IAEA Safety Standards for protecting people and the environment

Predisposal Management of Radioactive Waste

General Safety Requirements Part 5 No. GSR Part 5





PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

Safety standards survey

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PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

GENERAL SAFETY REQUIREMENTS

This publication includes a CD-ROM containing the IAEA Safety Glossary: 2007 Edition (2007) and the Fundamental Safety Principles (2006), each in Arabic, Chinese, English, French, Russian and Spanish versions. The CD-ROM is also available for purchase separately. See: http://www-pub.iaea.org/MTCD/publications/publications.asp

> INTERNATIONAL ATOMIC ENERGY AGENCY VIENNA, 2009

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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.

CONTENTS

1.	INTRODUCTION	1
	Background (1.1–1.9)	1
	Objective (1.10–1.11)	3
	Scope (1.12–1.17)	3
	Structure (1.18)	4
2.	PROTECTION OF HUMAN HEALTH AND	
	THE ENVIRONMENT	5
	Radioactive waste management (2.1–2.4)	5
	Radiation protection (2.5–2.9)	5
	Environmental concerns (2.10)	6
3.	RESPONSIBILITIES ASSOCIATED WITH	
	THE PREDISPOSAL MANAGEMENT OF	
	RADIOACTIVE WASTE	7
	General (3.1–3.3)	7
	Legal, regulatory and policy framework	8
	Requirement 1: Legal and regulatory framework (3.4)	8
	Requirement 2: National policy and strategy on	-
	radioactive waste management (3.5–3.6)	8
	regulatory body (3.7, 3.10)	0
	Operators	11
	Paguirament 4: Despensibilities of the operator (2 11 2 18)	11
	Integrated approach to sofety	11
	Dequirement 5: Dequirements in respect of	12
	security measures (3.19–3.20)	12
	Requirement 6: Interdependences (3.21–3.23)	13
	Requirement 7: Management systems (3.24)	14
4.	STEPS IN THE PREDISPOSAL MANAGEMENT OF	
	RADIOACTIVE WASTE	14
	General (4.1–4.5)	14

	Generation of radioactive waste	15
	Requirement 8: Radioactive waste generation	
	and control (4.6–4.9)	15
	Requirement 9: Characterization and classification	
	of radioactive waste (4.10–4.12)	16
	Processing of radioactive waste	17
	Requirement 10: Processing of radioactive waste (4.13-4.18)	17
	Storage of radioactive waste	18
	Requirement 11: Storage of radioactive waste (4.19–4.23)	18
	Radioactive waste acceptance criteria	19
	Requirement 12: Radioactive waste acceptance	
	criteria (4.24–4.26)	19
5.	DEVELOPMENT AND OPERATION OF PREDISPOSAL	
	RADIOACTIVE WASTE MANAGEMENT FACILITIES	
	AND ACTIVITIES	20
	$C_{\text{constraint}}$ (5.1, 5.2)	20
	General (5.1–5.2)	20
	Approach to safety	20
	Requirement 15: Preparation of the safety case and $(5, 2, 5, 4)$	20
	Reprint 14 Compared the reference and	20
	Requirement 14: Scope of the safety case and	01
	supporting safety assessment (5.5–5.7)	21
	Requirement 15: Documentation of the safety case and	22
	supporting safety assessment (5.8–5.10)	22
	Requirement 16: Periodic safety reviews (5.11–5.12)	22
	Development of predisposal radioactive waste	
	management facilities	23
	Requirement 17: Location and design of facilities $(5.13-5.14)$	23
	Requirement 18: Construction and commissioning	
	of the facilities (5.15–5.18)	23
	Requirement 19: Facility operation (5.19–5.20)	24
	Requirement 20: Shutdown and decommissioning	
	of facilities (5.21–5.23)	25
	Other provisions	26
	Requirement 21: System of accounting for and control	
	of nuclear material (5.24)	26
	Requirement 22: Existing facilities (5.25)	26
	REFERENCES	27

ANNEX:	PREDISPOSAL MANAGEMENT OF	
	RADIOACTIVE WASTE AND THE	
	FUNDAMENTAL SAFETY PRINCIPLES	29
CONTRIBUT	FORS TO DRAFTING AND REVIEW	33
BODIES FOR	R THE ENDORSEMENT OF	
IAEA SAFI	ETY STANDARDS	35

1. INTRODUCTION

BACKGROUND

1.1. Waste that contains or is contaminated with radionuclides arises from a number of activities involving the use of radioactive material. Such activities include the operation and decommissioning of nuclear facilities; the use of radionuclides in medicine, industry, agriculture, research and education; the remediation of sites affected by radioactive residues from operations of various types or from accidents; and the processing of raw material containing naturally occurring radionuclides. The nature of this radioactive waste is likely to be such that radiation safety considerations must be taken into account for its safe management. The importance of the safe management of radioactive waste for the protection of human health and the environment has long been recognized, and considerable experience has been gained in this field.

1.2. Predisposal management of radioactive waste, as the term is used in this Safety Requirements publication, covers all the steps in the management of radioactive waste from its generation up to disposal, including processing (pretreatment, treatment and conditioning), storage and transport.¹

1.3. The general principles of managing radioactive waste in a safe manner have been set out in the Safety Fundamentals publication entitled Fundamental Safety Principles [2]. The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention) [3] is consistent with the fundamental safety principles [2]. The present publication is concerned with the application of these principles to the management of radioactive waste prior to disposal. A brief description of the general approach to and the technical steps in the predisposal management of radioactive waste is given in the following paragraphs. Measures to prevent or restrict the generation of radioactive waste have to be put in place in the design of facilities and the planning of activities that have the potential to generate radioactive waste. Radioactive waste may be cleared from regulatory control if it meets clearance criteria, and effluents produced during operations may be discharged if this is authorized by the regulatory body. The reuse and

¹ 'Predisposal' is a contraction of 'pre-disposal'; it is not a form of disposal. Terminology used in this publication is defined and explained in the IAEA Safety Glossary [1] (see http://www-ns.iaea.org/standards/safety-glossary.htm).

recycling of material is sometimes carried out as a means of minimizing the amount of radioactive waste from an activity or facility. The remaining radioactive waste from all sources that is not cleared, discharged or reused needs to be managed safely over its entire lifetime, and there is, therefore, a need for the establishment of a national policy and strategy for the safe management of radioactive waste [3].

1.4. Processing of radioactive waste includes its pretreatment, treatment and conditioning and is primarily intended to produce a waste form that is compatible with the selected or anticipated disposal option. Radioactive waste will also be handled and may be stored between and within the basic steps in its management, and will also have to be in a form that is suitable for such handling and storage as well as for any transport.

1.5. It may be that not all processing steps are necessary for particular types of radioactive waste. The type of processing necessary will depend on the particular type of waste, its form and characteristics, and the overall approach to its management, including consideration of the generation of secondary waste. Where appropriate, the waste material resulting from processing may be reused or recycled, or cleared from regulatory control in accordance with the regulations in place.

1.6. Radioactive waste is prepared for disposal by the means described in para. 1.4. However, in many instances no disposal facilities are available and storage may be necessary for considerable periods of time before disposal facilities become available.

1.7. In some instances there are several potentially conflicting demands in the predisposal management of the waste that need detailed consideration to determine the optimal integrated solution. Such considerations include the balancing of exposures of workers and/or those of members of the public, the short term and long term risk implications of different waste management strategies, the technological options available and the costs.

1.8. To select the most appropriate type of pretreatment, treatment and conditioning for the radioactive waste when no disposal facility has been established, assumptions have to be made about the likely disposal option. It is necessary to address the interdependences and the potential conflicts between the operational demands of each of the various steps in waste management, while ensuring that the waste is contained and stored in a passive, safe condition. In striking a balance between choosing an option and retaining

flexibility, it is necessary to ensure that conflicts between operational demands that might compromise safety are avoided [2].

1.9. This publication supersedes those parts of IAEA Safety Standards Series No. WS-R-2, Predisposal Management of Radioactive Waste, Including Decommissioning, that are concerned with requirements for the predisposal management of radioactive waste. Reference [4] supersedes those parts of IAEA Safety Standards Series No. WS-R-2 that are concerned with the decommissioning of facilities.

OBJECTIVE

1.10. The objective of this Safety Requirements publication is to establish, on the basis of the principles established in Ref. [2], the requirements that must be satisfied in the predisposal management of radioactive waste. These requirements comprise both numbered 'shall' statements in bold type and concomitant statements of associated conditions that are also required to be met.

1.11. This publication sets out the objectives, criteria and requirements for the protection of human health and the environment that apply to the siting, design, construction, commissioning, operation and shutdown of facilities for the predisposal management of radioactive waste, and the requirements that must be met to ensure the safety of such facilities and activities.

SCOPE

1.12. This Safety Requirements publication applies to the predisposal management of radioactive waste of all types and covers all the steps in its management from its generation up to its disposal, including its processing (pretreatment, treatment and conditioning), storage and transport. Such waste may arise from the commissioning, operation and decommissioning of nuclear facilities; the use of radionuclides in medicine, industry, agriculture, research and education; the processing of materials that contain naturally occurring radionuclides; and the remediation of contaminated areas.

1.13. This publication establishes the safety requirements that apply to all facilities and activities that are involved in the management of radioactive waste before disposal.

1.14. Although this publication does not specifically address non-radiological hazards or conventional industrial health and safety issues, these issues also have to be considered by national authorities, both in their own right and in as much as they may affect radiological consequences.

1.15. This Safety Requirements publication does not repeat the safety requirements for legal and governmental infrastructure, radiation protection and safety, or emergency preparedness and response, which are established in the Safety Requirements publications that address these thematic areas [5–7]. It is based on the premise that, in general, arrangements will be in place to ensure that these requirements will be met. This publication does, nevertheless, establish some requirements in areas closely related to these thematic areas, to emphasize requirements that are of particular importance to the safety of predisposal radioactive waste management facilities and activities.

1.16. This publication is primarily targeted at complex situations that are typical in facilities for the predisposal management of radioactive waste arising from the nuclear fuel cycle. However, the regulatory body has to consider a graded approach to the application of the requirements for the predisposal management of radioactive waste, depending on the hazards, the complexity of facilities and activities, and the characteristics of the waste, and will have to apply the requirements as necessary and appropriate.

1.17. The predisposal management of radioactive waste may take place in separate, dedicated waste management facilities or within larger facilities operated for other purposes, such as nuclear power plants or spent fuel reprocessing plants. In this publication, the term 'facility' is used to refer to either of these possibilities.

STRUCTURE

1.18. The protection of human health and the environment is considered in Section 2 of this publication. Section 3 establishes requirements for the responsibilities associated with the predisposal management of radioactive waste. Requirements for the principal approaches to and the elements of the predisposal management of radioactive waste are established in Section 4. Section 5 establishes requirements for the safe development and operation of predisposal radioactive waste management facilities and safe conduct of activities. The Annex presents a discussion of the consistency of the safety requirements established in this publication with the fundamental safety principles [2].

2. PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT

RADIOACTIVE WASTE MANAGEMENT

2.1. The safety objective and the fundamental safety principles established in Ref. [2] apply to all facilities and activities in which radioactive waste is generated or managed, for the entire lifetime of facilities, including planning, siting, design, manufacture, construction, commissioning, operation, shutdown and decommissioning. This includes the associated transport of radioactive material and the management of radioactive waste.

2.2. The main options for the management of radioactive waste are presented in para. 4.1. To meet the safety objective, in considering options for the management of radioactive waste, due consideration has to be given to the protection of workers, the public (including future generations) and the environment.

2.3. Reference [8] requires both the regulatory body and the operator to establish a management system that addresses safety, health, environmental, security, quality and economic requirements in an integrated manner. A key component of such a system in an organization is a robust safety culture.

2.4. In controlling the radiological and non-radiological hazards associated with radioactive waste, the following aspects are also required to be considered: conventional health and safety issues, radiation risks that may transcend national borders, and the potential impacts and burdens on future generations arising from long periods of storage of radioactive waste [6].

RADIATION PROTECTION

2.5. Radiation protection considerations are governed by the principles of justification of a practice, optimization of protection and limitation of individual dose and risk [2, 6, 9–11]. In the context of the recommendations of the International Commission on Radiological Protection (ICRP) [9] and the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [6], the management of radioactive waste is considered part of the entire 'practice' giving rise to the waste, and as such does not require separate justification.

2.6. Requirements for radiation protection have to be established at the national level, with due regard to the BSS [6]. In particular, the BSS require radiation protection to be optimized for any persons who are exposed as a result of activities in the predisposal management of radioactive waste, with due regard to dose constraints, and require the exposures of individuals to be kept within specified dose limits.

2.7. National regulations will prescribe dose limits for the exposure of workers and members of the public under normal conditions. Internationally accepted values for these limits are contained in Schedule II of the BSS [6]. In addition to the provision for protection against the exposures that will arise from normal operations referred to in the preceding paragraphs, provision has to be made for protection against potential exposure. Requirements for protection against potential exposure are also established in the BSS [6]. They include management and technical requirements to prevent the occurrence of incidents or accidents and provisions for mitigating their consequences if they do occur.

2.8. When choosing options for the predisposal management of radioactive waste, consideration has to be given to both the short term and the long term radiological impacts on workers and members of the public; for example, by balancing present-day exposures resulting from the dispersal of radionuclides in the environment and potential exposure that could arise in the future from the disposal of radioactive waste [2, 10].

2.9. Doses and risks associated with the transport of radioactive waste have to be managed in the same way as those associated with the transport of any radioactive material. Safety in the transport of radioactive waste is ensured by complying with the IAEA Regulations for the Safe Transport of Radioactive Material [12].

ENVIRONMENTAL CONCERNS

2.10. Requirements for environmental protection that are associated with predisposal management of radioactive waste have to be established by the relevant national regulatory bodies, with all potential environmental impacts that could reasonably be expected being taken into consideration [2, 6].

3. RESPONSIBILITIES ASSOCIATED WITH THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

GENERAL

3.1. The clear allocation of responsibilities is essential to ensure safety in the predisposal management of radioactive waste. Internationally endorsed requirements on the allocation of such responsibilities, in particular those of the regulatory body, are established in IAEA safety standards [5, 6]. However, selected responsibilities of the various parties involved that are specific to the predisposal management of radioactive waste are outlined in the following.

3.2. Safety requirements are established with a view to ensuring that the objectives defined and discussed in Section 2 are achieved and the principles are applied. While safety is the prime responsibility of the operator², to whom the majority of the requirements apply, ensuring safety and developing a broader confidence in safety also requires the establishment of an effective regulatory process within a clearly defined legal framework [5].

3.3. It is possible that the predisposal management of radioactive waste will involve the transfer of radioactive waste from one operator to another, or that radioactive waste may even be processed in another State. In such situations, continuity of responsibility for safety is necessary throughout. In the event of the transfer of radioactive waste beyond national boundaries, article 27.1 of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management applies to Contracting Parties to the Joint Convention [3], and compliance with this article is considered good practice for all States. This article concerns the need for prior notification and consent of the State of destination, the need for adequate technical and administrative capacity in the States of destination, and the need to subject transboundary movement through transit States to the relevant international obligations.

² Generators of radioactive waste, including organizations carrying out decommissioning activities, and operators of predisposal radioactive waste management facilities are considered to be engaged in the management of radioactive waste. In this Safety Requirements publication they are hereinafter referred to as 'operator(s)'.

LEGAL, REGULATORY AND POLICY FRAMEWORK

Requirement 1: Legal and regulatory framework

The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions. Protection shall also be provided beyond national borders as appropriate and necessary for neighbouring States that may be affected. (See Ref. [5].)

- 3.4. Matters that have to be considered by the government include:
 - Setting clearly defined legal, technical and financial responsibilities for organizations involved in predisposal radioactive waste management activities;
 - Establishing an effective and independent regulatory body and providing it with adequate human and financial resources;
 - Ensuring the continuity of responsibility for safety through regulatory control (e.g. by means of a licensing system) over the different steps in waste management, including the transfer of waste;
 - Defining and putting in place the overall process for the development, operation and closure or decommissioning of facilities, including the legal requirements at each step, the decision making process and the process for the involvement of interested parties;
 - Ensuring that the necessary scientific and technical expertise remains available for the support of independent regulatory functions and other review functions at the national level.

Requirement 2: National policy and strategy on radioactive waste management

To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles [2] and with international instruments, conventions and codes that have been ratified by the State. The national policy

and strategy shall form the basis for decision making with respect to the management of radioactive waste. (See Ref. [5].)

3.5. The national policy on radioactive waste management has to set out the preferred options for radioactive waste management. It has to reflect national priorities and available resources and has to be based on knowledge of the waste to be managed (e.g. knowledge of the inventory and of waste streams) now and in the future. It has to assign responsibilities for various aspects of radioactive waste management, including regulatory overview.

3.6. The national strategy for radioactive waste management has to outline arrangements for ensuring the implementation of the national policy. It has to provide for the coordination of responsibilities. It has to be compatible with other related strategies such as strategies for nuclear safety and for radiation protection.

Requirement 3: Responsibilities of the regulatory body

The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process. The regulatory body shall review and assess the safety case³ and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation. The regulatory body shall provide for the issuing, amending, suspension or revoking of licences, subject to any necessary conditions. The regulatory body shall carry out activities to verify that the operator meets these conditions. Enforcement actions shall be taken as necessary by the regulatory body in the event of deviations from, or non-compliance with, requirements and conditions. (See Ref. [5].)

3.7. General requirements for the protection of human health and the environment are usually stated in national policy and set out in legislation. The regulatory body has to establish regulatory requirements specific to the

³ The safety case is a collection of arguments and evidence in support of the safety of a facility or activity. The safety case will normally include the findings of a safety assessment, and will typically include information (including supporting evidence and reasoning) on the robustness and reliability of the safety assessment and the assumptions made therein [1].

predisposal management of radioactive waste, on the basis of national policy and legislation and with due regard to the objectives and principles set out in Section 2.

3.8. To facilitate compliance with regulatory requirements, the regulatory body has to do the following:

- Provide necessary guidance on the interpretation of national standards and regulatory requirements that takes into consideration the complexity of the operations and the magnitude of the hazards associated with the facility and operations;
- Encourage dialogue between and participate in dialogues with the operator and other interested parties;
- Establish an appropriate definition and/or classification of radioactive waste [13];
- Establish criteria for the clearance of material from regulatory control, in accordance with national policy;
- Establish and clarify to the operator the processes used to evaluate safety and to review applications;
- Document the procedures that operators are expected to follow in the licensing process;
- Document the procedures that apply to the mechanisms for compliance verification and enforcement;
- Establish a mechanism by means of which information on incidents significant to safety is disseminated to interested parties;
- Enter into agreement, where appropriate, with other governmental bodies responsible for regulation in related fields to delineate areas of responsibility or of cooperation;
- Ensure that due consideration is given to non-radiological hazards throughout the entire predisposal management of radioactive waste.

3.9. The regulatory body has to carry out activities that are necessary to verify that requirements for safety and environmental protection are being met by the operator. These activities are required to be supported by an effective management system, including the establishment and maintenance of a strong safety culture [8].

3.10. To fulfil its regulatory functions, the regulatory body, where appropriate, may undertake research, acquire independent assessment capabilities and participate in activities for international cooperation.

OPERATORS

Requirement 4: Responsibilities of the operator

Operators shall be responsible for the safety of predisposal radioactive waste management facilities or activities.⁴ The operator shall carry out safety assessments and shall develop a safety case, and shall ensure that the necessary activities for siting, design, construction, commissioning, operation, shutdown and decommissioning are carried out in compliance with legal and regulatory requirements.

3.11. Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including:

- Demonstration of safety by means of the safety case, and for an existing facility or activity by means of periodic safety reviews;
- Demonstration of environmental protection by means of an assessment of environmental impacts;
- Derivation of operational limits, conditions and controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the safety case;
- Preparation and implementation of appropriate operating procedures, including monitoring;
- Application of good engineering practice;
- Ensuring that staff are trained, qualified and competent, and, where applicable, licensed by the regulatory body;
- Establishment and implementation of a management system [8];
- Maintenance of records and reporting as required by the regulatory body, including those records and reports necessary to guarantee the accountability for and traceability of radioactive waste throughout the different processes of radioactive waste management;
- Establishment and maintenance of a mechanism to provide and ensure adequate financial resources to discharge its responsibilities;

⁴ The Basic Safety Standards (BSS) [6] establish general and specific requirements for the allocation of responsibilities for the protection of people against exposure to radiation and for the safety of radiation sources.

- Development of an emergency preparedness and response plan;
- Consideration of non-radiological hazards and conventional health and safety issues.

3.12. The operator is required to establish and maintain a strong safety culture by means of an effective management system and a demonstrated commitment to safety on the part of senior management [8, 14].

3.13. The operator is required to establish and maintain emergency preparedness and response plans commensurate with the hazards associated with the radioactive waste facilities and activities, and to report incidents significant to safety in a timely manner to the regulatory body and other interested parties, as appropriate [7].

3.14. Where appropriate, the operator may delegate work associated with the aforementioned responsibilities to other organizations, but the operator has to retain overall responsibility and control.

3.15. The operator is responsible for implementing measures to ensure an appropriate level of security.

3.16. The operator is responsible for applying management systems to all steps and elements of the predisposal management of radioactive waste [8, 14].

3.17. The operator is responsible for establishing and implementing the overall strategy for the management of the waste that is generated, and for providing the required financial securities, taking into account interdependences among all steps in waste management, the available options and the national radioactive waste management policy.

3.18. Information about changes of ownership of waste or about changes in the relationship between owner and licensee has to be provided to the regulatory body.

INTEGRATED APPROACH TO SAFETY

Requirement 5: Requirements in respect of security measures

Measures shall be implemented to ensure an integrated approach to safety and security in the predisposal management of radioactive waste.

3.19. Where security measures are necessary to prevent the unauthorized access of individuals and the unauthorized removal of radioactive material, both safety and security are to be approached in an integrated manner [2, 8, 15].

3.20. The level of security is required to be commensurate with the level of radiological hazard and the nature of the waste [16].

Requirement 6: Interdependences

Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account.

3.21. Owing to the interdependences among the various steps in the predisposal management of radioactive waste, all activities from the generation of radioactive waste up to its disposal, including its processing, are to be seen as parts of a larger entity, and the management elements of each step have to be selected so as to be compatible with those of the other steps. This has to be achieved principally through governmental and regulatory requirements and approaches. It is particularly important to consider the established acceptance criteria for disposal of the waste or the criteria that are anticipated for the most probable disposal option.

3.22. Furthermore, there are relationships between the steps in the predisposal management of radioactive waste and the operations in which either radioactive waste or material that can be recycled or reused is generated. It is necessary that those persons responsible for a particular step in the predisposal management of radioactive waste, or for an operation in which waste is generated, adequately recognize these interactions and relationships so that the safety and the effectiveness of the predisposal management of radioactive waste may be considered in an integrated manner. This includes taking into account the identification of waste streams, the characterization of waste, and the implications of transporting and disposing of waste. There are two issues in particular to be addressed: compatibility (i.e. taking actions that facilitate other steps and avoiding taking decisions in one step that detrimentally affect the options available in another step) and optimization (i.e. assessing the overall options for waste management with all the interdependences taken into account). The use of well managed information of good quality is key to both aspects.

3.23. In considering possible options for the processing of waste, care has to be taken to avoid conflicting demands that might compromise safety. It is not consistent with an integrated approach to optimize one step in the predisposal management of radioactive waste in such a way that it imposes significant constraints on the subsequent steps or forecloses viable options.

Requirement 7: Management systems

Management systems shall be applied for all steps and elements of the predisposal management of radioactive waste.

3.24. To ensure the safety of predisposal radioactive waste management facilities and the fulfilment of waste acceptance criteria, management systems are to be applied to the siting, design, construction, operation, maintenance, shutdown and decommissioning of such facilities and to all aspects of processing, handling and storage of waste. Features that are important to safe operation, and that are considered in the management system, are to be identified on the basis of the safety case and the assessment of environmental impacts [2, 8, 14]. These activities are required to be supported by means of an effective management system that establishes and maintains a strong safety culture [8, 14].

4. STEPS IN THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

GENERAL

4.1. The principal approaches to the predisposal management of radioactive waste are commonly termed 'delay and decay', 'concentrate and contain' and 'dilute and disperse'. 'Delay and decay' involves holding the waste in storage until the desired reduction in activity has occurred through radioactive decay of the radionuclides contained in the waste. 'Concentrate and contain' means reduction of volume and confinement of the radionuclide content by means of a conditioning process to prevent or substantially reduce dispersion in the environment. 'Dilute and disperse' means discharging effluent to the environment in such a way that environmental conditions and processes ensure that the concentrations of the radionuclides are reduced to such levels in the

environment that the radiological impacts of the released material are acceptable.

4.2. The approaches 'delay and decay' and 'concentrate and contain' often involve the holding of waste in a storage facility or the emplacement of waste in a disposal facility. Radioactive waste therefore has to be processed, as necessary, in such a way that it can be safely placed and held in a storage facility or a disposal facility.

4.3. The approach 'dilute and disperse' is a legitimate practice in the management of radioactive waste, but only when carried out within authorized limitations established by the regulatory body [2].

4.4. Various factors, including the nature and the amount of radioactive waste, occupational and public exposures, environmental effects, and human health, safety, and social and economic factors, are to be considered when deciding between options in the predisposal management of radioactive waste. However, the preferred option, as far as is reasonably practicable, is to concentrate and contain the waste and to isolate it from the biosphere.

4.5. In the predisposal management of radioactive waste, decisions often have to be made at a time when no disposal facility is available and the waste acceptance criteria for disposal are unknown. A similar situation would arise if radioactive waste were to be stored over long periods of time for reasons of safety or for other reasons. In both cases, consideration has to be given to whether, for the purposes of safety, the radioactive waste will be stored in a raw, a treated or a conditioned form. The anticipated needs for any future steps in radioactive waste management have to be taken into account as far as possible in making decisions on the processing of the waste.

GENERATION OF RADIOACTIVE WASTE

Requirement 8: Radioactive waste generation and control

All radioactive waste shall be identified and controlled. Radioactive waste arisings shall be kept to the minimum practicable.

4.6. Measures to control the generation of radioactive waste, in terms of both volume and radioactivity content, have to be considered before the construction of a facility, beginning with the design phase, and throughout the

lifetime of the facility, in the selection of the materials used for its construction, and in the control of the materials and the selection of the processes, equipment and procedures used throughout its operation and decommissioning. The control measures are generally applied in the following order: reduce waste generation, reuse items as originally intended, recycle materials and, finally, consider disposal as waste.

4.7. Careful planning has to be applied to the siting, design, construction, commissioning, operation, shutdown and decommissioning of facilities in which waste is generated, to keep the volume and the radioactive content of the waste arisings to the minimum practicable [2].

4.8. The reuse and recycling of materials has to be applied to keep the generation of radioactive waste to the minimum practicable, provided that protection objectives are met.

4.9. The authorized discharge of effluent and clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, together with reuse and recycling of material, can be effective in reducing the amount of radioactive waste that needs further processing or storage. The operator has to ensure that these management options, if implemented, are in compliance with the conditions and criteria established in regulations or by the regulatory body. The regulatory body also has to ensure that the operator gives due consideration to non-radiological hazards in applying such options.

Requirement 9: Characterization and classification of radioactive waste

At various steps in the predisposal management of radioactive waste, the radioactive waste shall be characterized and classified in accordance with requirements established or approved by the regulatory body.

4.10. Radioactive waste has to be characterized in terms of its physical, mechanical, chemical, radiological and biological properties.

4.11. The characterization serves to provide information relevant to process control and assurance that the waste or waste package will meet the acceptance criteria for processing, storage, transport and disposal of the waste. The relevant characteristics of the waste have to be recorded to facilitate its further management.

4.12. Radioactive waste may be classified for different purposes, and different classification schemes may be used in the successive steps in waste management. The most common classification is that made from the perspective of its future disposal [13].

PROCESSING OF RADIOACTIVE WASTE

Requirement 10: Processing of radioactive waste

Radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, shall be processed as radioactive waste. The processing of radioactive waste shall be based on appropriate consideration of the characteristics of the waste and of the demands imposed by the different steps in its management (pretreatment, treatment, conditioning, transport, storage and disposal). Waste packages shall be designed and produced so that the radioactive material is appropriately contained both during normal operation and in accident conditions that could occur in the handling, storage, transport and disposal of waste.

4.13. The main purpose of processing radioactive waste is to enhance safety by producing a waste form, packaged or unpackaged, that fulfils the acceptance criteria for safe processing, transport, storage and disposal of the waste. Waste has to be rendered into a safe and passive form for storage or disposal as soon as possible. The processing of radioactive waste can yield effluent that is suitable for authorized discharge or material that is suitable for authorized use or clearance from regulatory control.

4.14. Waste has to be processed in such a way that safety is appropriately ensured during normal operation, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences if accidents occur. The processing has to be consistent with the type of waste, the possible need for its storage, the anticipated disposal option, and the limits, conditions and controls established in the safety case and in the assessment of environmental impacts.

4.15. Various methods are applied for processing radioactive waste of different types. Consideration has to be given to identifying suitable options and to assessing the appropriateness of their application. Decisions have to be taken within the overall approach to the predisposal management of radioactive

waste on the extent to which the waste has to be processed, with account taken of the quantities, activity and physical and/or chemical nature of the radioactive waste to be treated, the technologies available, the storage capacity and the availability of a disposal facility.

4.16. Radioactive waste has to be processed in such a way that the resulting waste form can be safely stored and retrieved from the storage facility up until its ultimate disposal.

4.17. Provisions have to be established by the operator for identifying, assessing and dealing with waste and/or waste packages that do not meet process specifications and requirements for its and/or their safe handling, transport, storage and/or disposal.

4.18. Consideration has to be given to the consequences of dealing with any secondary waste (both radioactive and non-radioactive) that is created during processing.

STORAGE OF RADIOACTIVE WASTE

Requirement 11: Storage of radioactive waste

Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage, and, to the extent possible, passive safety features shall be applied. For long term storage in particular, measures shall be taken to prevent degradation of the waste containment.

4.19. Within the context of radioactive waste management, storage refers to the temporary placement of radioactive waste in a facility where appropriate isolation and monitoring are provided. Storage has to take place between and within the basic steps in the predisposal management of radioactive waste. Storage is used to facilitate the subsequent step in radioactive waste management; to act as a buffer between and within waste management steps; to allow time for the decay of radionuclides prior to clearance or authorized discharge; or to hold waste generated in emergency situations pending decisions on its future management. 4.20. The design of the storage facility depends on the type of radioactive waste, its characteristics and associated hazards, the radioactive inventory, and the anticipated period of storage.

4.21. Storage is by definition an interim measure, but it can last for several decades. The intention in storing waste is that the waste can be retrieved for clearance, processing and/or disposal at a later time, or, in the case of effluent, for authorized discharge.

4.22. Provision has to be made for the regular monitoring, inspection and maintenance of the waste and of the storage facility to ensure their continued integrity. The adequacy of the storage capacity has to be periodically reviewed, with account taken of the predicted waste arisings, both from normal operation and from possible incidents, of the expected lifetime of the storage facility and of the availability of disposal options.

4.23. When it is proposed to store radioactive waste for a long period of time, consideration has to be given to the protection of present and future generations in accordance with the fundamental safety principles (Principle 7) [2].

RADIOACTIVE WASTE ACCEPTANCE CRITERIA

Requirement 12: Radioactive waste acceptance criteria

Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case.

4.24. Waste acceptance criteria have to be developed that specify the radiological, mechanical, physical, chemical and biological characteristics of waste packages and unpackaged waste that are to be processed, stored or disposed of; for example, their radionuclide content or activity limits, their heat output and the properties of the waste form and packaging.

4.25. Adherence to the waste acceptance criteria is essential for the safe handling and storage of waste packages and unpackaged waste during normal operation, for safety during possible accident conditions and for the long term safety of the subsequent disposal of the waste.

4.26. The operators' procedures for the reception of waste have to contain provisions for safely managing waste that fails to meet the acceptance criteria; for example, by taking remedial actions or by returning the waste.

5. DEVELOPMENT AND OPERATION OF PREDISPOSAL RADIOACTIVE WASTE MANAGEMENT FACILITIES AND ACTIVITIES

GENERAL

5.1. The development of authorizations and of limits, conditions and controls for the predisposal management of radioactive waste benefits from close communication and cooperation between the operators, regulatory bodies and other interested parties.

5.2. It is the responsibility of the regulatory body to derive and document in a clear and unambiguous manner the criteria on which the regulatory decision making process is based. It is important that any additional guidance provided by the regulatory body takes account of the wide range of predisposal radioactive waste management facilities that may be developed and the wide range of activities that may be conducted at these facilities.

APPROACH TO SAFETY

Requirement 13: Preparation of the safety case and supporting safety assessment

The operator shall prepare a safety case and a supporting safety assessment. In the case of a step by step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary.

5.3. The safety case has to be prepared by the operator early in the development of a facility as a basis for the process of regulatory decision making and approval. The safety case has to be progressively developed and refined as the project proceeds. Such an approach ensures the quality of the

technical programme and the associated decision making. For the operator, it provides a framework in which confidence in the technical feasibility and safety of the facility can be established at each stage of its development. This confidence has to be developed and enhanced by means of iterative design studies and safety studies as the project progresses. The step by step approach has to provide for the collection, analysis and interpretation of the relevant technical data, the development of plans for design and operation, and the development of the safety case for operational safety.

5.4. It is the operator's responsibility to compile the safety assessment as part of the safety case in accordance with the requirements of the regulatory body.

Requirement 14: Scope of the safety case and supporting safety assessment

The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility, and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met.

5.5. The design of the facility, the arrangements for operational management and the systems and processes that are used have to be considered and justified in the safety case. This has to involve the identification of waste arisings and the establishment of an optimal programme of waste management to minimize the amount of waste generated and to determine the design basis and operational basis for the treatment of effluents, the control of discharges and clearance procedures. The primary aim of the safety case is to ensure that the safety objectives and criteria set by the regulatory body are met.

5.6. The safety case has to address operational safety and all safety aspects of the facility and activities. The safety case has to include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation and in possible accident conditions.

5.7. The extent and detail of the safety case and the safety assessment have to be commensurate with the complexity of the operations and the magnitude of the hazards associated with the facility and activities.

Requirement 15: Documentation of the safety case and supporting safety assessment

The safety case and its supporting safety assessment shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support the decision at each stage and to allow for the independent review and approval of the safety case and safety assessment. The documentation shall be clearly written and shall include arguments justifying the approaches taken in the safety case on the basis of information that is traceable.

5.8. Justification has to involve explaining why particular choices were made and stating the arguments in favour of and against the decisions made, especially those decisions that relate to the main approaches taken in the safety case.

5.9. Traceability refers to the possibility of following the information that is provided in the documentation and that has been used in developing the safety case. For the purposes of both justification and traceability, a well documented record is necessary of the decisions and assumptions that were made in the development and operation of the facility, and of the models and data used in the safety assessment to obtain the set of results. Good traceability is important for the purposes of technical and regulatory review and for building public confidence.

5.10. Clarity refers to good structure and presentation at an appropriate level of detail such as to allow an understanding of the arguments included in the safety case. This necessitates that the documents present the work in such a way that the interested parties for whom the documents are intended can gain a good understanding of the safety arguments and their bases. Different styles and levels of documentation may be necessary, depending on the intended audience for the material.

Requirement 16: Periodic safety reviews

The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility.

5.11. The safety assessment has to be reviewed periodically to confirm that any input assumptions that need to be complied with remain adequately controlled within the overall safety management controls.

5.12. The safety assessment and the management systems within which it is conducted have to be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment has to be reviewed and updated:

- When there is any significant change that may affect the safety of the facility or activity;
- When there are significant developments in knowledge and understanding (such as developments arising from research or operational experience feedback);
- When there is an emerging safety issue owing to a regulatory concern or an incident;
- When there have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis.

DEVELOPMENT OF PREDISPOSAL RADIOACTIVE WASTE MANAGEMENT FACILITIES

Requirement 17: Location and design of facilities

Predisposal radioactive waste management facilities shall be located and designed so as to ensure safety for the expected operating lifetime under both normal and possible accident conditions, and for their decommissioning.

5.13. The features to be incorporated in the design will depend largely on the properties, total inventory and potential radiological and non-radiological hazards associated with the radioactive waste that is to be managed, as well as on the requirements of the regulatory body.

5.14. The need for operational maintenance, testing, examination and inspection has to be addressed from the conceptual design stage onward.

Requirement 18: Construction and commissioning of the facilities

Predisposal radioactive waste management facilities shall be constructed in accordance with the design as described in the safety case and approved by the regulatory body. Commissioning of the facility shall be carried out to verify that the equipment, structures, systems and components, and the facility as a whole, perform as planned.

5.15. It is the responsibility of the operator to construct facilities in accordance with the approved design, including conducting any verification tests that need to be performed (e.g. the testing of welds or foundations). The regulatory body has to be responsible for oversight of these activities for construction and verification.

5.16. Commissioning may be carried out in several stages that are subject to the review and approval of the regulatory body. In larger, more complex facilities, commissioning normally has to be carried out in the following stages: completion of construction and inspection, installation and testing of equipment, demonstration of performance, non-active (i.e. without radioactive waste) commissioning and active (i.e. with radioactive waste) commissioning.

5.17. Upon the completion of commissioning, a final commissioning report is usually produced by the operator. The report has to document the as-built status of the facility, which, in addition to providing information to facilitate operation, is important when considering possible future modifications to the facility and its shutdown and decommissioning. The report has to describe all the testing and provide evidence of the successful completion of testing and of any modifications made to the facility or to procedures in commissioning. The report has to provide assurance that all the conditions of authorization have been satisfied. This report has to be maintained with the operator as part of the documentation needed for operation and for the development of the decommissioning plan. The regulatory body has to assess this report to ensure that all conditions and requirements are satisfied before agreeing to the operation of the facility. The safety case has to be updated, as necessary, to reflect the as-built status of the facility and the conclusions of the commissioning report.

5.18. A modification of a facility with significant safety implications that requires a revision of the safety case has to be subject to the same regulatory controls and approvals as are applicable for the new facility.

Requirement 19: Facility operation

Predisposal radioactive waste management facilities shall be operated in accordance with national regulations and with the conditions imposed by the regulatory body. Operations shall be based on documented procedures. Due consideration shall be given to the maintenance of the facility to ensure its safe performance. Emergency preparedness and response plans, if developed by the operator, are subject to the approval of the regulatory body [7].

5.19. The operational limits, conditions and controls are not in all cases provided in the authorization document, but they may be given in a separate document (sometimes called the safety related technical specifications), referred to in the authorization document. All operations and activities important to safety have to be subject to documented limits, conditions and controls, and have to be carried out by trained, qualified and competent personnel.

5.20. All facility specific safety related criteria and documented operating procedures required by the regulatory body have to be submitted to the regulatory body for approval. Such procedures may include a programme of periodic maintenance, testing and inspection of systems that are essential to safe operation.

Requirement 20: Shutdown and decommissioning of facilities

The operator shall develop, in the design stage, an initial plan for the shutdown and decommissioning of the predisposal radioactive waste management facility and shall periodically update it throughout the operational period. The decommissioning of the facility shall be carried out on the basis of the final decommissioning plan, as approved by the regulatory body. In addition, assurance shall be provided that sufficient funds will be available to carry out shutdown and decommissioning [4].

5.21. Decommissioning of predisposal radioactive waste management facilities has to be considered in the design stage. The objective is to limit occupational exposures, the generation of waste and the potential for accidents during decommissioning.

5.22. The time periods between updates of the decommissioning plan will be dependent on the type of facility and the operational history and have to be agreed with the regulatory body.

5.23. Facilities have to be shut down and decommissioned in accordance with the conditions set by the regulatory body. The objective is to facilitate the future dismantling activities by reducing occupational exposures, minimizing the generation of waste and reducing the potential for accidents during decommissioning. Particular consideration has to be given to any transfer of responsibility for the facility that may occur at this stage [4].

OTHER PROVISIONS

Requirement 21: System of accounting for and control of nuclear material

For facilities subject to agreements on nuclear material accounting, in the design and operation of predisposal radioactive waste management facilities the system of accounting for and control of nuclear material shall be implemented in such a way as not to compromise the safety of the facility [17—19].

5.24. The system of accounting for and control of nuclear material relies on active surveillance and controls that require access to material and facilities, with concomitant implications for radiation exposure and possible reduction in containment and isolation provisions. These aspects have to be considered in the design and operation of the facility.

Requirement 22: Existing facilities

The safety at existing facilities shall be reviewed to verify compliance with requirements. Safety related upgrades shall be made by the operator in line with national policies and as required by the regulatory body.

5.25. The requirements established in this publication are intended to apply to all facilities. Since existing facilities might not be in compliance with all the requirements, decisions have to be taken, in line with national policies, with regard to the safety of these facilities. In such a case, a review initiated by the regulatory body has to be used to identify those facilities that are not in compliance with all the requirements and that need additional modifications or operational restrictions, or that need to be shut down.

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Annex

PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE AND THE FUNDAMENTAL SAFETY PRINCIPLES

A-1. As discussed in the following, several fundamental safety principles [A-1] incorporate the concepts of radioactive waste management, and measures need to be taken to ensure overall compatibility and compliance with the requirements set out in this publication.

A–2. A well designed and well implemented programme for the management of radioactive waste will provide for the protection of people and the environment against the hazards associated with radioactive waste. This is consistent with the fundamental safety objective, in respect of which the protection of human health and the environment is discussed in Section 2 of this publication. Principles are set out that determine a level of protection of human health and the environment both now and in the future (Principles 4–7). The principles are to be applied with regard to national boundaries, which is consistent with Principle 7.

A–3. A special requirement in Section 4 of this publication, consistent with Principle 7, is set out whereby radioactive waste is required to be managed in a manner that will not impose undue burdens on future generations. Section 3 addresses special provisions and requirements for an appropriate national policy, strategy and legal framework, whereby in accordance with Principles 1–3 responsibilities are to be clearly allocated for government, regulatory bodies and operators.

A–4. Requirements in Section 4 of this publication on various elements of predisposal management of radioactive waste stipulate that the waste generated is required to be kept to the minimum practicable and that interdependences among all steps and the application of waste acceptance criteria are required to be taken into consideration, in compliance with Principles 5, 6 and 8.

A–5. Consistent with Principle 3, this publication, in Section 5, sets out criteria and requirements to ensure the safety of predisposal radioactive waste management facilities and activities.

The IAEA Safety Objective and Fundamental Safety Principles [A–1]:

Safety objective

The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation.

Principle 1: Responsibility for safety

The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.

Principle 2: Role of government

An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.

Principle 3: Leadership and management for safety

Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.

Principle 4: Justification of facilities and activities

Facilities and activities that give rise to radiation risks must yield an overall benefit.

Principle 5: Optimization of protection

Protection must be optimized to provide the highest level of safety that can reasonably be achieved.

Principle 6: Limitation of risks to individuals

Measures for controlling radilation risks must ensure that no individual bears an unacceptable risk of harm.

Principle 7: Protection of present and future generations

People and the environment, present and future, must be protected against radiation risks.

Principle 8: Prevention of accidents

All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.

Principle 9: Emergency preparedness and response

Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.

Principle 10: Protective actions to reduce existing or unregulated radiation risks

Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

REFERENCE TO THE ANNEX

[A–1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, **INTERNATIONAL** MARITIME ORGANIZATION. OECD NUCLEAR ENERGY AGENCY, PAN HEALTH ORGANIZATION, UNITED AMERICAN NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).

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"The IAEA's standards have become a key element of the global safety regime for the beneficial uses of nuclear and radiation related technologies.

"IAEA safety standards are being applied in nuclear power generation as well as in medicine, industry, agriculture, research and education to ensure the proper protection of people and the environment."

Mohamed ElBaradei IAEA Director General

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