record of any significant damage and subsequent repairs (damage and repair certificate numbers).

2.35. When a packaging is to be serviced or maintained at a point remote from the location where the detailed records are stored, the owner or user should make available such information as may be required for the satisfactory accomplishment of servicing or maintenance tasks.

2.36. The quality of the recording media used for records relating to the transport of radioactive material should be consistent with the required

retention periods. Where records are preserved electronically, these records should be retrievable and readable for the required retention period. This may necessitate several software version updates, or the use of a controlled non-proprietary means and/or system. Irrespective of the storage medium used, consideration should be given to the storage of multiple copies, in several locations and with independent protection systems.

2.37. Transport related operations may require the transfer of documents from one organization to another organization. Where this occurs, records of relevant information should be promptly made available to the receiving organization.

2.38. To make it possible for another organization to read, understand and interpret the information, both contextual information (e.g. the rationales for safety arguments and choices, language and technical terminology, scientific understanding, and methods for collecting, analysing and interpreting measurements) and the actual recorded data should be retained and transmitted.

2.39. Recording media, equipment and systems will be needed to ensure to the extent possible that the information recorded will be available in the future. No single approach is likely to have all the characteristics desirable for achieving this ideal. Organizations should select the recording methods that are the most appropriate for the present and future needs of their business, taking into account possible future developments in electronic data storage.

3. MANAGEMENT RESPONSIBILITY

MANAGEMENT COMMITMENT

3.1. Senior management is responsible for the appropriate development, implementation, assessment and improvement of the management system to ensure the safe transport of radioactive material. Additional responsibilities for planning the management system are described in Section 2.

3.2. Visible and active support, strong leadership and the commitment of senior management are fundamental to the success of the management system.

Senior managers should communicate the goals, beliefs and values that underlie the organization's policies through their own behavior and management practices (see Ref. [7], para. 3.3).

3.3. The effectiveness of the management system is the responsibility of senior management, and one senior manager should be assigned to take direct responsibility for the coordination of related efforts. The whole organization should share the management's understanding and beliefs about the importance of the management system and the need to achieve the policies and objectives of the organization (see Ref. [7], para. 3.3). Managers should be made responsible for ensuring that individuals working under their supervision have been provided with the necessary training, resources and direction (see Ref. [7], para. 3.4).

3.4. Senior management is ultimately responsible for establishing the policy statements for subjects such as safety, health, environment, security and quality. The organizational structure for the management system should be clearly established within the organization. The lines of authority and communication should be defined.

3.5. Activities should be identified and documented, and the following actions should be taken:

(a) General and specific responsibilities should be explicitly defined.
(b) The responsibility and authority delegated for each activity should be clearly established; authority and responsibility should be adequate to ensure that the objectives are achieved with the desired efficiency.
(c) Interface control measures and coordination measures between different activities should be defined.

3.6. All aspects of management documentation including that related to transport should be monitored by the management. This monitoring may be delegated to nominated persons or other groups; however, the persons nominated should be independent of the activities being monitored. When performing monitoring activities, responsible managers should place emphasis on the identification of actual and potential problems and the initiation of corrective and/or preventive measures for the continual improvement of the system.

3.7. Senior management should provide sufficient and appropriate resources for the implementation of the organization's policies and the achievement of its goals and objectives.

SATISFACTION OF INTERESTED PARTIES

3.8. Every organization has interested parties (also known as 'stakeholders'), all of whom have needs and expectations. In order to ensure that the formally agreed expectations of interested parties are determined and met, and to enhance their satisfaction, senior management should identify all of the organization's interested parties and should understand their 'products' or interests and their requirements, needs and expectations. For a consignment, the interested parties may be:

— Consignors;
— Consignees;
— Carriers;
— The public;
— Governmental bodies.

3.9. The requirements, needs and expectations of interested parties may include:

— Legal aspects of the transport of dangerous goods (e.g. State or provincial regulations);
— Restrictions on the transport of radioactive material across local jurisdictional boundaries;
— Operational limitations derived from agreements with local authorities or organizations, operating logistics or other sources;
— Attitudes, concerns and expectations of the public about the safety of transport and the ability to respond to problems that may arise.

ORGANIZATIONAL POLICIES

3.10. Senior management is responsible for developing organizational policies and the organization's objectives. The organizational policies should be tailored to the scope of the work, customers[13] and interested parties of the organization involved in transport, and the organization's specified objectives. Senior management should take measures to ensure that the organizational

[13] In this context, a 'customer' is an organization that or person who receives a product or service. A customer can be internal or external to the organization.

policies are understood, implemented, maintained and regularly reviewed and updated by the relevant individuals.

3.11. The organizational policies should be documented in the formal description of the management system. Specific objectives should also be developed to address:

— Expectations of internal and external customers;
— Expectations of other interested parties;
— Present and future needs of the organization;
— Compliance with applicable codes, regulations and requirements (e.g. environmental safety and health, financial, security and legal requirements);
— Improvements in the management system.

3.12. The organization's management objectives should be consistent with all policies. They should be measurable and should be regularly reviewed to verify their appropriateness.

PLANNING[14]

3.13. The goals, strategies, plans and objectives established for various activities and levels within the organization should be consistent with the overall strategic planning of the organization (see para. 2.7).

3.14. The objectives described in the plans should be widely communicated within the organization (see Ref. [7], para. 3.15). "Senior management shall ensure that the implementation of the plans is regularly reviewed" (Ref. [3], para. 3.11).

RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM

3.15. "An individual reporting directly to senior management shall have specific responsibility and authority for:

[14] In this context, 'planning' means the act of devising or projecting the realization or achievement of an objective or goal.

"— Coordinating the development and implementation of the management system, and its assessment and continual improvement;
— Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;
— Resolving any potential conflicts between requirements and within the processes of the management system." (Ref. [3], para. 3.13)

3.16. "The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system." (Ref. [3], para. 3.14)

4. RESOURCE MANAGEMENT

PROVISION OF RESOURCES

4.1. Senior management should ensure that the resources that are essential to implementation of the strategy for the management system and to achievement of the organization's objectives are identified and made available (see Ref. [7], para. 4.1). These resources may include, but are not limited to:

— Individuals with appropriate skills;
— Infrastructure;
— The working environment;
— Financial resources;
— Design and development;
— Facilities and equipment;
— Inspection, testing and measurement;
— Instrumentation and computer hardware and software.

HUMAN RESOURCES AND COMPETENCE AND TRAINING

4.2. The aims and objectives of the management system should be emphasized through an awareness programme, which may include induction training for new employees and periodic training for existing employees. Such training programmes should apply to all individuals in the organization, including senior management.

4.3. The objective of training should be to provide individuals with the necessary knowledge and skills that, together with attitudes and experience, will enhance their competence. In education and training, emphasis should be placed on the importance of safety, of meeting requirements, and of the needs and expectations of interested parties (see Ref. [7], para. 4.8).

4.4. Senior management should establish a system for identifying initial competences and evaluating the training provided and the resulting improved competences.

4.5. Levels of training and competence for all relevant individuals should be established and provided for by the organization. In the personnel selection and recruitment process, particular attention should be paid to the identification of training needs and the timely acquisition of necessary competences.

4.6. Appropriate records of education, training, skills and experience should be maintained and retained as quality records.

INFRASTRUCTURE AND WORKING ENVIRONMENT

4.7. Senior management should define the infrastructure necessary for safety and for achieving the organization's objectives. The infrastructure includes resources such as workspace, equipment, support services, information and communication technology, and transport facilities (see Ref. [7], para. 4.26).

FINANCIAL RESOURCES

4.8. Resource management should include activities for determining the needs for, and sources of, financial resources. The control of financial resources should include activities for comparing actual usage against plans and for taking any necessary action. Senior management should plan for, make available and control the financial resources necessary for:

— Applying safety standards;
— Maintaining the safety culture;
— Implementing and maintaining an effective and efficient management system;
— Achieving the organization's goals (see Ref. [7], para. 4.5).

INVOLVEMENT OF INDIVIDUALS

4.9. Senior management should improve the effectiveness and the efficiency of the organization and its management system through the involvement and support of all individuals. As an aid to achieving its objectives for performance improvement, the organization should encourage the involvement and development of individuals by:

— Providing ongoing training and career succession planning;
— Defining individuals' responsibilities and authorities;
— Establishing individual and team objectives, and managing the performance of processes and the evaluation of results;
— Facilitating involvement in the setting of objectives and in decision making;
— Recognizing and rewarding good performance;
— Facilitating the open, effective communication of information;
— Continually reviewing the needs of individuals;
— Creating conditions to encourage innovation;
— Ensuring effective teamwork;
— Communicating suggestions and opinions;
— Measuring individuals' satisfaction;
— Investigating the reasons why individuals join and leave the organization;
— Encouraging openness and commitment to change;

see Ref. [7], para. 4.3.

MANAGING INFORMATION AND KNOWLEDGE

4.10. Data should be converted to information for the continual development of an organization's knowledge, and senior management should treat data as a fundamental resource that is essential for making factually based decisions and stimulating innovation. To manage information, senior management should, inter alia:

— Identify the organization's information needs;
— Convert information to knowledge of use to the organization;
— Use the data, information and knowledge to set and meet the organization's strategies and objectives;

— Evaluate the benefits derived from use of the information in order to improve the management of information and knowledge;

see Ref. [7], para. 4.4.

5. PROCESS IMPLEMENTATION

DEVELOPING PROCESSES

5.1. To develop the processes necessary for the effective implementation of the management system for the transport of radioactive material, the organization should consider the following:

— The satisfaction of interested parties;
— Planning;
— Grading of the application of the management system requirements;
— Process management;
— The approach to decision making;
— Communication;
— Knowledge management;
— Human resources;
— Infrastructure and the working environment;
— Control of products and services;
— Purchasing;
— Management of organizational change and resolution of conflicts;
— Documentation of the management system;
— Control of records;
— Measurement, assessment and improvement;
— Interactions between the processes;
— Documentation of the processes;

see Ref. [7], para. 5.6.

5.2. Management and work processes associated with the transport of radioactive material (e.g. design, fabrication, assembly, inspection, testing, maintenance, repair, modification, use, procurement, handling, shipping, storage, cleaning and disposal of packagings and/or packages) should be

identified, developed, implemented, maintained and improved in a controlled fashion. They should generate the necessary objective evidence[15] to demonstrate that objectives are being achieved, and they should satisfy management system requirements.

5.3. The management system for transport activities can be the entire management system or part of the management system, depending on the size and structure of the organization. The documentation of the management system should describe the methods and procedures used at all stages in the transport of radioactive material and throughout the lifetime of a packaging and/or package. The organization should then have the appropriate parts of the documentation of the management system (sometimes called the management system manual or the procedures) issued to management, individuals, suppliers and customers.

5.4. The long term success of the management system will depend on whether all individuals have an appropriate awareness and understanding of the objectives, principles and benefits of the management system functioning in their organization, and support its initial development. The management system should provide for training, as necessary, of individuals performing activities to ensure that a suitable level of proficiency is achieved and maintained.

5.5. "A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system" (Ref. [3], para. 6.7). This requirement is normally fulfilled by addressing the internal auditing criteria and the management review features found in most management system specifications or standards. These auditing functions and management reviews should be carried out promptly and thoroughly in the early stages of application and development so that (a) the overall system can benefit where change is identified as necessary and (b) it can be observed whether the system is functioning in the desired manner. In some States, it may be necessary at this stage to obtain approval for the prescribed management system from the competent authority. Additionally, changes to approved management systems may require review and re-approval by the competent authority.

[15] Objective evidence may be qualitative or quantitative information, records, statements of fact or other acceptable information pertaining to the quality of an item or service. Objective evidence is based on observation, measurement or testing, and can be verified.

5.6. The management system should assist in the control of all normal functions of the organization relating to the assigned task by ensuring that:

(a) The management system's structure, organization and responsibilities are all specified.
(b) There are agreed written working instructions for the work to be done to the required standard.
(c) Adequate objective evidence is generated to demonstrate that the required standards have been achieved.
(d) Audits are carried out to confirm that the specified activities are being conducted or requirements are being fulfilled.
(e) Feedback information arising from the investigation of audit findings, deviations or concessions, etc., is used to improve the management system and to prevent the recurrence of problems.

5.7. Work processes should be controlled to help the management of any organization to have a better understanding and better control of its operations and thus more easily to prevent the degradation of transport safety or non-compliance with transport regulations, such as in the following examples:

(a) Failure of packages in transport, with potential loss of containment, shielding, etc.;
(b) Failure to package radioactive material properly;
(c) Poor condition of packaging owing to lack of maintenance; this is of particular concern in the case of exposure devices and source changers used for radiography purposes;
(d) Failure to prepare, label or document packages properly;
(e) Incorrect declaration of the transport index (TI) or criticality safety index (CSI) for packages;
(f) Failure to placard a vehicle correctly;
(g) Improper removal of placards and labels from vehicles;
(h) Insecure stowage or improper handling of packages, resulting in loss of and/or damage to packages;
(i) Improper stowage of packages, preventing adequate dissipation of heat;
(j) Improper application of exclusive use shipment controls;
(k) Failure to comply with conditions for transport under special arrangement.

5.8. Control of work processes may be achieved through work process design, validation, use of procedures and instructions, process surveillance and monitoring.

5.9. Meaningful and effective in-service handling instructions, inspection and testing should be considered in the design of work processes to permit:

(a) Early detection of any defect;
(b) Determination of the most appropriate corrective action;
(c) Review of the appropriate aspects of design, manufacture and component supply, use, testing, servicing, maintenance and transport operations to see what changes, if any, are necessary to identify and prevent similar occurrences;
(d) Implementation of any necessary changes in a controlled and recorded manner.

5.10. Process validation should be performed and the results should be reported in accordance with documented procedures.

5.11. There are special processes (e.g. welding, heat treatment) for which the compliance with specifications cannot easily be verified because the output depends strongly on the process itself, or on the machinery and/or skill of the operators. In such cases, indirect control should be applied by monitoring the processing methods.

5.12. All processes used should be validated, that is, demonstrated as effective using methods and conditions representative of the intended application, as witnessed by an expert in the discipline, and any precautions and limitations should be documented.

5.13. Inspection and testing, which are important elements for controlling work processes, should be planned, documented, executed and recorded. Acceptance criteria should be identified for each inspection step in the work processes used in all phases of transport.

PROCESS MANAGEMENT

5.14. Irrespective of the size of the organization or the scale of its activities, there are certain minimum requirements that should be addressed in any management system.

5.15. Recognizing that a carrier's activities are different from, for example, those of a packaging designer, a carrier's management system will be different from that of a packaging designer. The management system of each should

address some generic management system elements such as organization and document control, but other elements do not always need to be featured. For example, in a carrier's management system, design control is not usually relevant.

5.16. Where an organization is involved in more than one activity, for example, design and manufacture, or is both user and carrier, the management system should reflect this multiple involvement and should address the appropriate criteria and organizational, operational and design interfaces.

DESIGN CONTROL

5.17. Control measures for the design process should provide for the translation of specified requirements of customers, users and regulators into technical specifications, drawings, procedures or instructions for materials, products and processes. Measures should be established to ensure that all design parameters (e.g. criticality physics, cooling and decontamination of an item) have been properly considered, reviewed and approved by the responsible design organization; that the parameters are in accordance with applicable performance codes, standards and specifications; and that requirements for maintenance, repair, in-service inspection and testing, handling, storage and cleaning are specified in the design documents. The final design specification should be such that the product or service is producible, verifiable and controllable under the relevant transport conditions, and that it meets final criteria for acceptance and fitness for use.

5.18. The designer should consider the requirements relating to safety, health, the environment, security, quality, economic factors and other design base codes and standards, including elements of the organization's management policy that may go beyond existing regulatory or statutory requirements. Such elements may include life cycle considerations, usability, 'user friendliness', reliability, ergonomics, product disposal and identified risks. Measures should be established to ensure that appropriate codes and standards are used in the design of the packaging. In the absence of such codes and standards for the formulation of design activities, alternative approaches should be specified and documented.

5.19. The organization should identify and plan for the control of all design process input[16] to support efficient and effective design output.

5.20. The design output should satisfy the requirements and expectations of customers and other interested parties, particularly regulators.

5.21. The organization should assign specific responsibilities for various design duties to individuals inside or outside the organization and should ensure that all those who contribute to the design are aware of their responsibilities.

5.22. In its delegation of responsibilities, the organization should ensure that design activities generate clear and definitive technical data for use in procurement, the execution of work and the verification of conformance of products and processes with specifications and other requirements.

5.23. Where several departments within one organization or several organizations are involved in design, responsibilities should be clearly identified and should be specified in writing. Measures should be established to ensure that there is adequate communication of design information, including that relating to changes, in a controlled and documented manner between departments and organizations.

5.24. The inputs to the design process should be unambiguous and should adequately define characteristics important to quality, such as:

— Customers' needs and expectations;
— Regulatory and statutory requirements;
— Requirements for quality and safety;
— Design base codes and standards;
— Specifications and drawings;
— Feedback information from past experience and information on new developments;
— Requirements for operation, installation, application and disposal;
— Physical parameters for the safe and proper functioning of the intended design;
— Acceptance criteria.

[16] In this context, 'design input' means the criteria, parameters, bases, data or other design requirements upon which the detailed final design is based.

5.25. Designers should also consider means for the prevention of misuse of the equipment being designed.

5.26. Output from design and development, as the final product of the design process, should be documented to demonstrate its conformance with the agreed design input requirements and the defined acceptance criteria. Such output should be subject to review and approval at the defined level of management in the organization responsible for design. Design output documents may include:

— Data demonstrating the comparison of design process outputs to design process inputs;
— Specifications for product definition, acceptance, process control, material and testing;
— Specific training and qualification requirements;
— Information for users and transport organizations.

Such output from design and development can be in the form of hard copies or electronic data, or in other acceptable media.

5.27. Systematic reviews of design and development should be performed, in accordance with suitable arrangements and in a timely manner. The purpose of such reviews is to evaluate the output of the design process in order to satisfy the needs and expectations of customers and other interested parties, to identify any problems in design output and to propose any necessary corrective actions.

5.28. Competent personnel other than those who participated in the original design should participate in the review process for design and development. Records of the review process should be retained in accordance with the specified retention periods.

5.29. The design verification methods to be applied should be identified and agreed between the designer and customers, and any other interested parties. Actions for design verification may be taken independently or in support of design reviews. The following methods may be applied:

(a) Alternative calculations, to verify the original calculations and analyses.
(b) Testing, for example, by means of model or prototype tests. If this method is adopted, the test programmes should be clearly defined and the results should be documented, including any failures.

(c) Independent verification of the original calculations and other design activities.
(d) Evaluation against similar products.
(e) Evaluation against lessons learned from experience.

5.30. Verification activities for design and development should be recorded to permit adequate evaluation by technical personnel other than those responsible for the original design and development activities.

5.31. Validation activities for design and development should be performed in accordance with planned arrangements to ensure that the resulting product of the design process meets the requirements for the specified application or the intended use. Suitable validation methods can include:

— Validation of engineering designs prior to manufacture, installation or application (e.g. transport packagings for radioactive material, handling equipment and modifications to existing equipment);
— Validation of software prior to use;
— Validation of the product or service against interfacing services by means of package commissioning activities, handling trials or other activities.

5.32. Records of the validation process should be retained in accordance with specified retention periods.

5.33. Design and development changes should be identified and controlled, and records should be retained. All changes should be reviewed, verified and validated, as appropriate, and should be subject to approval before implementation. Changes in design that could result in conditions different from those prescribed on the approval certificate should be subject to approval by the competent authority before implementation. The changes should be subjected to the same control measures for design and development as those applied to the original design.

5.34. Care should be taken in the change process to ensure that:

(a) Production and field experience indicating a need for design change is fed back for analysis;
(b) Design changes do not cause degradation in product quality;
(c) Proposed changes are evaluated for their impact on all product characteristics specified in the design baseline.

MANAGING THE DIFFERENT PHASES OF TRANSPORT

5.35. As mentioned earlier, an organization may be involved in more than one basic transport activity, for example, design and manufacture, use and carriage, or even all phases from design to carriage. The management system for any particular organization should be specially designed and developed to suit the organization's needs and activities. However, for the sake of convenience, the different phases of transport and their applicable criteria are discussed separately in the following paragraphs.

5.36. Irrespective of the type of organization involved or the kind of activity it engages in, the interfaces between that organization and others should be identified and controlled.

5.37. The designer of a transport packaging should be able to assure the manufacturer, user and certifying body, as appropriate, that all necessary steps and design processes have been taken into account during all the phases of design. For example, the designer needs to ensure that the final design specifications, drawings and procedures have been produced with account taken of regulatory requirements, design bases, codes and standards. The designer should also be able to demonstrate that any proposed changes, modifications or deviations from the accepted design have been carefully considered, justified, controlled, documented and implemented, and are in accordance with, or better than, the controls applied to the original design.

5.38. If the designer is responsible for the manufacture and testing of prototypes, provision should be made within the management system to ensure that any prototype packagings, including scale models, are specified and constructed correctly, and are consistent with the materials and fabrication methods used for production packagings. Testing of the prototype (regulatory proof testing) should be performed using appropriate equipment and calibrated instruments working within their recognized capabilities and limits of accuracy. Only by the control of all design related activities can the subsequent manufacturer, user and certifying body have a reasonable assurance that the finished package complies with the designer's intent, and that any prototype packaging that undergoes physical testing to verify that it satisfies the regulatory requirements is a true representation of the finished product.

5.39. The management system of the manufacturer should be capable of demonstrating clearly that the packaging has been manufactured in strict

accordance with the agreed specifications as prescribed by the designer or customer. All relevant aspects of manufacturing or production control should be addressed, including the planning of production; timely acquisition of the necessary equipment; expertise; planned and sequential manufacturing and inspection arrangements; traceability and verification of materials and components throughout the manufacturing process; individual process controls; and final product verification. Where production has deviated from the agreed specifications or modifications have been incorporated, it should be ensured that this has been done in a controlled and authorized manner with appropriate reference to the designer or design authority, and with the creation of the necessary records.

5.40. The consignor should ensure that the packagings used for the transport operation are the correct ones and that they are appropriate for their intended contents. The consignor should also ensure that the packagings are in a fit state for transporting the material. Reusable packagings should be properly serviced and maintained. It should be ensured that maintenance is not scheduled for a period when the packaging is in use for a transport operation. The user should ensure that new packagings have been correctly made and prepared for transport.

5.41. The consignor very often prepares the material for loading or filling before carrying out final transport operations. For all radioactive materials, preparation, loading and filling are required to be done under carefully controlled appropriate conditions in accordance with detailed procedures to ensure compliance with the Transport Regulations [1].

5.42. According to the Transport Regulations, the consignor is responsible for appropriate monitoring of the package before dispatch as well as for the correct marking and labelling of the package, overpack, freight container or tank. The consignor is also responsible for preparation of the necessary transport documents; consignors should be aware of the differences between various national regulations when conducting international transport movements. Irrespective of whether a separate carrier is to be used, the consignor should be satisfied that the carrier knows how to transport radioactive material safely and in compliance with the Transport Regulations.

5.43. The users of packagings, who are frequently the owners or consignors of packages containing radioactive material, sometimes prepare the radioactive material for loading or filling and conduct the loading or filling operation under carefully controlled conditions in accordance with detailed procedures. Such

users also have to perform various tasks in order to dispatch a package safely, and their management system should be appropriately designed with sufficient flexibility for achieving this.

5.44. There can be considerable differences in the types of work in which carriers are engaged, and their management systems should be developed so as to be appropriate for their type of business.

5.45. For the transport of radioactive material, the carrier should ensure that its personnel are adequately trained and know the regulatory requirements applicable to the mode(s) of transport to be used, and how to comply with them.

5.46. The carrier should know what transport documents are required and what information they should contain, what action to take in an incident or emergency, and how the vehicle or container should be placarded and/or labelled. Segregation distances between driver and load may need to be determined for limiting radiation exposures of people and the exposure of photographic film.

COMMUNICATION AND INTERFACES

5.47. In establishing internal and external communication processes, it should be recognized that communication may need to be sustained over the lifetime of a packaging. The management system, including associated procedures, should provide for the recognition and control of interfaces (internal and external) wherever they occur; the procedures should be sufficiently detailed that the transfer points for responsibility and operational physical control are clearly established and known.

5.48. All people and organizations concerned with the transport of radioactive material should have a clear understanding of their own interfacing responsibilities and the limits of their operation and control, and also those of others. Such an understanding can be achieved by means of the definition of responsibilities. Where internal interfaces occur, the organization should identify them clearly within its management system, such as in the documentation or procedures for a particular activity. Where external interfaces occur, they should be identified and agreed upon, and care should be taken to ensure that responsibilities are clearly defined in appropriate documents such as purchase orders, specifications and contracts.

5.49. Within a large or medium sized organization, the correct specification and understanding of interfaces can prevent, for example, a package from being dispatched before all the necessary checks such as package closure checks, leak tests or labelling checks have been completed. Similarly, failure in design can result from inadequate communication (interface control) between the designer and user, with a package not meeting specified or regulatory requirements during testing or use. This may occur because both parties have assumed, but not confirmed, that all necessary requirements have been taken into account by the other party in their interfacing activities.

5.50. Such verification should be made to confirm that all aspects of the transport operation are under appropriate control, with no shortfalls in actions or responsibilities when a design, package or shipment is passed from one organization to another. Relevant interfaces may also exist between, for example, those involved in design and those involved in carrying out modifications. Interfaces between groupings such as design, testing and manufacture, or consignor, user, carrier and consignee, will frequently occur; however, other, less frequent interfaces should also be considered, as these often create or add to problems and misunderstandings in transport.

5.51. Internal interface control is as important as external interface control. Within an organization there should be no gaps in responsibility or activity, although there may be some overlaps. It may be desirable in some aspects of package preparation and dispatch to have some deliberate overlap of activity to serve as a verification check. Essential but unassigned tasks should not be carried out where no responsibility and hence no formal control exists. Therefore, each of the different sections or departments of an organization should ensure not only that its internal interfaces are clearly defined, understood and agreed, but also that they are recognized and described in procedures and instructions pertinent to that particular section or department.

5.52. External interfaces have wider implications and are analysed more carefully than internal interfaces, as a result of pressures arising from considerations of commerce or prestige, etc. However, there is far more potential for external breakdowns in communication and interface control than for breakdowns within a single organization. Different working methods and practices can create wider gaps in responsibility and control between organizations. Compliance with the Transport Regulations can only be achieved if the points at which responsibility and control are passed from one organization to another are clearly understood and agreed, and clearly defined

in an appropriate documented form (contractual documents, purchase documents, specifications, agreements).

5.53. The determination of and agreement on external interfaces is sometimes more complicated because several sections of one organization may be dealing with another organization simultaneously; for example, a procurement section may place orders with a supplier while the design office negotiates specification details and the inspection section defines acceptance criteria with the same supplier. Unless all of these different external interfaces are recognized and controlled, problems may arise that could eventually compromise transport safety.

5.54. Because of the importance of interface definition and control, senior management should ensure that the organization has defined mutually acceptable processes for communicating effectively and efficiently with its customers and with other interested parties.

5.55. In relations between consignors and carriers, definition and control of interfaces are of particular importance, since the carrier is required not only to be provided with the necessary information as specified in the Transport Regulations, but also to know whom to contact, and by what means, in the event of an incident or emergency. If there are two or more carriers concerned, as for example in a multimodal transport operation, the consignor should ensure that there is sufficient understanding on the part of all the carriers and shipping agents of the normal requirements and of any applicable special requirements, including emergency arrangements and contacts.

5.56. Interfaces between an organization and all relevant competent authorities and other agencies whose approval may be necessary should be recognized, established and maintained by inclusion in the relevant management system, to ensure that formal notifications required by the Transport Regulations are correctly received within specified time frames. The interfaces should also be used to provide for the timely acquisition of information concerning changes to regulatory requirements and other issuances of the competent authority.

PURCHASING

5.57. Purchased materials, components, assemblies and services become part of the organization's product (package contents, packaging or transport

operation) and directly affect the safety and quality of this product. The quality of services such as calibration and special processes[17] should be considered. The procurement of supplies should be planned and controlled. The purchaser should establish a close working relationship and feedback system with each supplier. When appropriate, during the purchasing process, reference should be made to the Appendix to this publication, dealing with the graded approach to application of the management system to items and services.

5.58. The purchasing activities should include measures to control the following elements, as applicable:

— Identified requirements for all purchase documents including specifications, drawings and purchase orders;
— Use of qualified suppliers;
— Agreement on appropriate quality levels;
— Agreement on inspection methods;
— Provisions for settlement of non-conformances and corrective actions;
— Arrangements for inspection on receipt;
— Specified quality records.

5.59. Those responsible for procurement should develop appropriate methods to confirm that the supplier has a demonstrated capability to meet all the requirements of the purchaser. Measures should be established to ensure that designated individuals or organizations evaluate proposed suppliers on the basis of the following criteria as applicable to the type of procurement:

— Technical ability;
— Established quality requirements;
— Production capability;
— Delivery capability;
— Past performance and experience in supply;
— Results of supplier evaluations or audits by the organization;
— Supplier response and communications;
— Viability of the supplier for the period of the contract and for post-contract support.

[17] The term ‘special processes’, described in para. 5.11, can be used or applied when more complex processes are used, or when the output of such processes is difficult to measure directly.

5.60. Those responsible for procurement should develop appropriate methods to ensure that the requirements for the supplies are clearly defined and communicated and are fully understood by the supplier. These methods may include: written procedures for the preparation of specifications, drawings and purchase orders; vendor and purchaser conferences and pre-award evaluations before the release of purchase orders; and other methods appropriate for the supplies being procured.

5.61. Successful procurement of supplies begins with a clear definition of the requirements. Usually these requirements are contained in the contract specifications, drawings and purchase documents that are provided to the supplier.

5.62. Purchase documents should contain data clearly describing the product or service ordered. Purchase data may include the following:

— The type, class, style, grade or other precise identification;
— The title or other positive identification, and the applicable issue of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of products, procedures, processes, equipment and individuals;
— Quality requirements to be met.

5.63. Clear agreement should be reached with the supplier on the methods by which conformance with the purchaser's requirements will be verified. Such agreement can minimize difficulties in the interpretation of requirements as well as clarify inspection, testing or sampling methods. Verification activities should be carried out at agreed locations, for example, supplier's premises, purchaser's premises or independent test facilities.

5.64. Any material, software, equipment or components supplied by the customer organization to the supplier for incorporation into the final product should be suitably controlled. Procedures should be established to ensure that such material is verified for acceptability on receipt and is suitably stored and maintained. Details of any such material that is lost, damaged or otherwise rendered unsuitable for incorporation into the final product should be recorded and notified to the customer organization.

IDENTIFICATION, TRACEABILITY[18] AND PRESERVATION OF MATERIALS

5.65. All materials, including raw materials, components, assemblies, packagings and software, should conform to appropriate specifications and quality requirements before being introduced into production or service. Such materials should be appropriately identified, stored, segregated, handled and protected during production or service to maintain their suitability for use.

5.66. Arrangements should be established for the applicable identification and control of packagings, package contents, materials and components, software, associated transport equipment, etc., during all phases of transport, such as:

— Initial design and development;
— Testing;
— The entire production process;
— Handling and loading;
— Package labelling and identification;
— Dispatch and receipt;
— Carriage;
— Service, maintenance and storage.

5.67. Appropriate arrangements should be developed to preserve the necessary traceability throughout the relevant phases of transport so that unique identification and traceability of the product, package, shipment, etc., is achieved. Records of identification and traceability should be appropriately maintained.

5.68. The handling, storage and shipment of materials, parts, components, etc., require proper planning and control; this applies not only to initial delivery, but also to use in transport operations. Provisions should be established to prevent damage to or deterioration of any materials, including the packaging and its contents, that may be affected by environmental conditions such as temperature and humidity.

[18] In this context, 'traceability' is the ability to follow the history, application or location of an item. Traceability implies knowledge of the origin of material and parts, the process history, and the subsequent distribution and location.

PROCESS CONTROL

5.69. Many aspects of transport can be considered to be general processes needing control. Examples of such general processes are:

— The design process;
— The procurement process;
— The manufacturing process;
— The delivery process.

5.70. Those responsible for the authorization of changes in processes should be clearly designated, and, where necessary, further approvals should be sought as appropriate. The implementation of process changes should be evaluated to verify that the change has had the desired effect on the quality of the product or service and that no unanticipated detrimental effects have occurred. The evaluation should be appropriately recorded.

5.71. Inspections or tests should be considered at appropriate points in the process to verify conformance. The locations and frequencies of the inspections or tests will depend on the importance of the characteristics and the ease of verification at the stage of production. In general, the verification should be as close as possible to the point of production of the feature or characteristic.

5.72. Provisions should be made for the adequate control of packagings and their radioactive contents during all relevant phases of the transport operations process.

5.73. Process control of transport operations may be accomplished by controlling the documentation, for example, by the use of a quality plan[19] (see Table 1 for a typical example). Such a quality plan may list the sequence of actions and activities involved in the transport process, identify responsibilities for those actions, refer to detailed procedures or specifications as appropriate, and identify quality records to be produced at certain stages of the operations. Hold points may be identified within the sequence of actions to allow for adequate verification at key stages of the process.

[19] In this context, a 'quality plan' is a document setting out the specific quality practices, resources and sequence of activities relevant to a particular process, product, service, contract or project.

TABLE 1. EXAMPLE OF PART OF A QUALITY PLAN

Quality Plan				Rev.
Title				Page X/Y
Action/activity	Controlling document	Responsibility	Records	Date, signature
1. Check availability, maintenance and status of equipment	Procedure 02	OP	DOC/XX/..	
2. Obtain approval		EN	Certificate of approval	
3. Check approvals/package contents		RO		
4. HOLD — verify completion of 1, 2, 3 before proceeding.				

5.74. All carriage, in-transit, storage and handling operations may also be considered to be processes requiring appropriate control.

5.75. Process control should be applied to those processes for which verification by monitoring or measurement cannot be established solely by post-process inspection. Where such processes are to be performed, details of the process and its controls should be submitted to the responsible group or organization for review or approval prior to the commencement of work.

5.76. Consideration should be given to processes in which control is particularly important to the quality of the product or service and for which controlled conditions are essential. Special consideration may be necessary if characteristics of the product or service cannot be easily measured, if special skills are required in operation or maintenance, or if a product, service or process cannot be fully verified by subsequent inspection and testing. Particular attention should be paid to processes controlled by computers or electronic systems; it should be ensured that related software is validated and kept up to date.

5.77. In the case of special processes, more frequent verifications may be necessary in order to keep a check on the following:

(a) The accuracy and variability of equipment used to make or measure the product or service, including adjustment of settings and calibration;
(b) The skill, knowledge and certification, where appropriate, of operators, and their ability to meet quality requirements;
(c) Special environments, age or other factors affecting quality;
(d) Certification records maintained for personnel, processes and equipment, as appropriate;
(e) Procedures used and codes referencing acceptance criteria.

5.78. Processes such as welding, heat treatment, non-destructive testing and manufacture of specialized materials, while commonly used in packaging manufacture, are not always performed by the users of the packaging. However, if a packaging requires major repairs, the use of special processes by the users may be necessary.

5.79. Procedures should be established to ensure that the processes are controlled in accordance with the following criteria:

(a) The process and the controls are capable of producing products of the specified quality.
(b) Procedures, equipment and personnel are qualified in accordance with applicable codes, standards and specifications.
(c) Where the processes are not covered by available standards or codes, the methods of qualification of personnel, procedures and equipment are defined.
(d) The operations are performed by qualified personnel and are accomplished in accordance with documented process controls with evidence of verification recorded.
(e) Qualification records of personnel, processes, procedures and equipment are established and maintained.
(f) Process parameters are established and monitored.

INSPECTION, MEASUREMENT AND TEST CONTROL

5.80. In-process, final and other required inspections, measurements and tests associated with all prototype work, testing, manufacture, use, servicing and maintenance activities should be identified and controlled.

5.81. Inspection and analysis of services provided should be carried out and recorded. All relevant aspects of the service supplied should be verifiable against agreed specifications or other requirements.

5.82. Inspection, analysis or measurement of services and products should be carried out by individuals who or organizations that have no direct or conflicting responsibility for the activity under examination, are suitably qualified to carry out such activities and have the authority to put into effect 'holding procedures' to prevent the use of non-conforming items or services in transport.

5.83. Provision should be made for appropriate testing of the packaging or its constituent parts in all phases of the lifetime of the packaging, in accordance with the applicable specifications, standards and regulatory requirements. Such testing, which may be carried out by more than one organization and hence in more than one management system, should include conceptual testing, regulatory proof testing for normal conditions and accident conditions, material proof tests, manufacturing tests and in-service testing, as well as servicing and post-maintenance tests. All such tests or test programmes should be fully documented and controlled, and should be carried out under prescribed test conditions, using prescribed equipment and acceptance criteria. All equipment used during testing should be calibrated against the appropriate standards for the parameters being checked. The precision and accuracy of the calibration should be known.

5.84. If the facilities of other qualified organizations are used for inspection, measurement, testing or calibration services, the necessary controls and traceability should be maintained.

5.85. Measures should be established to ensure that inspection and measurement activities include the following:

(a) Identification of the characteristics and activities to be inspected or measured;
(b) Definition of acceptance criteria;
(c) Identification of the individuals or groups responsible for performing the inspection activities;
(d) Recording of objective evidence of inspection, measurement or analysis results;
(e) Identification of hold points or witness points, where applicable;

(f) Confirmation that all inspection/measurement requirements have been achieved.

5.86. Controls on inspection and measurement should be established to ensure that items important to safety meet the specified requirements, consistent with the graded approach. Provisions should be established for the control of accepted items until they are placed in stock or released for use, and for the proper disposition of rejected items.

5.87. In-process controls should be established to ensure that process specifications and their supporting documents provide for indirect control by the monitoring of processing methods, process parameters, equipment and personnel.

5.88. Final inspections should be established as a control to ensure that non-conforming inspected items that have undergone rework or repair meet the original specified requirements and are fit for use. Appropriate records of re-inspections of such reworked or repaired items, traceable to the original inspection records, should be included in the inspection records for the packagings.

5.89. Inspection and measurement records should be reviewed to verify that all requirements for inspection and measurement have been fulfilled.

5.90. Measures should be established to ensure that:

(a) Personnel carrying out inspection or measuring activities are qualified in accordance with applicable codes, standards and training programmes.
(b) Such qualifications and certifications are kept up to date.
(c) Such personnel are independent of the individuals performing the activity being inspected or measured.

5.91. Controls should be established to ensure that necessary testing activities, including prototype qualification tests, production tests, proof tests and operational tests, are accomplished in accordance with specified requirements. Controls should also be established to ensure that modifications, repairs and replacements are tested in accordance with the original requirements for design and testing.

5.92. The following aspects may be included in typical tests of transport packagings:

— Structural integrity;
— Leaktightness (of the containment system as well as of auxiliary equipment);
— Component performance;
— Shielding integrity;
— Thermal integrity.

5.93. Controls should be established to ensure that test prerequisites identified in the appropriate design specifications are properly transcribed into test procedures.

5.94. Controls should be established to ensure that test results are recorded. Test results should be evaluated, and their acceptability should be confirmed by qualified individuals or groups on behalf of the organization.

5.95. Controls should be established to ensure that inspection, measurement and testing equipment (e.g. gauges, fixtures, reference standards and devices used to measure product characteristics) is calibrated, adjusted and maintained, at prescribed intervals or prior to use. The inspection, measuring and testing equipment should be labelled or tagged to indicate its calibration status, and the calibration records should be maintained. Measures should be established to ensure that in-house reference standards or intermediate standards used in calibrating inspection, measuring and testing equipment are traceable to nationally recognized standards. Calibration standards should have known valid relationships to nationally recognized standards. If no known recognized standard exists, the basis for calibration should be determined and recorded.

5.96. When inspection, measuring and testing equipment is found to be out of calibration, measures should be taken to validate previous inspection and test results up to the time of the previous calibration.

5.97. The status of inspection and testing activities should be identified either on the individual items, in a batch of items or in documentation that is traceable to the items. This is necessary to demonstrate that the required inspections and tests have been performed and that the items conform or do not conform to specified requirements. Item status should be indicated by means of tags, markings, stamps, manufacturing records, inspection records or other suitable means.

SERVICING

5.98. Senior management should establish measures to control all servicing activities[20]. Items that may need servicing include packagings, transport related equipment, conveyances, parts and components. Appropriately controlled and specified servicing will ensure the continued acceptability of such items for the safe transport of radioactive material. Servicing controls should include:

— Identification of the item to be serviced;
— Application of acceptance criteria during servicing activities;
— Definition of service intervals;
— Recording of servicing activities carried out.

5.99. When completed, the serviced items should be subject to verification to confirm that they meet specified requirements.

MANAGING ORGANIZATIONAL CHANGE

5.100. Changes may arise from the political and business environment and from within the industry itself as it strives to reduce costs and improve efficiency to survive. When organizational change is necessary, no reductions in the level of safety achieved should be acceptable, even for short periods of time, without appropriate justification and approval (see Ref. [7], para. 5.56).

5.101. Senior management should remain aware that it has the ultimate responsibility for safety and should ensure that safety considerations are given a priority commensurate with their significance during any process of major change (see Ref. [7], para. 5.58). Individuals should be made aware of how their responsibilities will change both during and after organizational changes (see Ref. [7], para. 5.59).

5.102. A form of safety assessment should be developed to evaluate any changes that could affect safety. For the changes with more significant effects, advice should be sought from internal experts and external experts when required. Following the safety assessment, the organization should consider the safety implications of the changes in the light of the assessment results.

[20] Some aspects of servicing can also be described as maintenance.

5.103. Communication with interested parties, including personnel, should be carried out honestly and openly, addressing the safety and other implications of the changes and explaining the steps to be taken. The appropriate mechanisms for the feedback of information to monitor the effects of the changes that are implemented should be set up (see Ref. [7], para. 5.64).

5.104. The individual who has authority to approve changes to be implemented should be clearly designated. For each change, and on the basis of the significance of the change, controls should be applied to ensure that it is possible to identify the individual in the organization who is authorized to approve the change (see Ref. [7], para. 5.68).

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

GENERAL

6.1. Provision should be made by the organization's management for periodic reviews and assessment of the management system. Such reviews should be carried out by senior members of the organization's management or by competent independent individuals.

6.2. Reviews should consist of well structured and comprehensive evaluations that may include:

— Results of audits, inspections, surveillance and surveys;
— Feedback from interested parties;
— Process performance;
— Status of corrective and preventive actions;
— Follow-up actions from previous management reviews;
— Changes that could affect the management system;
— Recommendations for improvement;
— Problems and issues resulting from non-conformance, deficiencies or deviations;
— Safety review and evaluations;
— Graded quality and safety classifications and the consequences of failures.

6.3. Findings, conclusions and recommendations reached as a result of review and assessment should be implemented by the organization to achieve improvements and should be communicated to individuals, interested parties and senior management.

MONITORING AND MEASUREMENT

6.4. The management system should ensure that standards of performance are established. These standards should be directly related to the product provided by the organization and be based on the objectives set by senior management. Once the standards have been established, performance should be measured against them. These measurements should be monitored at regular intervals to ascertain whether or not improvements in the quality of the product or process are necessary. Performance indicators should be used, and other appropriate methods of measurement should be developed (see Ref. [7], para. 6.4).

SELF-ASSESSMENT

6.5. "Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work" (Ref. [3], para. 6.2). The following are examples of what could be assessed in a self-assessment performed on work processes used in transport related activities:

— The application of existing work processes;
— The impact of legal aspects affecting the transport of radioactive material;
— Operational limitations derived from agreements with local authorities or organizations, operating logistics or other sources;
— Whether public concerns, attitudes and expectations have been taken into account.

INDEPENDENT ASSESSMENT

6.6. Assessments to verify the implementation and effectiveness of the management system for transport activities may be performed by the organization itself. However, assessors should not assess their own work, and they should be independent of the line management responsible for managing and implementing the process being assessed. Independent organizations and

national authorities may also conduct such assessments, consistent with industry practice and national regulatory provisions.

6.7. Documented procedures should be established to ensure that internal audits are carried out on a regular basis to verify compliance with all aspects of the management system and to confirm its continuing effectiveness. Similarly, external audits to verify the management system arrangements of suppliers should be planned and carried out in accordance with a documented procedure. Audits should be conducted by qualified persons selected for their independence from the activity under audit.

6.8. The documented audit results should be brought to the attention of the management responsible for the activity under audit. The responsible senior management should take timely improvement actions or corrective actions in response to the audit findings. It should be verified that the corrective actions are effective, and this verification should be recorded.

6.9. The audit process should address the following:

— Authority to audit;
— Organizational independence of auditors;
— Identification and qualification of auditors;
— Allocation of resources to support the audit;
— Availability of the necessary documentation and personnel for the audit;
— Provisions for access by the auditors to all appropriate levels of management;
— Methods for the verification of corrective and preventive actions by the auditors;
— Response and commitment by senior management;
— Development of audit schedules;
— Determination of audit frequency;
— Formal audit reporting arrangements.

6.10. Schedules should be established for internal audits, and for external audits where applicable. Audit schedules should cover the following aspects:

— Responsibility for the audit programme;
— Elements of the management system to be audited;
— Timing of audits.

6.11. Auditors should be selected and assigned by senior management on the basis of their qualifications and experience. It is the responsibility of the auditing organization to establish qualifications for prospective auditors and requirements for the use of technical specialists to conduct auditing activities.

6.12. The nature and scope of the audit should be discussed and agreed at a pre-audit meeting between the team of auditors and the organization being audited.

6.13. A post-audit meeting should be conducted between the audit team and the management of the organization being audited to present the results and to agree on a response programme for any corrective action necessary.

6.14. The audit report should include the audit findings and any recommended corrective actions, and a timeline for completion and implementation of the agreed corrective actions. It is the responsibility of the organization being audited to come to an agreement on corrective actions with the auditor and to initiate the corrective action processes. In the event that corrective actions cannot be taken immediately, the response of the audited organization should include scheduled dates for initiation and completion of the corrective actions. Where necessary, controls should be put into effect to prevent the recurrence of non-conformances.

6.15. The audit team leader should verify that the organization being audited provides a timely response to the audit report, that the response is adequate and that the corrective action has been satisfactorily accomplished within the prescribed schedule. Senior management should be informed by the auditor of the progress of all follow-up actions and of the timing of completion of the audit.

MANAGEMENT SYSTEM REVIEW

6.16. In conducting planned reviews of the management system for the transport of radioactive material, consideration should be given to whether its structure and content are still effective in meeting the organization's objectives. Reviews of the management system should be carried out on a periodic basis.

6.17. Inputs that will allow evaluation of the efficiency and effectiveness of the management system for the transport of radioactive material in the management system review should cover:

— The status of the organization's objectives and results of the improvement activities;
— The status of actions from past management system reviews;
— The performance of the organization in achieving its objectives, plans and goals;
— The results of assessments of all types;
— Feedback on the satisfaction of interested parties;
— Advances in technology, research and development;
— Results of benchmarking activities;
— The performance of suppliers;
— New opportunities for improvement;
— The control of process and product non-conformances;
— The status of activities in strategic partnerships;
— Other factors that may impact the organization, such as financial, social or environmental conditions;
— Relevant statutory and regulatory changes

(see Ref. [7], para. 6.47).

NON-CONFORMANCES[21] AND CORRECTIVE AND PREVENTIVE ACTIONS[22]

6.18. The steps for controlling non-conformances should be established in a documented procedure. The procedure should clearly identify responsibilities and steps for the generation, review, disposition and allocation of resources for the correction, prevention and closure of non-conformances. Records of non-conformances should be retained for a specified retention period. Whenever possible, provision should be made to examine previous production items or batches, or the conduct and results of previous operations or services.

6.19. Non-conforming products should be properly identified, segregated, controlled, recorded and reported until appropriate action is taken (see Ref. [7],

[21] A 'non-conformance' is a deficiency in characteristics, documentation or procedures that renders the quality of an item or service unacceptable or indeterminate.

[22] 'Corrective actions' are measures taken to correct conditions adverse to quality and, where necessary, measures to prevent recurrence; 'preventive actions' are actions taken to eliminate the cause of a potential non-conformance or other undesirable situation.

para. 6.58). Similarly, non-conforming operations or services should be reviewed and should be suspended if necessary until appropriate decisions are made.

6.20. The impact of the non-conformance should then be evaluated and reviewed, and the non-conforming item should be:

(a) Accepted; or
(b) Reworked or corrected within a specified time period; or
(c) Rejected and discarded or destroyed to prevent its inadvertent use

(see Ref. [7], para. 6.58).

Likewise, unsatisfactory operations or services should be reviewed to determine where changes or improvements are necessary. Competent authority approval should be obtained if any proposed changes or waivers affect existing approvals of packages, shipments, etc.

6.21. Appropriate steps should be taken to prevent the recurrence of non-conformances. Consideration should be given to establishing a non-conformance database. When trends or patterns of non-conformance are detected, these should be analysed, and preventive measures should be developed.

6.22. Non-conformances may warrant remedial, investigative corrective or preventive actions tailored to the severity of the problem and specific conditions noted. Non-conforming items should be reviewed by designated persons to determine whether they can be corrected by being repaired, reworked or reclassified, or whether they should be scrapped or used as is, as specified in para. 6.20. Whichever is the case, the disposition of non-conformances should be documented, justified and authorized.

6.23. The disposition of changes, concessions or deviations that have been accepted should be authorized and recorded. Non-conforming items that have been 'accepted as is' should be subject to approval by technically competent personnel.

IMPROVEMENT

6.24. Senior management should ensure that the focus is on improving the quality of processes and services by establishing priorities, promulgating policy,

promoting safety culture, allocating resources, communicating lessons learned and resolving significant management issues and problems that hinder the organization from achieving its objectives. Senior management should balance safety and mission priorities when considering improvement actions.

6.25. Senior management should encourage personnel to develop and explore new ideas for improving processes and services. Effective improvement requires that each individual participate; it cannot always be delegated to a particular person or group.

6.26. Management commitment can be demonstrated by empowering individuals to identify problems in processes, to develop alternative approaches for addressing problems (e.g. reducing process variability or cycle time), to implement the approved solution, to evaluate the improvement and to provide lessons learned to other organizations.

6.27. Problems with performance and other quality related information, both positive and negative, from various internal and external sources, should be reviewed and analysed to identify opportunities for improvement of the management system, processes, items, products or services. Implemented improvements should be monitored, and methods should be established to verify their effectiveness.

Appendix

GRADED APPROACH FOR MANAGEMENT SYSTEMS FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL

GENERAL

A.1. The graded approach (also referred to as the graded process) is a process by which the scope, depth and rigour of the management controls to be applied to a specific packaging or transport related component or activity are commensurate with certain aspects, including, but not limited to:

- The magnitude of any hazard (radiological and non-radiological) involved in the item's failure;
- The impacts of the item's failure on safety and security;
- The impacts of the item's failure on the project, facility or business mission;
- Unique characteristics of the item;
- The impacts of the item's failure on other pertinent factors.

A.2. The graded approach should be used to evaluate possible risk factors that could hinder the achievement of safety and other relevant objectives, and to determine the appropriate controls to address those risks. The grading process should not be used to obtain exemptions from the management system, since by definition the management system applies to all business and work activities and organizations, including vendors. The logic, method of implementation and basis for grading should be documented in the management plan, periodically reviewed in the light of changes that may have occurred and, if appropriate, revised to reflect those changes.

A.3. The graded approach should be developed as early in the process as practicable. This will enable a uniform application of the grading process, based on risk informed application of the management system in design, fabrication, maintenance, inspection, testing, and transport and use of packages and packagings.

A.4. Risk is a fundamental consideration in determining the extent to which controls should be applied. Risk is a quantitative or qualitative expression of possible impacts on, for example, safety, the project or finances in which both the probability of an event causing harm or loss and the consequences of the

event are considered. Determination (or estimation) of the probability or likelihood of the occurrence should be a part of the risk expression.

A.5. The graded approach should also cover other factors such as environment, safety and health related risks, cost effectiveness, and impact on the mission and operations. The resulting risk factors, risk levels and associated controls should be tailored to meet the company's unique needs and all internal and external requirements.

STEPS IN THE GRADED APPROACH FOR PACKAGING

A.6. Organizations involved in the design and manufacture of packagings typically use a component based graded approach and qualitative expressions of risk based on the safety consequences of failure of the packaging component. Logical steps in the graded approach are:

(1) Identification of the package type according to the Transport Regulations [1];
(2) Classification of the package by the development of a list of the packaging components and software to be used in its design, fabrication, use, inspection or testing, and assignment of a quality category (grade) to each (Table 2);
(3) Specification of the management controls required and assignment of a quality category (grade) to each (Table 3).

A.7. Many quality requirements are specified by the codes or standards for design, fabrication, inspection and testing that are determined in the initial stages of the package design. These codes, for example, often impose controls on the procurement, receipt, storage and use of the package materials.

A.8. Quality codes and standards may vary between different components of a single container type, and between similar components of containers of different types. The container materials, for example, may include bulk material such as metal plate, sheet, castings, weld metal and forgings. Items fabricated by subtier vendors (seals, bolts, pressure relief valves, rupture discs, special closure assemblies, etc.) may also be included. Typically, traceability of material, control of chemical and physical properties of the material, and isolation of the material from non-conforming material are used to ensure proper fabrication. Where applicable, subtier vendors should control the quality of the component materials used.

TABLE 2. EXAMPLES OF QUALITY CATEGORIES BASED ON CONSEQUENCES OF FAILURE

Quality category	Safety classification	Consequences of failure
Grade 1	Safety class – critical to safe operation	Grade 1 items are those directly affecting package leaktightness or shielding, or, for packages of fissile material, those directly affecting geometry and thus criticality control. Examples include the primary and secondary containment vessels, outer and inner O-rings on the vessels, and lead shield, as well as software used in their design, fabrication, use, inspection or testing.
Grade 2	Safety significant – major impact on safety	Grade 2 items are systems, structures or components whose failure could indirectly affect safety in combination with a secondary event or failure. Examples include impact absorbers that provide impact protection between the primary and secondary containment system during an accident, and software used in their design, fabrication, use, inspection or testing.
Grade 3	Production support – minor impact on safety	Grade 3 items are those affecting systems, structures or components whose malfunction would not affect the effectiveness of the packaging and so would be unlikely to affect safety. Examples include devices that indicate tampering, such as security lock wires and seals, and package identification plates.

Note: Items whose failure does not impact the safety or quality of the product or service need not be included in this graded system. An example of such non-graded items is software that facilitates routine operation, handling and/or use of the package or packaging.

A.9. Fabrication requirements may also vary between different components of a single type of container and between similar components of containers of different categories, according to the materials of construction. For example, welds that attach or join components should be in the same quality category as the higher level component unless a lower classification can be justified. Welds that join a component (such as a cylinder longitudinal seam weld) should be in the same quality category as the component of which they are a part. Many requirements for processes (e.g. welding and heat treating) are defined within the code used for construction. However, for some special processes (e.g. pouring of gamma shielding material), no specific code exists, and approved

TABLE 3. GRADED MANAGEMENT CONTROLS

Graded management controls	Quality categories		
	Grade 1	Grade 2	Grade 3
The design is based on the most stringent industry codes or standards, and design verification is accomplished by prototype testing or formal design review.	X		
The suppliers and subtier suppliers have a management system based on applicable criteria established in an acceptable national or international standard.	X		
The manufacturing planning specifies complete traceability of raw materials and the use of certified welders and processes.	X		
The procurement documentation for materials for services specifies that only suppliers from qualified vendor lists are used.	X	X	
A comprehensive programme for specifying commercial grade items and controlling counterfeit parts is required.	X	X	
Verification planning (testing and inspection) requires the use of qualified inspectors (i.e. individuals performing non-destructive examinations such as radiography and ultrasonic testing are qualified in accordance with recommended practices described in appropriate national or international standards).	X	X	
Only qualified auditors and lead auditors perform audits.	X	X	
Comprehensive design, fabrication and assembly records, results of reviews, inspections, tests and audits, results of the monitoring of work performance and materials analyses, and results of maintenance, modification and repair activities are maintained.	X	X	
The design is based on the most stringent industry codes and standards, but design verification can be achieved by the use of calculations or computer codes.		X	
The manufacturing planning need not require traceability of materials, and only specified welds are done by qualified welders.		X	
Only the lead auditor need meet certain qualification requirements.		X	

TABLE 3. GRADED MANAGEMENT CONTROLS (cont.)

Graded management controls	Quality categories		
	Grade 1	Grade 2	Grade 3
Verification activities still require the use of independent inspectors qualified to appropriate codes, standards or other industry specifications.		X	X
The procurement of materials need not be from a qualified vendor list.			X
Items are purchased from a catalogue of 'off the shelf' items.			X
When the item is received, the material is identified and checked for damage.			X
Self-assessments rather than independent assessments are the primary method of assessing and verifying performance.			X
Records are maintained in temporary files for a specific retention period (e.g. six months) after shipment.			X

procedures are needed to perform the task. Each procedure should be qualified to ensure its conformance to requirements.

A.10. Since there may be no manufacturer available with an approved management system for Grade 1 component materials such as foam, honeycomb or wood (used in impact limiters), concrete or lead (used in shielding), and polymers (used in seals), packaging or cask vendors may be allowed to use the manufacturer's management system to procure Grade 1 components. This will place more responsibility on the designers to specify the most important properties and characteristics of materials, and on the manufacturers to comply with these specifications.

RELATIONSHIP OF GRADING TO PACKAGE TYPE

A.11. The level of management system applied to a package is required to be commensurate with the hazard posed by the radioactive contents. The following guidance is applicable to each category of package listed but is not intended to cover all situations. However, it gives a general indication of the

degree to which the management system is to be applied. Clearly, a higher quality category, relative to package type, than that suggested can be used.

Excepted packages and industrial packages Type 1 (IP-1)

A.12. In the determination of the radioactive contents and package radiation levels, the instrumentation and processes used should be subject to Grade 1 management controls. In all other aspects, such as design, manufacture, etc., Grade 3 should be applied.

Non-fissile Type A packages and industrial packages Type 2 (IP-2) and Type 3 (IP-3)

A.13. Matters affecting shielding integrity and containment should be subjected to Grade 1 management controls. All other matters should be subjected to Grade 2 management controls, except where there is minimal effect on safety, in which case Grade 3 is appropriate.

Special form radioactive material

A.14. In all matters affecting compliance with the requirements for special form radioactive material, Grade 1 management controls are appropriate.

Fissile packages (other than Type B packages)

A.15. In the case of criticality assessment and other factors affecting the assumptions in the criticality assessment, Grade 1 management controls are appropriate. All other aspects should be subjected to Grade 2 management controls, except where there is minimal effect on safety, in which case Grade 3 management controls are appropriate.

Type B packages (non-fissile and fissile)

A.16. In all aspects contributing to the integrity of shielding and containment, together with criticality safety (where applicable), Grade 1 management controls are appropriate. All other aspects should be subjected to Grade 2 management controls, except where there is minimal effect on safety, in which case Grade 3 management controls are appropriate.

Shipments and special arrangements

A.17. The management system should be applied to shipments and special arrangements according to the individual features of each case.

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2005 Edition, IAEA Safety Standards Series No. TS-R-1, IAEA, Vienna (2005).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. TS-G-1.1 (ST-2), IAEA, Vienna (2002).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).

[4] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems: Requirements, ISO 9001:2000, ISO, Geneva (2000).

[5] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Environmental Management Systems: Specification with Guidance for Use, ISO 14001:1996, ISO, Geneva (1996).

[6] NUCLEAR REGULATORY COMMISSION, Packaging and Transportation of Radioactive Material, Quality Assurance, 10 CFR 71, Subpart H, US Govt Printing Office, Washington, DC (2001).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006).

Annex I

TWO EXAMPLES OF MANAGEMENT SYSTEMS

This annex is intended to assist the developer of a management system to identify the appropriate scale and complexity of the programme. Care should be taken in the interpretation of Table I–1, as the frequency of transport, package type and size of organization all have an influence on the management system.

TABLE I–1. EXAMPLES OF MANAGEMENT SYSTEMS

Management system elements	Small industrial type packages, transported infrequently by small, simple organizations	Larger Type B packages, transported frequently by large, complex organizations
Structuring the management system	A simple programme. A single-tier, process based documented system.	A comprehensive, process based programme including an interrelated and detailed multi-tiered structure and functions.
Organization	A simple company structure and responsibility chart covering key personnel and their positions. Simple process definition and work instructions. Training measures and interface definitions.	A multidivisional organization, with corporate and divisional responsibilities. Specialist support departments, detailed internal–external interface definition, multilevel process definition and work instructions, and a comprehensive training programme.
Control of documents	A simple procedural system involving a small number of documents and simple controls.	A more fully prescribed integrated system involving a large number of documents, formal controls, database management, filing and indexing, approval, review, internal interdepartmental and external release controls, departmental document interface controls and responsibilities.

TABLE I–1. EXAMPLES OF MANAGEMENT SYSTEMS (cont.)

Management system elements	Small industrial type packages, transported infrequently by small, simple organizations	Larger Type B packages, transported frequently by large, complex organizations
Control of records	A simple system that identifies and provides for the control and retrieval of essential records.	A comprehensive system that identifies and provides for the collection, collation, storage and retrieval of a wide range of essential and/or required records.
Human resources and competence and training	Simple arrangements to identify necessary competences and provide relevant training.	Suitably comprehensive provisions for the identification of all necessary competences and the delivery of training to all personnel involved.
Process controls (including those applicable to transport and special processes)	A simple process definition with necessary supporting documentation and instructions.	A multilayered system of focused process definition and control, supported by comprehensive documentation, work instructions, quality plans, etc.
Design control	A simple, process based system of design control relative to the complexity of the product.	A comprehensive, process based system of design control relative to the complexity of the product.
Purchasing (procurement control)	A simple procurement process that establishes purchasing information and provides for supplier evaluation and verification of purchased items.	A suitably comprehensive procurement process that establishes all necessary purchasing information and provides for supplier evaluation and verification of purchased items commensurate with their complexity.
Material identification, traceability and preservation	Simple process controls covering the identification, traceability, control, handling, storage, preservation and shipping of items. Simple maintenance instructions.	A comprehensive system of process controls covering the identification, traceability and control of all materials, parts and components, including handling, storage, preservation and shipping. A comprehensive programme of planned maintenance of packaging.

TABLE I–1. EXAMPLES OF MANAGEMENT SYSTEMS (cont.)

Management system elements	Small industrial type packages, transported infrequently by small, simple organizations	Larger Type B packages, transported frequently by large, complex organizations
Inspection, measurement and test control	Basic inspection, measurement and test capabilities, supported by relevant process specifications, instructions and controls.	Comprehensive integrated processes controlling appropriate inspection, measurement and test facilities, consistent with the complexity of the product.
Servicing	Simple process controls that identify all essential servicing data and provide for the accomplishment and verification of required servicing.	A comprehensive system of controls that identifies all equipment in need of servicing and essential servicing data, and provides for the accomplishment and verification of required servicing.
Self-/independent assessments	A simple system of auditing the management system, associated process controls and related activities.	A comprehensive system of auditing the complete management system, associated process controls, relevant interfaces with other organizations and related activities.
Non-conformance control	A simple process to identify and control all non-conforming products to prevent their use.	A suitably comprehensive system of process controls that provides for the identification and disposition of non-conforming products.
Corrective and preventive actions	A simple system of controls to recover and prevent the continuance of non-conforming situations.	A comprehensive integrated multilevel system of controls that implements suitable corrective and preventive actions.

Annex II

EXAMPLES OF MANAGEMENT SYSTEMS STANDARDS

Elements and sub-elements of the present Safety Guide	Management systems requirements, standards and paragraph numbers			
	IAEA GS-R-3 [II–1]	ISO 9001:2000 [II–2]	10 CFR 71 Subpart H [II–3]	ASME NQA-1:2000 [II–4]
MANAGEMENT SYSTEM				
General	2.1–2.4	1.1		
Safety culture	2.5			
Grading the application of management system requirements	2.6, 2.7	4.1		
Documentation and control of documents	2.8–2.10, 5.12, 5.13	4.2.3	71.113	6-100, 6-200, 6-300
Control of records	5.21, 5.22	4.2.4		2-500, 3-900, 9-400, 10-700, 11-600, 12-400, 17, 18-800
MANAGEMENT RESPONSIBILITY				
Management commitment	3.1–3.5	5.1		
Satisfaction of interested parties	3.6	5.2, 8.2.1		
Organizational policies	3.7	5.4.1		
Planning	3.8–3.11	5.4.2		
Responsibility and authority for the management system	3.12–3.14	5.5		
RESOURCE MANAGEMENT				
Provision of resources	4.1, 4.2	6.1		
Human resources and competence and training	4.3, 4.4	6.2	71.105, 71.137	2-200, 2-300, 2-400, 2-500
Infrastructure and working environment	4.5	6.3, 6.4		

Elements and sub-elements of the present Safety Guide	Management systems requirements, standards and paragraph numbers			
	IAEA GS-R-3 [II–1]	ISO 9001:2000 [II–2]	10 CFR 71 Subpart H [II–3]	ASME NQA-1:2000 [II–4]
Financial resources	4.1			
Involvement of individuals	4.3, 4.4			
Managing information and knowledge	4.2			
PROCESS IMPLEMENTATION				
Developing processes	5.1–5.5			
Process management	5.6–5.10			
Design control	5.6–5.10		71.107	3-100, 3-200, 3-300, 3-500, 3-600
Managing the different phases of transport				
Communication and interfaces	5.26, 5.27	5.5.3	71.103	1-300, 3-700
Purchasing	5.23–5.25		71.109, 71.115	4-100, 4-200, 4-400, 7-200
Identification, traceability and preservation of material		7.5.3	71.117, 71.127	8
Process control	5.14–5.20	7.5.1, 7.5.2	71.119	9
Inspection, measurement and test control		7.1, 7.5.3, 7.6, 8.2.3, 8.2.4	71.121, 71.123, 71.125, 71.129	10-100, 10-200, 10-300, 10-400, 10-500, 10-600, 11, 12, 14
Servicing		7.5.1, 7.5.2, 8.2.2, 8.2.3		
Managing organizational change	5.28, 5.29			
MEASUREMENT, ASSESSMENT AND IMPROVEMENT				
General				
Monitoring and measurement	6.1	8.2.3, 8.2.4		

Elements and sub-elements of the present Safety Guide	Management systems requirements, standards and paragraph numbers			
	IAEA GS-R-3 [II–1]	ISO 9001:2000 [II–2]	10 CFR 71 Subpart H [II–3]	ASME NQA-1:2000 [II–4]
Self-assessment	6.2			
Independent assessment	6.3–6.6			
Management system review	6.7–6.10	5.6	71.137	18-100, 18-200, 18-300
Non-conformances and corrective and preventive actions	6.11–6.16	8.3, 8.5.2, 8.5.3	71.131, 71.133	15, 16
Improvement	6.17, 6.18	8.5		

Note: Care should be taken in the use of this table. Note that the wording of elements differs between the standards.

REFERENCES TO ANNEX II

[II–1] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).

[II–2] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems: Requirements, ISO 9001:2000, ISO, Geneva (2000).

[II–3] NUCLEAR REGULATORY COMMISSION, Packaging and Transportation of Radioactive Material, Quality Assurance, 10 CFR 71, Subpart H, US Govt Printing Office, Washington, DC (2001).

[II-4] AMERICAN SOCIETY OF MECHANICAL ENGINEERS, Quality Assurance Requirements for Nuclear Facility Applications, ASME NQA-1:2000, ASME, New York (2000).

Annex III

EXAMPLE OF A DOCUMENTED MANAGEMENT SYSTEM FOR AN INFREQUENT CONSIGNOR

Prepared:	Ref:
Checked:	Issue:
Approved:	Page:

1. POLICY

It is the policy of *ABC Ltd* to consign radioactive material in a safe manner in accordance with an integrated management system.

2. NATURE AND SCOPE OF ACTIVITIES

ABC Ltd is a consignor of radioactive sources throughout the country at infrequent intervals. The actual transport of the radioactive material is carried out using our own vehicles or is contracted out to specialist transport organizations.

3. ORGANIZATION

3.1. The company employs two staff in the consignment of radioactive material. These two staff are the managing director, who is responsible for the operations, and the assigned deputy, who takes over responsibility for these operations in the managing director's absence.

Note: This annex presents an example. The terminology used may differ from that used in the main text. The content of this annex should not be understood as recommendations or considered to be the only manner of addressing the subject matter. It is understood that the check box should appear at the top of each page of the document as part of an appropriate document control system.

3.2. The management structure diagram shows the two above persons and their responsibilities in the radioactive material transport business.

3.3. The services of consultants or professional advisers are sought as and when required, and a current listing of professional experts is maintained.

4. DOCUMENT CONTROL

4.1. Each document pertinent to the operation of the management system is controlled and is designated as a 'controlled document'. Each such document is maintained in a control file.

4.2. Procedures and work instructions are approved for use by the managing director and are controlled by date and issue number.

5. RECORDS

5.1. Records to support and demonstrate compliance with regulatory requirements and the satisfactory functioning of the management system are filed and maintained.

5.2. Mandatory shipping certificates and other quality related documents, such as documents containing data on calibrations, tests, inspections and audits, are included within these records.

6. STAFFING AND TRAINING

6.1. It is the policy of this company to employ persons of the requisite skills, knowledge, education and training to carry out their specific tasks safely and in compliance with the regulations.

6.2. To achieve this, those staff directly concerned with activities involving the transport of radioactive material receive specific training in the regulations and in the arrangements of the management system. All staff are trained in company procedures as and when required.

6.3. Training may either be in-house training, on the job training or training by a specific external course, depending on need.

6.4. Training procedures are formulated, and records are maintained of each individual's training and proficiency.

7. PURCHASING

7.1. *ABC Ltd* controls the purchase of all relevant goods and services in a manner designed to ensure compliance with regulations.

7.2. *ABC Ltd* uses only companies recognized as competent suppliers of goods or services whose management system arrangements are subject to third party assessments.

7.3. *ABC Ltd* specifies in its purchase orders that suppliers should supply their goods and services in a quality assured manner (either by working to their own independently verified management system or by means of an agreed quality plan).

7.4. A list of the suppliers is maintained for reference.

8. MATERIALS CONTROL

8.1. Packaging material is controlled according to identified procedures.

8.2. These procedures cover the identification of packaging codes and specifications, and the storage, use, inspection, testing, servicing, maintenance, opening and closure of packagings and packages.

8.3. Materials for consignment are similarly controlled.

9. INSPECTION AND TEST CONTROL

9.1. The packaging used for consignment may remain in storage and unused for extended periods.

9.2. The packagings are inspected and, where appropriate, are tested according to the schedules of the manufacturers and suppliers during storage or before use to confirm their continued acceptable condition. Details of any

defects found are recorded and assessed to ensure that the packaging is acceptable for use.

9.3. Should repair or reconditioning be required, the packagings are normally returned to the manufacturer or supplier for the work to be done. Alternatively, the work may be undertaken by an acceptable repairer.

9.4. Prior to the dispatch of any item containing radioactive material, the package is monitored to determine the transport index and to assign the category label.

9.5. Measurement and test equipment used by this company is subject to regular calibration. This calibration is controlled by the requisite procedures as defined by the manufacturer, at intervals not exceeding 14 months.

9.6. Records of instruments, including their serial numbers, calibration status and usage, are kept.

10. CONTROL OF USE AND CARE OF PACKAGES AND PACKAGINGS

10.1. Packages and packagings are subject to control at all stages to comply with regulations to prevent deterioration and any hazard in the safe transport of radioactive material.

10.2. Procedures for preparation, servicing and maintenance, opening, filling, closure and use or operation of packages and packagings are available as supplied by the relevant manufacturer, the agent of the manufacturer or this company, as appropriate.

11. AUDITS

11.1. Internal audits are conducted of all of our operations at specified times and intervals depending on the volume of business.

11.2. The aims of these audits are to determine any deficiencies and non-conformances and to recommend and implement corrective actions.

12. NON-CONFORMANCE CONTROL

12.1. Procedures are in place for the control of items, services and documents that do not conform to specified requirements. Non-conforming items, services or documents are identified, segregated and reported.

13. CORRECTIVE ACTIONS

13.1. Procedures for the provision and implementation of corrective actions (which may stem from errors found at internal audits or from deviations and non-conformances in consignment, carriage, use, inspection and testing) are put into effect by designated personnel.

Annex IV

EXAMPLE OF A DOCUMENTED DESCRIPTION OF THE MANAGEMENT SYSTEM FOR AN INFREQUENT CARRIER

Prepared:	Ref:
Checked:	Issue:
Approved:	Page:

1. POLICY

It is the policy of our company to provide a transport service to our customers and to perform this service in a safe manner in compliance with the regulations.

2. NATURE AND SCOPE OF ACTIVITIES

The service we provide is a wide ranging and diversified transport operation to carry packages and items of many types, employing vehicles and drivers and office staff. The structure of our organization is shown in our management structure diagram. There are occasions when we are required by a customer to transport radioactive material, approximately three times per year. This is deemed to be an infrequent operation and an irregular aspect of our business. It is, however, our policy to apply the management system of our organization to this area of our activities.

Note: This annex presents an example. The terminology used may differ from that used in the main text. The content of this annex should not be understood as recommendations or considered to be the only manner of addressing the subject matter. It is understood that the check box should appear at the top of each page of the document as part of an appropriate document control system.

3. ORGANIZATION

3.1. The responsibility and authority of the personnel who manage, perform and verify work in relation to the transport of radioactive material are defined.

3.2. Measures are taken to identify and record quality problems and to implement solutions through designated channels, by verification, inspection and auditing of our documented programme.

3.3. Responsibility for implementation and maintenance of the management system is defined.

4. DOCUMENT CONTROL

4.1. There are procedures for the control of documents used by this company. Most of these documents (or copies thereof) are maintained for reference purposes, but for operations involving the transport of radioactive material, records are maintained separately or are clearly identified; any relevant statutory or regulatory records are also maintained.

4.2. The procedures provide for all aspects of the control of documents, including review, approval, issue and distribution, and modification.

5. RECORDS

5.1. Documents relevant to the carriage of radioactive material are kept on file; other records are kept for a specified time depending on their nature and customer requirements.

6. STAFFING AND TRAINING

6.1. It is the policy of our company to employ staff who have the requisite education, experience and training to perform specific activities.

6.2. Training of our staff is undertaken in matters pertaining to the transport of radioactive material.

6.3. Drivers are required to undergo a specific recognized training course; records of their training and proficiency are maintained.

7. CONTRACT REVIEW

7.1. Procedures exist for the verification of incoming contracts and orders, to verify that responsibilities and requirements are clearly defined and that we have the capability to meet these requirements.

8. PURCHASING

8.1. Procedures control the procurement of items and services used in relation to the transport of radioactive material that may directly or indirectly affect the safety of such transport and compliance with the regulations.

9. PROCESS CONTROL

9.1. All activities in transport are controlled through the use of a management system manual.

10. INSPECTION AND TEST CONTROL

10.1. Procedures for the examination of packages are produced as required in the execution of our business but are normally limited to the following aspects:

(1) Correct labelling: the presence or absence of the requisite labels;
(2) Ensuring that packages are undamaged, correctly sealed and fit for transport.

11. CONTROL OF USE AND CARE OF PACKAGES

11.1. There are procedures for the control of use and care of packages, but at present these are limited to the following: stowage, tie-down and prevention of damage.

12. AUDITS

12.1. There are procedures for conducting internal audits to ensure that our system and business are operating to specified requirements.

12.2. External audits of other companies are not conducted.

12.3. Records of audits are kept, and any corrective actions are implemented to agreed timescales.

13. NON-CONFORMANCE CONTROL

13.1. There are procedures for the control of packages or other aspects that do not conform to specified requirements. Examples are damaged packages, incorrectly labelled packages and inadequate paperwork.

14. CORRECTIVE ACTIONS

14.1. There are procedures for correcting errors or discrepancies in our transport and handling operations, but these may require referral to the consignor.

Annex V

EXAMPLE OF A PROCEDURE FOR CONTROL OF RECORDS

Prepared:	Ref:
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1. PURPOSE

The purpose of this procedure is to establish a set of rules dealing with documented results.

2. SCOPE

These rules apply to all records as defined in management system documents.

3. RESPONSIBILITIES

3.1. Document control manager: To decide how to dispose of technical records when the period of storage has expired.

3.2. Author of a procedure:

— To identify necessary records;
— To propose a record keeper;
— To define how records are stored (optional);
— To collect, file and store the records;

Note: This annex presents an example. The terminology used may differ from that used in the main text. The content of this annex should not be understood as recommendations or considered to be the only manner of addressing the subject matter. It is understood that the check box should appear at the top of each page of the document as part of an appropriate document control system.

— To maintain the legibility of records;
— To facilitate access to the records for authorized persons.

3.3. Quality manager: To decide how to dispose of managerial records when the period of storage has expired.

4. RECORDS PREPARATION

4.1. Identification of records must take the following into account:

(a) Records are the documentation of the results of work done according to a procedure or working instruction of the management system. Therefore, records have to be defined by the author in the procedure.
(b) Records may be produced by any person responsible for the work described in a procedure or working instruction.
(c) Records may be kept in any medium, including electronic media, but they must always be legible.
(d) Handwritten records (e.g. laboratory log books, checklists, forms, graphs, notes) must not be easily erasable (e.g. they must not be written in pencil).
(e) If records are kept in electronic form, they must be backed up as described by the pertinent procedure by means of a removable data storage medium, which shall[1] be stored in a location separate from the room in which the original data are contained.

4.2. The content of a technical record shall be defined by the accompanying procedure or working instruction and should include, as a minimum:

— Title;
— Index number;
— ID of the instrument used to produce the recorded data (if applicable);
— Data;
— Calibration data and any factor influencing the accuracy of the data (if applicable);
— Additional information to enable a repetition of the data evaluation process;
— Signature;
— Date.

[1] The use of the word 'shall' in Annex V does not imply that the statement is an IAEA safety requirement.

5. COLLECTION

5.1. The person responsible for collecting records deriving from a procedure must be stipulated within the procedure.

5.2. For quality records deriving from managerial procedures, the person responsible for collecting the records is the quality manager, who shall receive all records, even if they have been created by different 'persons in charge of work' as defined in different procedures.

6. INDEXING

6.1. The index is a unique number describing the record.

6.2. Indexing is done by the person who has produced the record. It shall be done as described in the originating procedure or in the following form:

REC / nature / service / consecutive number / year

e.g.	REC / Audit / MAN / 01 / 2000	describing the first audit report in the year 2000;
	REC / Reader / TLD / 122 / 2000	describing the 122nd run of reading TLDs in the year 2000.

6.3. Consecutive numbering shall start at 1 each year for every type of record.

7. FILING

7.1. Each person nominated as a record keeper through a procedure shall compile a list of existing records (a file).

7.2. This file itself is another record and shall be treated according to this procedure.

8. STORAGE

8.1. According to the Basic Safety Standards, records dealing with personal data (external monitoring and internal monitoring results, personal dose records, etc.) have to be kept for longer periods.

8.2. According to the Basic Safety Standards (para. I.49):

> "Exposure records for each worker shall be preserved during the worker's working life and afterwards at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after the termination of the work involving occupational exposure."

8.3. Records are required to be stored for the specified period of time in a way that protects the integrity of the recorded data. The storage location should, preferably, be defined in the respective procedure, or should otherwise be made known to all persons who might have to find the record.

8.4. Access to records should be limited to the personnel concerned.

9. MAINTENANCE

9.1. Records have to be legible over the entire storage period. The legibility has to be checked at regular intervals depending on the type of storage medium of the record.

9.2. For printed records, the person responsible for record keeping and storage may do this by means of a visual check made every three years on a few records. If there are doubts about the continued legibility of the records through the next storage period, the records must be recopied, retyped, put on microfilm or scanned into an electronically stored file.

9.3. For electronically kept records, the check shall include not only legibility control of the storage medium, but also a test run of the evaluation software used at this time to access the data. If there are doubts about the continued legibility of the records through the next storage period, the records must be copied onto a new storage medium (preferably not an erasable one) or printed.

10. DISPOSAL

10.1. When the end of the storage period for technical records is reached, the document control manager, who at this point will be responsible for the work that has generated the records, shall decide on the method of disposal.

10.2. The quality manager shall make the same decision concerning managerial records.

11. CHANGES

11.1. In the case of errors in an original record (e.g. wrong numbers copied by hand, inaccurate data entered into a computer, invalid calibration used), this record is to be corrected. The correction is required to be made so that the original (wrong) value remains legible.

11.2. In the case of handwritten records, the wrong value is to be crossed out and the correct one noted properly. The correction is to be dated and signed by the author.

11.3. Electronically kept records are to be copied to another file with the same file name but extended with a version number (e.g. Rev. 1), thus indicating that a change has been made to the stored data. This newly generated file may then be edited with the correction, and this should contain the valid data.

11.4. These changes may only be made by the record keeping technician, the control manager supervising the document or the quality manager.

11.5. The document control manager is to be informed about any change in a technical record.

12. RECORDS

12.1. Lists of existing records (files) are to be kept by the staff nominated for record keeping as stated in a procedure.

13. BIBLIOGRAPHY

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

Annex VI

EXAMPLE OF A PROCEDURE FOR HANDLING PACKAGES CONTAINING RADIOACTIVE MATERIAL, INCLUDING RECEIPT AND DISPATCH

Prepared:	Ref:
Checked:	Issue:
Approved:	Page:

SUMMARY: This document contains the measures for handling in a safe manner packages that contain radioactive material.

1. OBJECTIVE

The objective of this procedure is to establish the actions to be taken for correctly handling packages that contain radioactive material.

2. SCOPE

This procedure applies to all activities that involve the handling of packages that contain radioactive material.

3. BIBLIOGRAPHY

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems – Fundamentals and Vocabulary, ISO 9000:2000, ISO, Geneva (2000).

Note: This annex presents an example. The terminology used may differ from that used in the main text. The content of this annex should not be understood as recommendations or considered to be the only manner of addressing the subject matter. It is understood that the check box should appear at the top of each page of the document as part of an appropriate document control system.

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INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. TS-G-1.4, IAEA, Vienna (2007).

Management system manual.

4. RESPONSIBILITIES

4.1. Quality manager: Review of the procedure.

4.2. Officer responsible for the activity: Verification of the application of the procedure.

4.3. Workers: Application of the procedure.

4.4. Quality manager: Archive of generated documents.

5. ACTIONS TO BE TAKEN

5.1. The officer responsible for the activity verifies that the staff who handle packages that contain radioactive material have been instructed in the use of this procedure. This instruction will be documented in the form 'Instruction in the application of procedures', included in Attachment 1.

5.2. The staff involved in the handling of packages must take account of the following conditions:

(a) Packages that have the I-WHITE label can be handled without restriction, and there is no limit to the quantities that can be stored together.

(b) Packages with II-YELLOW and III-YELLOW labels should be handled from the furthest distance possible, and the person handling them should stay in the vicinity of the packages for the shortest possible time.
(c) In cases where several packages have to be handled at the same time, the packages with the highest transport index should be placed at the furthest possible distance from the person who is handling them.
(d) Packages that contain radioactive material should not be stored or handled close to explosive, inflammable or corrosive material.
(e) In the event of an emergency, the instructions established in the procedures for emergencies should be carried out.

5.3. The officer responsible for the activity determines the number of packages that can be stored together.

5.4. The officer responsible for the activity determines the places for storing the packages, segregating them from unexposed photographic film.

5.5. The officer responsible for the activity determines the areas to be used for storing the packages, in consideration of the restrictions placed on the area owing to the presence of other dangerous goods.

5.6. The officer responsible for the activity should make sure that packages with significant thermal generation are stored in the proper place.

6. RECORDS

6.1. Confirmation of the completion of each handling step shall[1] be recorded in the form of Attachment 1.

7. ATTACHMENT

Attachment 1: Form 'Instruction in the application of procedures'.

[1] The use of the word 'shall' in Annex VI does not imply that the statement is an IAEA safety requirement.

Attachment 1.

Instruction in the application of procedures		
Procedure:		
Date:		
Name of instructor:		
Signature of instructor:		
No.	Name	Signature

Annex VII

EXAMPLE OF A PACKAGING MAINTENANCE PROCEDURE IN A COMPLEX ORGANIZATION

Prepared:	Ref:
Checked:	Issue:
Approved:	Page:

1. PURPOSE

The purpose of this document is to define the policy for the maintenance of packagings in the group of companies.

2. SCOPE

The scope of this document covers the minimum requirements of the company, to be applied to all packagings owned by the company.

3. DEFINITIONS

3.1. 'Turnaround' means each time the packaging is unloaded or loaded.

3.2. 'Cycle' means a transport shipment, including loading and unloading.

3.3. 'Maintenance' includes re-inspection and any subsequent repair.

Note: This annex presents an example. The terminology used may differ from that used in the main text. The content of this annex should not be understood as recommendations or considered to be the only manner of addressing the subject matter. It is understood that the check box should appear at the top of each page of the document as part of an appropriate document control system.

3.4. ‘Maintenance management’ means all activities in support of maintenance, including records.

3.5. ‘Approved supplier’ means an organization approved by the company to supply specified goods or services.

4. RESPONSIBILITIES

4.1. The United Kingdom company shall[1] be responsible for the management of packaging maintenance of United Kingdom registered packagings.

4.2. The French company shall be responsible for the management of packaging maintenance of French registered packagings.

5. METHOD

5.1. Planned preventive maintenance shall be carried out on all company packagings as follows:

(a) Every turnaround: See the appropriate certificate of approval of the package design for instructions.
(b) Every 15 transport cycles over a maximum period of 3 years: Maintenance details as contained in the package design.
(c) Every 60 transport cycles over a maximum period of 6 years: As in safety reports, package design, safety report supplements, maintenance schedules or maintenance specifications, or as referenced from same.

5.2. Some States may have additional or different requirements over and above those covered in para. 5.1. Before maintenance is carried out in accordance with para. 5.1 of this procedure, the requirements of the State where the equipment is to be used shall be taken into account.

5.3. All maintenance shall be carried out in accordance with written procedures. The written procedures shall be supplied by the company or the

[1] The use of the word ‘shall’ in Annex VII does not imply that the statement is an IAEA safety requirement.

'approved supplier'. Procedures supplied by an approved supplier shall be reviewed by the company prior to use.

6. RECORDS

6.1. A record of maintenance or repair shall be provided each time that maintenance or repair is carried out in accordance with paras 5.1–5.3 of this procedure. Certificates shall make reference to the unique packaging or package design and serial number, and to the maintenance or repair documents that have been applied.

6.2. Records of all maintenance shall be kept by the office designated as being responsible for that maintenance management in accordance with company procedures.

6.3. Records shall include a packaging log book that shall be compiled for each packaging. The log book shall contain the following information as a minimum:

(a) Package design and unique serial number;
(b) List of the operating quality plan numbers;
(c) List of commissioning certificate numbers or commissioning certificates;
(d) List of commissioning tests carried out;
(e) List of maintenance quality plan numbers;
(f) List of maintenance certificate numbers;
(g) List of modification certificate numbers;
(h) List of repair certificate numbers;
(i) Table of shipments;
(j) List of non-conformance corrective actions outstanding.

Annex VIII

EXAMPLE OF AN INTERNAL AUDIT PROCEDURE IN A SMALL ORGANIZATION

Prepared:	Ref:
Checked:	Issue:
Approved:	Page:

SUMMARY: This document contains the procedure for establishing an internal audit for the independent assessment.

1. POLICY

It is the policy of this company to implement a system of internal quality audits. The purpose of these audits is to ensure that the systems, procedures and company objectives set out in our management system (or management system manual) are being adhered to.

2. FREQUENCY AND RESPONSIBILITY

Audits will be scheduled and conducted on an annual basis by a manager who has been trained in auditing methods and is, as far as possible, independent of the area or activity being audited.

Note: This annex presents an example. The terminology used may differ from that used in the main text. The content of this annex should not be understood as recommendations or considered to be the only manner of addressing the subject matter. It is understood that the check box should appear at the top of each page of the document as part of an appropriate document control system.

3. AUDIT PLANNING

3.1. Audits will be planned so that all aspects of the company's management system are audited during the annual period. All relevant activities will be checked for conformance with the arrangements described in our management system manual or procedures.

3.2. An audit plan stating the activity or operation, time and other pertinent details (form AUD 1, as attached) will be issued to the staff concerned prior to the audit. While internal audits will generally be planned in advance, unannounced or more frequent audits may be conducted where there are doubts concerning the effectiveness of the management system. Such doubts may arise from customer complaints or by evidence of faulty materials or services or breaches of regulations.

4. METHOD OF AUDIT

4.1. Audits will be carried out on time in accordance with the established audit plan.

4.2. The auditor will refer to the management system manual, procedures and specific work instructions, and will audit each activity for conformance with those prescribed arrangements. The auditor may select aspects of current or past projects to ensure that objectives were or are being achieved by the prescribed methods.

4.3. Any deficiencies, discrepancies or deviations found will be noted on management system audit report form AUD 2, as attached, together with corrective actions and timescales noted for improvement or rectification.

4.4. A summary report of each audit carried out that records the scope of the audit and its findings and recommendations with relevant management system audit report forms (AUD 2) attached is prepared and provided to the responsible senior manager.

4.5. Consistent with the agreed timescales (which must not be longer than six months), the auditor will verify and record that the necessary corrections have been made and that they are effective.

4.6. Only when all corrective actions have been satisfactorily implemented and verified will the auditor close the audit.

5. AUDIT RECORDS

5.1. The audit plan shall[1] be recorded in the form of form AUD 1, as attached.

5.2. Audit findings and corrective actions shall be recorded in the form of form AUD 2, as attached.

5.3. Records of audits shall be maintained by the auditor for a period of five years and will be subject to management review.

6. ATTACHMENTS

Attachment 1: Audit Plan – Form AUD 1 issue 1

Attachment 2: Management System Audit Report — Form AUD 2

[1] The use of the word 'shall' in Annex VIII does not imply that the statement is an IAEA safety requirement.

Attachment 1.

Audit Plan — Form AUD 1 issue 1			
Activity/system	Reference document	Audit scheduled	Auditor and date of audit
Management system manual, administration procedures	Management system manual and administration procedure 2	January	
Document control	Procedure 5	February	
Inspection and test	Procedure 7/8	July	
Transport activities	Procedure 3	May/November	
Procurement activities	Procedure 4	March	
Material control	Procedure 6	April	
Control of use/care of packages	Procedures 9 and 10	June	
Non-conformance control	Procedure 11	September	
Corrective actions	Procedure 11	September	
Records	Procedure 13	October	
Training	Procedure 12	October	
Audits	Procedure 14	December	

Attachment 2.

<table>
<tr><th colspan="3">Management System Audit Report — Form AUD 2</th></tr>
<tr><td colspan="3">Activity/aspects audited:. . . . .
. . . . Date: . . . .
Management system manual/Procedure reference: . . . .
Auditor: . . . . Report No.: . . . .
Details of audit — Activities, documents, procedures, examined or verified</td></tr>
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<tr><td colspan="3"></td></tr>
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<tr><td colspan="3">Non-compliance(s)</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td>Auditor signature:</td><td colspan="2">Auditee signature:</td></tr>
<tr><td colspan="3">Corrective actions and proposed timescales</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td></td><td colspan="2">Auditee signature:</td></tr>
<tr><td colspan="3">Actions confirmed and authorized</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Auditor closing statement</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3"></td></tr>
<tr><td></td><td>Signature:</td><td>Date:</td></tr>
</table>

Annex IX

EXAMPLE OF A PREVENTIVE AND CORRECTIVE ACTION PROCEDURE

Prepared:	Ref:
Checked:	Issue:
Approved:	Page:

SUMMARY: This document contains the procedure for establishing preventive and corrective actions that may be necessary to eliminate potential and real non-conformances in the activities relating to the safe transport of radioactive material.

1. OBJECTIVES

The objectives of this procedure for preventive and corrective actions are:

(a) To establish the activities for implementing preventive actions, and to eliminate the potential cases of non-conformance in the management system applied in the transport of radioactive material and to prevent their occurrence.
(b) To ensure the implementation of corrective actions:
   — To correct, reduce or eliminate the causes of detected non-conformances;
   — To reduce or eliminate the complaints of clients;
   — To prevent the recurrence of non-conformances;
   — To improve the quality management system.

Note: This annex presents an example. The terminology used may differ from that used in the main text. The content of this annex should not be understood as recommendations or considered to be the only manner of addressing the subject matter. It is understood that the check box should appear at the top of each page of the document as part of an appropriate document control system.

2. SCOPE

This procedure is to be applied to the prevention of potential non-conformances and to the correction of real non-conformances relating to the transport of radioactive material.

3. BIBLIOGRAPHY

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems — Fundamentals and Vocabulary, ISO 9000:2000, ISO, Geneva (2000).

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems – Requirements, ISO 9001:2000, ISO, Geneva (2000).

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INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Safe Transport of Radioactive Material, IAEA Safety Standard Series No. TS-G-1.4, IAEA, Vienna (2007).

Management system or management system manual.

Non-conformance control procedure.

4. RESPONSIBILITIES

4.1. Manager responsible for investigation:

— Receipt and record of non-conformances;
— Designation of investigators of non-conformances.

4.2. Assigned investigators:

— Investigation and analysis.

4.3. Manager responsible for the activity:

— Implementation of the preventive or corrective action;
— Control of the implementation of the preventive or corrective action;

— Verification of the effectiveness of the corrective or preventive action;
— Archive of the generated records.

5. ACTIONS TO BE TAKEN

5.1. Any individual who is aware of a non-conformance completes the specified form and submits it to the manager responsible for the activity.

5.2. The manager responsible for the activity who receives a report of a possible non-conformance investigates and judges whether the situation is a non-conformance or not, and passes the report on to an independent manager, who will verify the existence of the non-conformance. If there is no non-conformance, the manager explains the decision to the member of staff who submitted the report and closes the case.

5.3. If there is indeed a non-conformance, the manager responsible for investigation proceeds according to the non-conformance control procedure.

5.4. The manager responsible for investigation designates a team of investigators to identify the causes of the non-conformance and to propose preventive or corrective action(s). Proposed actions are recorded in the form to record preventive action (Attachment 1) or the form to record corrective action (Attachment 2), as appropriate.

5.5. The assigned investigators investigate and analyse the non-conformances and propose preventive or corrective action(s) to the responsible manager(s).

5.6. The responsible manager(s) agree on the preventive and corrective measures to be implemented. While preventive actions shall[1] be appropriate to the effects of the potential problems, corrective actions shall be appropriate to the effects of the non-conformances encountered.

5.7. The manager responsible for the activity implements the preventive or corrective action(s).

[1] The use of the word ‘shall’ in Annex IX does not imply that the statement is an IAEA safety requirement.

5.8. The manager responsible for the activity checks the implementation of the preventive or corrective action(s).

5.9. The manager responsible for the activity verifies the effectiveness of the preventive or corrective action(s).

5.10. The manager responsible for investigation undertakes the follow-up of the preventive and corrective action(s) within the deadline scheduled by the manager responsible for the activity.

5.11. The manager responsible for investigation archives the records generated.

6. RECORDS

6.1. Preventive actions shall be recorded in the form of Attachment 1.

6.2. Corrective actions shall be recorded in the form of Attachment 2.

6.3. Records of these actions shall be maintained for a period of five years by the manager responsible for investigation and will be subject to management review.

7. ATTACHMENTS

Attachment 1: Form to record preventive action

Attachment 2: Form to record corrective action

Attachment 1.

Form to Record Preventive Action No. . . . .
Description of the observation: . . . . Date: Name of responsible officer: . . . . . Signature: . . . . . . Position of responsible officer: . . . . .
Analysis, evaluation and preventive action: . . . . Date: Name of responsible officer: . . . . . Signature: . . . . . . Position of responsible officer: . . . . .
Follow-up of the preventive action: . . . . Date: Name of responsible officer: . . . . . Signature: . . . . . . Position of responsible officer: . . . . .

Attachment 2.

Form to Record Corrective Action No. . . . .
Origin of the corrective action: Non-conformance or possibility for improvement No. . . . . . Complaint or suggestion of client No. . . . .
Result of the investigation and analysis: . . . .
Plan for corrective action: . . . .
Deadline for implementing the proposal:. . . . .
Date: Name of responsible officer: . . . . . Signature: . . . . . . Position of responsible officer: . . . . .
Check of implementation: . . . .
Date: Name of responsible officer: . . . . . Signature: . . . . . . Position of responsible officer: . . . . .
Verification of the effectiveness: Satisfactory Yes ❑ No ❑ Comments about the effectiveness: . . . .
Date: Name of responsible officer: . . . . . Signature: . . . . . . Position of responsible officer: . . . . .

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