

Guide | 44

TRANSPORT

**Quality management
system applicable to the
transport of radioactive
substances on public
highways**

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Preamble

The ASN collection of guides is intended for professionals concerned by the nuclear safety and radiation protection regulations (licensees, users or transporters of ionising radiation sources, general public, etc.). These guides can also be issued to the various stakeholders, such as the local information committees (CLIs).

Each guide sets out recommendations which aim to:

- explain the regulations and the rights and obligations of the persons concerned by the regulations;
- explain the regulatory objectives and, as applicable, describe the practices ASN considers to be satisfactory;
- give practical tips and information concerning nuclear safety and radiation protection.

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1. INTRODUCTION

1.1. Background

To ensure the safe transport of radioactive substances on public highways and in accordance with the applicable regulations, a quality management system must be established and applied for all the activities associated with radioactive substance transport operations. The inspections conducted in recent years by ASN (*Autorité de Sûreté Nucléaire*), the French nuclear regulator, have revealed the following issues with some transport players:

- shortcomings in personnel training and recording of the training courses followed;
- insufficient material and human resources;
- poor control of their documentation system;
- lack of rigour in the oversight of operations and of their subcontractors;
- poor identification and traceability of the equipment used;
- deficiencies in the addressing of significant events;
- the existence of nonconformities and perhaps even fraud.

1.2. Purpose of the guide

This document is intended for professionals involved in radioactive substance transport operations. It details ASN's expectations regarding the content of a quality management system (formerly called "management system") required by the regulations (see references in section 2.1 below), its maintenance and its implementation.

1.3. Scope of application

This guide concerns all activities associated with radioactive substance "transport operations" on public highways which have to be covered by a quality management system, and more specifically:

- the design and manufacture of the packaging,
- the filling and emptying of a tanker or of the packaging,
- the loading, unloading and carriage,
- the handling and maintenance of a package,

in accordance with the modal regulations on the transport of dangerous goods.

However, it does not cover the quality management system required for the transport of high-activity sealed sources or equivalent batches of sources in application of the Order of 29 November 2019 on the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts, issued in application of Article R. 1333-147 of the Public Health Code. Nevertheless, some provisions of ASN Guide 44 may be common to the quality management systems required by the international transport regulations or by the Order of 29 Novembre 2019.

Likewise, this quality management system may be part of a broader system, put in place by the company for the purpose of an ISO 9001 certification, for example.

1.4. Document status

This guide was made available for public consultation from 15 November to 15 December 2022. It replaces guide DGSNR/SD1/TMR/AQ on "*quality assurance applicable to the transport of radioactive materials*" of July 2005.

2. REGULATORY FRAMEWORK

In accordance with the various international modal transport regulations (ADR, RID, ADN, IMDG and ICAO Technical Instructions, see **Erreur ! Source du renvoi introuvable.** below), a quality management system must be established and applied for all activities associated with radioactive substance transport operations. For the sake of simplification, only the references of the provisions of the ADR shall be indicated in the remainder of this document. Nevertheless, all of the ADR provisions are applicable to all the modes of transport (road, rail, air, maritime and inland waterways).

IAEA SSR-6 Rev. 1 (2018 Edition): "Transport operations"

106. [...]Transport comprises all operations and conditions associated with, and involved in, the movement of radioactive materials; these include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage, including in-transit storage, shipment after storage, unloading and receipt at the final destination of loads of radioactive material and packages. [...]

The definition of the management system given in paragraphs 228 and 306 of the Regulations for the Safe Transport of Radioactive Materials of the International Atomic Energy Agency (IAEA) SSR-6 [1], set out in paragraph 228 of the guide to the application of these regulations SSG-26 **Erreur ! Source du renvoi introuvable.**, is taken up in paragraph 1.2.1 of the ADR.

IAEA SSR-6 Rev. 1 (2018 Edition): Management system

228. Management system shall mean a set of interrelated or interacting elements for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

306. A management system based on international, national or other standards acceptable to the the competent authority shall be established and implemented for all activities within the scope of [Regulation SSR-6], to ensure compliance with the relevant provisions of these Regulations. Certification that the design specification has been fully implemented shall be available to the competent authority.

The manufacturer, consignor or user shall be prepared:

- a. To provide facilities for inspection during manufacture and use;
- b. To demonstrate compliance with these Regulations to the competent authority.

Where competent authority approval is required, such approval shall take into account, and be contingent upon, the adequacy of the management system.

IAEA SSG-26 (2018 Edition): Management system

228.1. The term "management system" is defined in the IAEA Safety Glossary and reflects and includes the concept of "quality control" (controlling the quality of products) and its evolution through "quality assurance" (the system for ensuring the quality of products) and "quality management system" (the system for managing quality). The management system is aimed at providing adequate confidence that the standard of safety prescribed in the Transport Regulations is achieved in practice.

228.2. In addition to the internationally recognized standards dealing with quality management systems (e.g., ISO 9001:2015), IAEA Safety Standards Series No. GSR Part 2 "Leadership and Management for Safety" establishes requirements for the management system.

228.3. Recommendations on how to comply with the requirements of the Transport Regulations with regard to the management system are provided in IAEA Safety Standards TS-G-1.4 "The Management System for the Safe Transport of Radioactive Material".

Paragraph 1.2.1 of the ADR (2021 Edition)

"Management system": for the carriage of radioactive material, means a set of interrelated or interacting interactive elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

The implementation of a management system is required by paragraph 1.7.3.1 of the ADR, whose application is rendered mandatory in French law by the Order of 29 May amended relative to the transport of dangerous goods over land (called the "TMD Order").

Paragraph 1.7.3.1 of the ADR (2021 Edition)

A management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities within the scope of ADR, as identified in 1.7.1.3, to ensure compliance with the applicable provisions of the ADR. Certification that the design specification has been fully implemented shall be available to the competent authority. The manufacturer, consignor or user shall be prepared:

- a) To provide facilities for inspection during manufacture and use; and
- b) To demonstrate compliance with ADR to the competent authority.

Where competent authority accreditation or approval is required, this accreditation or approval shall take into account and be contingent upon the adequacy of the management system.

The IAEA Guide TS-G-1.4 **Erreur ! Source du renvoi introuvable.** provides details on the management system and its implementation. Its point 2.1 stipulates more particularly that a management system must be applied throughout the life of a transport package to guarantee safe transport. Thus, the activities associated with the transport operations which must be covered by a management system are more specifically:

- the design of package models (all types of package¹, other than packages exempted from the regulations specified in 2.1) and radioactive materials in special form, and notably the establishing of the attached

¹ Excepted packages, industrial packages, type A packages, type B(M) packages, type B(U) packages, type C packages, packages loaded with uranium hexafluoride and packages loaded with fissile materials

safety files and the demonstration that these models comply with the regulatory safety requirements (in particular the performance of tests, trials and digital calculations);

- the manufacture of transport packagings and radioactive materials in special form and the associated inspections;
- the utilisation, maintenance and repair of packagings;
- the consignment, notably the choice of packaging appropriate for the content to transport, the pre-departure inspections, the marking, labelling and loading of the package on the transport unit, stowage, preparation of the transport documents, indication of the means of transport, etc. ;
- the carriage operations (in BNIs, on public highways), including parking and in-transit storage;
- the acceptance, particularly the acceptance inspections and unloading of the packages from the means of transport;
- the identification and addressing of deviations and nonconformities;
- the management of incident and accident situations;
- the organisation of the above operations.

ASN considers that each company involved in a transport activity must establish and implement a management system designed to ensure the safety and radiation protection, as provided for in 2.1 of Guide TS-G-1.4 Erreur ! Source du renvoi introuvable., of the operations it performs or to which it contributes.

2.1. Regulatory texts, standards and guides concerning the management system

The following texts underpin the regulatory framework:

- [1] Regulations for the Safe Transport of Radioactive Material, IAEA No. SSR-6 Rev. 1, 2018 Edition
- [2] Advisory Material for the IAEA Regulations for the Safety Transport of Radioactive Material, Specific Safety Guide No. SSG-26, 2018 Edition
- [3] Guide to the Management System for the Safe Transport of Radioactive Material, IAEA No. TS-G-1.4, 2008 Edition
- [4] International standard ISO 9001, "Quality Management Systems – Requirements", 2015 Edition
- [5] Standard NF ISO 19443:2018, "Quality Management systems – Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)", February 2019
- [6] Agreement concerning the international carriage of dangerous goods by road (ADR)
- [7] Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)
- [8] European Agreement concerning the international carriage of dangerous goods by inland waterways (ADN)
- [9] International Maritime Dangerous Goods Code (IMDG Code)
- [10] Technical Instruction for the Safe Transport of Dangerous Goods by Air (ICAO TI)
- [11] Commission Regulation (EU) n° 965/2012 of 5 October 2012 amended, laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) n° 216/2008 of the European Parliament and of the Council
- [12] Order of 23 November 1987 amended on the safety of ships (known as the "RSN Order")
- [13] Order of 29th May 2009 amended on the land transport of dangerous goods (known as the "TMD order")

[14] NF EN 12798 (2007): Transport quality management systems; Transport by road, rail and inland waterways

ASN has also published four guides for professionals who are involved in the transport of radioactive substances and interact with the management system:

[15] ASN Guide No. 17 "Content of radioactive substance transport incident and accident management plans"

[16] ASN Guide No. 29 "Radiation protection in radioactive substance transport activities"

[17] ASN Guide No. 31 "Procedures for notifying events associated with the transport of radioactive substances by land, sea or air"

[18] ASN Guide No. 34 "Implementation of the regulatory requirements applicable to on-site transport operations"

These guides are available on the ASN website.

3. OBJECTIVES, GENERAL CONTENT AND LEVEL OF DETAIL OF THE MANAGEMENT SYSTEM

3.1. Objectives of the management system

The management system is based on a continuous improvement approach and has the following objectives in particular:

- foster compliance with the legal and regulatory requirements applicable to radioactive substance transport operations;
- ensure the radiation protection of people (workers and the public) and the safety of transport operations;
- ensure that all the operations linked to the transport of radioactive substances comply with:
 - the requirements indicated in any baseline requirements document applicable to transport (instructions, procedures, package utilisation and maintenance instructions, manufacturing specifications, package model approval certificate or its certificate of conformity for packages that are not subject to the approval of a competent authority, etc.);
 - the requirements of the management system;
- identify the improvements to be made based on experience feedback.

Each company involved in transport activities can define additional objectives or apply the abovementioned objectives more precisely and define performance/achievement indicators.

The application of the abovementioned objectives is proportionate to the risks that the company's activity represents in terms of safety or radiation protection. If the level of risk is moderate, it is probably unnecessary to define any objectives other than the general objectives mentioned above.

3.2. Content of the management system and its degree of detail

The degree of detail of the management system and its level of requirement are adapted to the activity and size of the company; they are proportionate to the risks of this activity with respect to protection of the interests

mentioned in Article L. 593-1 of the Environment Code. These risks are linked to the dangerousness of the substances transported, the equivalent dose rate presented by the packages and the vehicles loaded with these packages, as well as to the transport movements. If the company carries out several transport activities with different risk levels, its management system may be organised into different sections presenting different the levels of detail and requirements in accordance with this principle.

The graded approach (ISO 19443 Erreur ! Source du renvoi introuvable.)

Application of the requirements relative to quality management, its documentation, its monitoring and its measurement is proportionate to its importance for nuclear safety.

The management system is formalised by a set of documents presenting more specifically:

- the objectives of the management system and the provisions (standards, guides, etc.) on which it is based or which it uses as a reference, breaking them down if applicable;
- the continuous improvement of the provisions in place, which includes the provisions for:
 - detecting deviations, understanding the causes and defining and implementing the appropriate corrective actions or improvements;
 - identifying the good practices and promoting or imposing their application;
- management of resources of all types necessary to achieve the objectives, in particular the human resources, the distribution of tasks/objectives within the company, the training necessary to achieve the objectives, etc. ;
- management of documents and records;
- verification of the conformity of the transport operations carried out.

4. ORGANISATION

4.1. Scope of the management system

First of all, each company:

- identifies the operational and support processes and activities covering all the transport activities carried out by the company, routinely or not;
- analyses and determines the sequencing of the processes and the relations that bind them to ensure their functioning, optimise their interactions and reduce the risks inherent to these activities;
- list the players involved in defining and implementing the processes.

When a company performing radioactive substance transport operations decides to outsource all or part of one or more of its processes, it defines measures to maintain control over the process(es). These measures are indicated in the management system and, if applicable, in the contract binding the parties.

4.2. Roles and responsibilities of the various players

The management system includes documents describing the radioactive substance transport or transport-related activities carried out by the company and the company's organisation relating to these activities. It describes more particularly the responsibilities of the functions or persons involved, the hierarchical levels,

the interactions between the various functions and entities within the company on the one hand and with the entities external to the company on the other².

The management system defines the roles and responsibilities in both normal situations and in the event of an accident during a transport operation, if the company plays a role in the management of such an accident. The organisation for managing incident and accident situations is defined in the company's radioactive substance transport incidents and accidents management plan (see the recommendations of ASN Guide No. 17 **Erreur ! Source du renvoi introuvable.**). In order for this plan to be as operational as possible, ASN recommends that it be based on stand-alone documents, separate from the rest of the management system if necessary.

A person within the company is appointed to manage this management system. This person has a thorough knowledge of the company's activity and the functioning of each department. The personal qualities required to exercise this function include rigour, good organisational skills, interpersonal capacities, writing and team leadership skills

The persons and entities tasked with ensuring the development, implementation and continuous improvement of the management system have the skills, the means and the authority necessary to accomplish their duties (see chapter 5). These persons and entities encourage all the company personnel to contribute to the defining, implementation and improvement of the management system.

The company also takes appropriate measures to ensure good coordination between the various external contractors and the company personnel.

4.3. Knowledge of the management system

To ensure that the provisions of the management system are put into practice, the company takes measures (induction process for new arrivals, training, internal communication when modifications are introduced, etc.) to ensure that the personnel and external contractors know their roles and responsibilities in the development or implementation of the management system, according to their functions and their activities. This includes more specifically the methods of reporting information (when, how, and to whom), and the provisions of the management system that concern them (especially the procedures they have to apply).

The management system describes the measures put in place to inform and coordinate, when necessary, the various players concerned.

² For example:

- for a company exclusively ensuring the carriage of radioactive substance packages, the interfaces with the package consignor, the companies loading the packages into or unloading them from the vehicle, and the addressee of the packages are to be clearly defined;
- for a company exclusively ensuring the maintenance of packagings, the interfaces with the packaging owner and the packaging designer are to be clearly defined;
- for a company exclusively ensuring the manufacture or all or part of a packaging or of its internal arrangements, the interfaces with the packaging designer and, if applicable, the packaging owner, are to be clearly defined.

5. CONTINUOUS IMPROVEMENT

5.1. Aim of continuous improvement

The aim of the continuous improvement process is to enhance the safety of radioactive substance transport operations and the radiation protection of the workers involved in these operations and of the public, by ensuring that the provisions of the management system are appropriate and effective.

The companies performing the activities associated with the transport of radioactive substances put in place a continuous improvement process which consists in:

- acquiring experience feedback, collecting and analysing the information that is relevant for the radiation protection and safety of transport operations, particularly the information from the detection of deviations and identification of good practices (see **Erreur ! Source du renvoi introuvable.** below), but also that acquired during the periodic evaluations of the management system effectiveness (see **Erreur ! Source du renvoi introuvable.** below);
- reviewing the measures hitherto planned to achieve the goals of the management system in the light of experience feedback and identifying the possible improvements;
- deciding on the implementation of the identified improvements, according to how they contribute to achieving the objectives and aspects relating to their implementation, including their cost;
- planning then implementing these improvements in compliance with the regulatory requirements and the established procedures;
- then assessing the effectiveness of these improvements with regard to their assigned objectives, which enriches the experience feedback and therefore further contributes to the continuous improvement process.

5.2. Periodic or continuous assessment of management system effectiveness

5.2.1. Periodic assessment

The effectiveness of the management system is assessed with respect to its objectives at an appropriate frequency for the risks and the complexity of the company's activities. The assessments can focus either on the management system as a whole or just on certain aspects of it (specific processes for example). In either case, the management system manager ensures that the entire management system has been examined within a reasonable time frame (a few years at the most).

The relevance of the management system objectives is also assessed periodically.

Whenever the size of the company permits, the choice of assessors and the method of performing the assessments shall ensure the objectivity and impartiality of the assessment process. More specifically, the assessors do not examine their own work.

The results of the assessment and the associated documents are made known to the persons responsible for the activity, who decide and implement or have others implement, measures to remedy any shortcomings observed and make the improvements considered necessary.

When justified on account of the risks and complexity of the activities:

- These periodic assessments are carried out by persons specially trained for this purpose and in accordance with written procedures, to verify that:
 - the management system effectively covers all the company's activities relating to the transport of radioactive substances;
 - its content is proportionate to the risks;
 - its provisions are observed and enable the set objectives to be achieved efficiently.
- Additional assessments are carried out if the company organisation undergoes major changes or if particularly significant shortcomings are observed.

If the company's activities are complex or present major risks for radiation protection or safety, ASN recommends that part of the assessments be carried out by persons from outside the company and having management systems expertise.

5.2.2. Putting in place continuous monitoring

If justified on account of the risks and complexity of the transport activities, the periodic assessments are supplemented by continuous monitoring to ensure proper implementation of the management system using appropriate indicators to assess achievement of the objectives.

5.3. Deviations and good practices

The procedures for detecting and analysing deviations and good practices is an essential part of process of learning from experience and continuous improvement of the management system, as described in section 4.2 of this guide.

The management system provides for measures to detect deviations from the applicable provisions and good practices. These measures foster information feedback from the operators. Management must make it clear that the aim of information feedback is not in the first instance to establish responsibilities with a view to taking disciplinary action, but indeed to improve safety and radiation protection in the radioactive substance transport operations. To give an example, ASN does not consider it satisfactory for the assessment of a team to depend solely on the number of deviations detected.

The deviations and good practices detected are recorded, centralised and analysed by people with the necessary skills to perform this analysis. Centralising and recording the deviations makes it possible more specifically to identify any recurrences or common modes which may be indicative of a more serious problem. The analysis of deviations seeks to identify:

- the causes of the deviations, whatever the technical or organisational nature;
- the actual and potential consequences of the deviations, in order to identify those that could have led to an aggravated situation if the circumstances had been less favourable.

All deviations are analysed. The analysis nevertheless remains proportionate to the significance of the deviations.

Based on the conclusions of the analyses, corrective or preventive actions are identified and implemented to prevent similar or more serious deviations from occurring. The implementation time is proportionate to the risks the deviations represent.

Deviations presenting a particular significance are considered as events concerning the safety of transport operations (EIT) or significant events relating to radioactive substance transport operations (EST). The regulations require certain deviations to be notified to ASN, in accordance more specifically with the procedures indicated in ASN Guide No. 31 **Erreur ! Source du renvoi introuvable.** Non-significant deviations, which are not subject to on-line notification to ASN, must nevertheless be detected, traced and analysed. The ASN inspectors can verify that they are properly detected, recorded, analysed and processed in application of the management system.

Identified good practices are assessed in order to determine the benefits and the feasibility of scaling up their utilisation, then deciding whether or not to scale them up.

Over and beyond the good practices identified in the company, the continuous improvement process must also focus on the deviations or good practices detected by other transport players, trade organisations or inspection authorities when the corresponding information is made available either publicly or within professional networks. In this case it is up to the company to decide whether these deviations or good practices could concern it and whether lessons can be learned from them to improve the safety or radiation protection of the radioactive substance transport operations it carries out or is involved in.

6. HUMAN AND MATERIAL RESOURCES

6.1. General provisions

The company carrying out the activities relating to the transport of radioactive substances determines and deploys the material and human resources necessary to:

- conduct all its activities relating to radioactive substance transport in compliance with the regulatory requirements and the provisions of its management system;
- assess the effectiveness of the management system;
- improve the provisions of the management system in order to enhance the safety and radiation protection of the transport operations it carries out or is involved in.

6.2. Skills management

The company personnel have the necessary knowledge and skills to fulfil their functions and perform their assigned activities, including in the event of an incident or accident involving radioactive substance transport. These skills are acquired through initial and continuous training and experience. The regulations contain several requirements with regard to training:

- chapter 1.3 of the ADR **Erreur ! Source du renvoi introuvable.** stipulates that the persons involved in the carriage of dangerous goods shall be trained appropriately for their functions and duties, so that they know firstly the regulatory requirements, and secondly the hazards that the transported dangerous goods represent;

- paragraph 1.7.2.5 of the ADR **Erreur ! Source du renvoi introuvable.** and the Labour Code provide mandatory training of persons likely to be exposed to ionising radiation so that they know the precautions to take to restrict their own occupational exposure and the exposure of other persons (see ASN Guide 29 **Erreur ! Source du renvoi introuvable.** for further information);
- the personnel are also trained in the management of radioactive substance transport incidents and accidents, in a manner proportionate to the risks (see ASN Guide No. 17 **Erreur ! Source du renvoi introuvable.** for further information).

To define its training programmes, the company first determines the skills necessary for the various job functions in order to ensure that, in view of the knowledge and know-how of its personnel, the training courses dispensed internally or by outside organisations meet the regulatory requirements and enable these skills to be acquired.

Where necessary, periodic refresher courses are provided and tracked to ensure compliance with refresher training requirements. If there is a significant change in the provisions of the regulations or of the management system, the need for an *ad-hoc* training course is assessed.

The content of the training courses, the names of the persons trained and the dates of the courses are recorded and retained for an appropriate length of time.

6.3. Safety culture

The IAEA defines the "safety culture" concept as being "*the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance*".

Companies performing activities linked to the transport of radioactive substances put in place a working environment and management practices that foster the establishing of a safety culture in their personnel and their subcontractors. At individual level, this culture is materialised in particular by:

- the diligence to report any anomaly, error or malfunction that could compromise the safety and radiation protection of these operations or the achievement of the management system objectives;
- a questioning attitude ("stop and think") which consists, before performing an operation, in ensuring that the risks for safety and radiation protection are understood or, in the case of an abnormal or unexpected event, that an initial assessment of its risks has been made.

7. MANAGEMENT OF DOCUMENTS AND RECORDS

7.1. Document management

The management system defines the requirements applicable to the management of documents (including in electronic format) relating to the transport operation activities (procedures, work instructions, operating processes, plans, etc.) or for assessing the implementation and effectiveness of the management system. The aim of these requirements is to ensure that:

- the documents are checked and approved before being issued for application;

- the documents are reviewed and updated as and when necessary (particularly if there is a change in regulations or the state of the art);
- the documents issued are mutually consistent. This implies more specifically making sure that if one document is modified, the other documents that may be impacted are revised if necessary;
- the unintentional use of expired or conflicting documents is prevented insofar as possible. This implies making sure that the documents are readily identifiable and accessible at the work stations of the people who need to use them.

Whenever possible, the persons designated to check and approve the documents shall not be the authors of the documents and shall have the necessary competencies and authority.

The document system is kept up to date. The operators concerned are informed of any revision to an applicable document and, if necessary, are trained within a time frame compatible with its next use.

Care must also be taken to:

- remove expired or conflicting documents from the work stations to avoid any risk of error,
- ensure traceability of the successive versions of all documents issued in order to track their changes.

7.2. Management of records

In order to meet the requirements of paragraph 1.7.3.1 of the ADR **Erreur ! Source du renvoi introuvable.**, the "records" are documents which are drawn up and retained to provide proof, to ASN in particular, that:

- the transport operations have been carried out in conformity with all the applicable regulatory requirements;
- the management system functions effectively and its provisions are observed.

A documented procedure is established to ensure the identification, conservation, protection, accessibility and duration of conservation of the records. The records are available, accessible, clear, legible, identifiable, precise and dated. The equipment items are also identified and traced on this account.

For example, the packaging manufacturer establishes records during manufacture to demonstrate compliance with the regulatory requirements and conformity with the assumptions of the safety case for the package model. This concerns inspection reports in particular. These records are retained by the manufacturer for the entire lifetime of the packaging. This is also the case for the packaging maintenance records, the only difference being that the records must be retained by the packaging owner at least until the next maintenance operation of the same type. These records serve to prove the conformity of the packaging with the requirements applicable to the package model concerned.

For the other records, the archival time is to be justified by the company concerned. The company must be capable of proving that its activities relating to the transport of radioactive substances are conducted safely, until a periodic assessment is carried out (the retention period shall be at least equal to the time between two periodic assessments).

In this respect, the IAEA transport regulation SSR-6 specifies the minimum retention period time for certain documents:

SSR-6 [1]

555. The consignor shall retain a copy of each of the transport documents containing the information specified in paras 546, 547, 551, 552 and 554, as applicable, for a minimum period of three months.

When the documents are kept electronically, the consignor shall be able to reproduce them in a printed form.

587. The carrier shall retain a copy of the transport document and additional information and documentation specified in the [...] Regulations.

The documents and information indicated in paragraph 555 to be retained are respectively:

SSR-6 [1]

546. [...] shall include in the transport documents with each consignment **the identification of the consignor and consignee**, [...]

547. [...] a **certification or declaration** [from the consignor]

551. [...] a **packing certificate** [in the case of maritime transport]

552. The information required in the transport documents [..., may be incorporated] into a single document, or if not, the documents shall be attached. [...]

554. [...] a **statement regarding actions, if any, that are required to be taken** [..., relative to the] supplementary requirements for loading, stowage, carriage, handling and unloading [..., to] restrictions on the mode of transport or conveyance and any necessary routeing instructions [..., and to] emergency arrangements appropriate to the consignment.

8. INSPECTION OF TRANSPORT OPERATIONS

8.1. General

To ensure compliance with the regulatory requirements, the management system provides for inspections to be carried out on the operations relating to the transport of radioactive substances and details the provisions that govern them. The frequency and the extent of these inspections are adapted to the risks of the inspected activity: it can be a check performed by the operator (by filling out a check-list for example), second-level sampling or systematic inspections performed by a second operator, inspections by an independent inspection organisation (internal or external to the company), etc. These inspections are carried out by persons having the required competencies.

The results of the inspections are recorded and retained (see section 6.2 of this guide). The documents available to the operators performing the inspections are in a form that limits the risks of error. It is recommended, for example, that the documents on which the results are recorded contain unambiguous validation criteria for determining whether the activities have been satisfactorily accomplished or not.

If measuring devices are used to perform the inspections, in order to ensure the reliability and accuracy of the measurements, they are calibrated or verified by an organisation that has the necessary competencies and the calibration or verification is repeated at a frequency defined by the manufacturer or the inspection organisation (or by the regulations if applicable). A good standard practice is to enter the reference of the measuring device used on the records, along with the expiry date of its periodic inspection.

The operators performing the inspections are trained in the use of these instruments and ensure, before performing the inspection, that the main characteristics of these measuring instruments (including among other things their measurement range, resolution, sensitivity, accuracy, freedom from bias and repeatability) are appropriate and that they are used in the conditions under which these characteristics are guaranteed. In particular, the devices for measuring dose rates are used for the type of radiation and the energy range planned for by the manufacturer.

8.2. Monitoring subcontractors and suppliers

By "supplier" we mean all the companies that manufacture equipment necessary for at least one transport operation (for example, the manufacturer of the nuts for the packagings, etc.) with the exception of the manufacture of radioactive substances.

In some cases, the company responsible for a transport operation may subcontract certain tasks to outside companies or use equipment supplied by an outside company. In this case, the ordering customer company specifies the required characteristics for the subcontracted activity or the equipment supplied in a document, along with the applicable provisions to guarantee its conformity with the requirements of the regulations, including those relating to the package model and the management system. In particular, given that the subcontractors take part in a transport operation, they themselves shall put in place a management system that is appropriate for the risks and complexity of the activities they carry out.

When justified by the risks, the subcontractors and suppliers are monitored by the ordering customer in order to ascertain that the requirements it has specified are effectively satisfied or that any deviations detected are addressed appropriately. The extent and general methods of monitoring are defined by the ordering customer and made known to the subcontractors and suppliers concerned. This may, for example, include inspection of products on reception, checking the operator qualification documents, performing inspections and audits on the subcontractor's or supplier's site, etc. When the subcontracted activities or equipment supplied present high risks, the monitoring includes the periodic assessments performed by the ordering customer.

The monitoring results are recorded and retained as indicated in section 6.2 of this guide. A periodic evaluation of the subcontractors and suppliers is carried out on the basis of these results and the monitoring actions are adapted if necessary. Subject to compliance with the contract regulations, the subcontractors and suppliers are chosen taking the results of this evaluation into account (if the company in charge has already worked with this subcontractor or supplier) or on the basis of an initial evaluation (in the case of a new subcontractor or

supplier). Depending on the risks, the initial evaluation may consist in an audit before placing the first order or a simple verification of documents. Whatever the case, the aim of the initial evaluation is to ascertain prospectively the capability to supply equipment or carry out activities that meet the requirements of the specifications.

If justified by the risks, these measures are extended to the 2nd-tier subcontractors and suppliers (that is to say the subcontractors and suppliers of the initial subcontractors) or more.

The management system of the responsible company specifies the provisions for selecting and monitoring the subcontractors and suppliers.

If the constraints of the available industrial fabric should make it necessary to call upon a company which has already shown weaknesses in the past, it is advisable to significantly reinforce the monitoring of this company.

8.3. Risk of fraud

The management system takes into account the possibility of fraud, particularly the falsification of documents, omissions, deceit within the company or with the subcontractors and suppliers.

With the operations presenting significant risks, such as the manufacture and maintenance of the packagings corresponding to a package model approved by a competent authority, the company shall take appropriate measures to prevent and detect any fraudulent acts. More particularly it shall ensure that the persons performing the inspections are aware of this risk, that they do not have financial incentives directly linked to performance of the inspection operations and are hierarchically independent of the entities tasked with commercial relations and monitoring the smooth running of the operations.

Appendix 1

ACRONYMS

ADN	European agreement concerning the international carriage of dangerous goods by inland waterways
ADR	Agreement concerning the international carriage of dangerous goods by road
ASN	<i>Autorité de sûreté nucléaire</i> - French nuclear safety authority
BNI	Basic Nuclear Installation
IAEA	International Atomic Energy Agency
ICAO	International Civil Aviation Organisation
IMDG	International Maritime Dangerous Goods Code
RID	Regulation concerning the international carriage of dangerous goods by rail

No. 2

Transport of radioactive materials in airports

No. 7

Civil transport of radioactive packages or substances on the public highway

No. 17

Content of radioactive substance transport incident and accident management plans

No. 27

Stowage of radioactive packages, materials or objects for transportation

No. 29

Radiation protection in radioactive substance transport activities

No. 31

Notification procedures for events related to the TSR

No. 34

Implementation of the regulatory requirements applicable to on-site transport operations

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