

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

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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

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

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

Safety standards survey

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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

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2008

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FOREWORD

by Mohamed ElBaradei
Director General

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

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

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

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

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

THE IAEA SAFETY STANDARDS

BACKGROUND

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

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

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

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

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

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

THE IAEA SAFETY STANDARDS

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

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

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

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

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

Safety Fundamentals

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

Safety Requirements

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

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

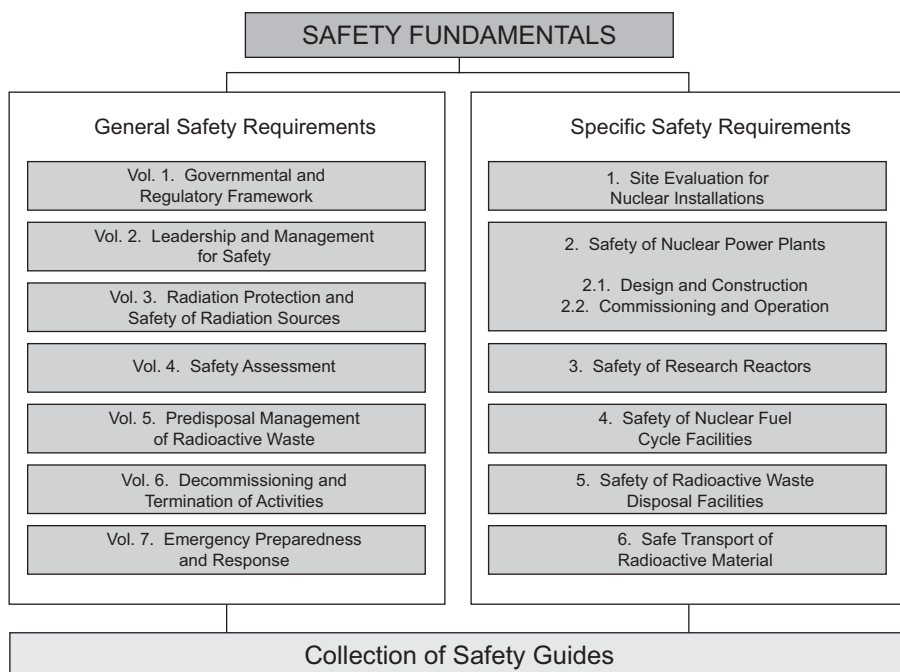


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

Safety Guides

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

APPLICATION OF THE IAEA SAFETY STANDARDS

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

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

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

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

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

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

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

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

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

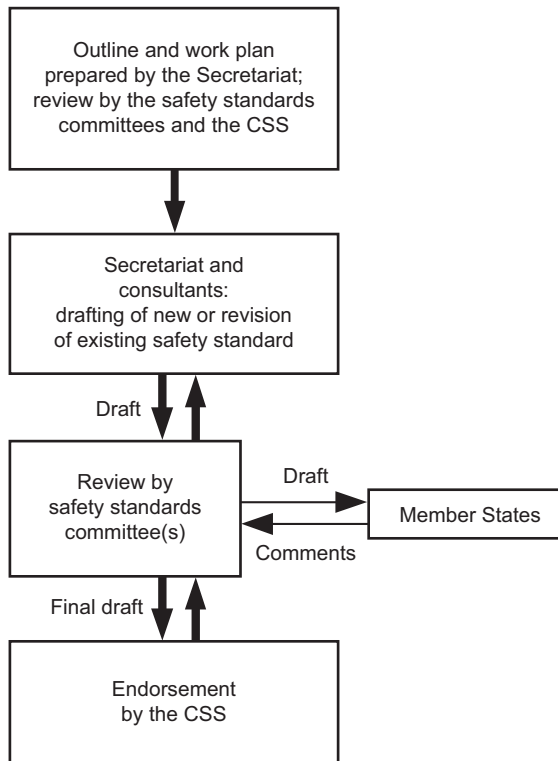


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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

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

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

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

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

INTERPRETATION OF THE TEXT

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

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

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

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

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1. INTRODUCTION

BACKGROUND

1.1. The transport of radioactive material 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 users¹ 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 products²) 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 management³ 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. procedures⁴);
- (c) Detailed work control documents (e.g. instructions⁵, 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 business⁶ 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 plans⁷, 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 RECORDS⁸

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 qualification⁹ reports;
- Process validation reports;
- Internal audit reports (and external audit reports, where appropriate);
- Material certification¹⁰ and related data;
- Calibration data for inspection, measurement and test equipment¹¹;
- Manufacturing and fabrication records;
- Non-conformance and corrective action reports;
- Servicing and maintenance records;
- Consignment documents;
- Training and personal qualification¹² 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, customers¹³ 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.

PLANNING¹⁴

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;