

IAEA Safety Standards

for protecting people and the environment

The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste

General Safety Guide

No. GSG-3



IAEA

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IAEA SAFETY STANDARDS

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

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

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

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

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

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RELATED PUBLICATIONS

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

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

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

Security related publications are issued in the **IAEA Nuclear Security Series**.

The **IAEA Nuclear Energy Series** comprises informational publications to encourage and assist research on, and the development and practical application of, nuclear energy for peaceful purposes. It includes reports and guides on the status of and advances in technology, and on experience, good practices and practical examples in the areas of nuclear power, the nuclear fuel cycle, radioactive waste management and decommissioning.

THE SAFETY CASE AND
SAFETY ASSESSMENT FOR THE
PREDISPOSAL MANAGEMENT OF
RADIOACTIVE WASTE



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

IAEA SAFETY STANDARDS SERIES No. GSG-3

THE SAFETY CASE AND SAFETY ASSESSMENT FOR THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

GENERAL SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2013

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FOREWORD

by Yukiya Amano
Director General

The IAEA's Statute authorizes the Agency to “establish or adopt... standards of safety for protection of health and minimization of danger to life and property” — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For 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 regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

NOTE BY THE SECRETARIAT

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. The process of developing, reviewing and establishing the IAEA standards involves the IAEA Secretariat and all Member States, many of which are represented on the four IAEA safety standards committees and the IAEA Commission on Safety Standards.

The IAEA standards, as a key element of the global safety regime, are kept under regular review by the Secretariat, the safety standards committees and the Commission on Safety Standards. The Secretariat gathers information on experience in the application of the IAEA standards and information gained from the follow-up of events for the purpose of ensuring that the standards continue to meet users' needs. The present publication reflects feedback and experience accumulated until 2010 and it has been subject to the rigorous review process for standards.

Lessons that may be learned from studying the accident at the Fukushima Daiichi nuclear power plant in Japan following the disastrous earthquake and tsunami of 11 March 2011 will be reflected in this IAEA safety standard as revised and issued in the future.

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. Requirements, including numbered ‘overarching’ requirements, are expressed

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

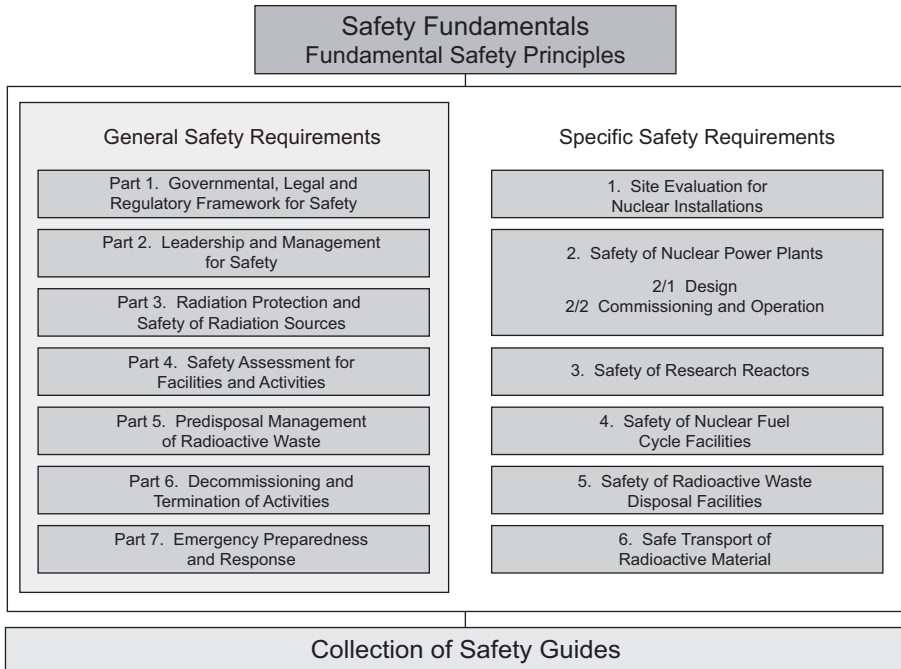


FIG. 1. The long term structure of the IAEA Safety Standards Series.

as ‘shall’ statements. 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 Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

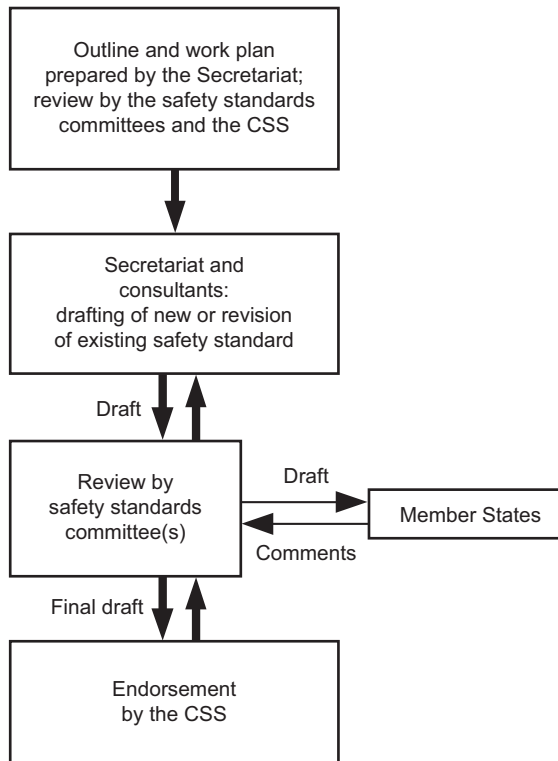


FIG. 2. The process for developing a new safety standard or revising an existing stand-

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

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

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

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

INTERPRETATION OF THE TEXT

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

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

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

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

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1. INTRODUCTION

BACKGROUND

1.1. The general principles for the safe management of radioactive waste are established in the Fundamental Safety Principles [1]. The safety requirements for the predisposal management of radioactive waste require that a safety case¹, together with the necessary supporting safety assessment, be developed and undertaken for each facility² or activity [2].

1.2. The safety case is the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a waste management facility or activity³, covering the suitability of the site and location and the design, construction and operation of the facility, the assessment of radiation risks and assurance of the adequacy and quality of all of the safety related work associated with the facility or activity. Safety assessment, an integral and important part of the safety case, is driven by a systematic assessment of radiation hazards. The latter involves quantification of radiation dose and radiation risks that may arise from the facility or activity for comparison with dose and risk criteria, and provides an understanding of the behaviour of the facility or activity under normal conditions and anticipated operational occurrences and in the event of accidents. The safety case and supporting safety assessment provide the basis for demonstration of safety and for licensing. They will evolve with the development of the facility or activity, and will assist and guide decisions on siting, location, design and operations. The safety case will also be the main basis on which dialogue with interested parties will be conducted and on which confidence in the safety of the facility or activity will be developed.

¹ While the concept of a ‘safety case’ for waste management facilities and activities as outlined in this Safety Guide is used in many States, the terminology may be different in some States. In France, the term ‘dossier’ is used to describe the safety case. In Germany and Switzerland, the term ‘Sicherheitsnachweis’ is used, while in Spain, the term ‘estudio de seguridad’ is used.

² The term ‘facility’ as used in this Safety Guide means a facility with its associated land, buildings and equipment in which radioactive material is used, processed, handled or stored on such a scale that consideration of safety is required.

³ The term ‘radioactive waste management facilities and activities’ also includes spent fuel management facilities and activities if the spent fuel is considered to be waste, and could be applied to similar activities where the spent fuel is considered to be a resource.

1.3. Waste management facilities and activities are varied in nature, size and complexity, and have different hazards associated with them, both from normal operation and from accidents. The magnitude and content of the radioactive inventory is also varied. Furthermore, a waste management facility or activity could be one of several facilities or activities on a site and may be independent of the other facilities, may be connected to other facilities or may be an integral part of a larger facility. Commensurately, the extent and complexity of the safety case and supporting safety assessment will differ according to the facility or activity, and will also evolve through its lifetime (e.g. construction, commissioning, operation). In view of these considerations, a graded approach is required to be applied to the development and review of the safety case and supporting safety assessment [3]. The recommendations contained in this Safety Guide are comprehensive and sufficient for the most complex and hazardous facilities. Their use in a graded manner is intended to be illustrated in a number of Safety Reports to be developed to cover a range of facilities.

OBJECTIVE

1.4. The objective of this Safety Guide is to provide recommendations for development and review of the safety case and supporting safety assessment for facilities and activities dealing with the predisposal management of radioactive waste and spent fuel storage facilities. It summarizes the most important considerations in assessing and demonstrating the safety of facilities and activities, and documents the steps that should be followed in developing the safety case and performing the safety assessment.

1.5. The Safety Guide aims to assist operators, regulatory bodies and supporting technical specialists in the application of a graded approach to the development and review of the safety case and supporting safety assessment. The Safety Guide provides guidance for a regulatory framework in which a safety case is developed and assessment is undertaken throughout the lifetime of a facility. The guidance contained in this Safety Guide can be used irrespective of how the safety case and safety assessment process are addressed within individual national regulatory frameworks.

SCOPE

1.6. This Safety Guide provides recommendations and guidance on the development and review of the safety case and supporting safety assessment

prepared or conducted for a predisposal waste management facility or activity. It covers all aspects of the safety case and safety assessment, including the use of a graded approach.

1.7. The Safety Guide applies to the planning and, in particular, throughout the design, construction, commissioning, operation and modification of the facility.

1.8. The Safety Guide provides recommendations and guidance on a systematic methodology for evaluation of the adequacy and acceptability of waste management arrangements and the radiological impacts on workers, the public and the environment from planned activities and from accidents at a predisposal waste management facility or in a related activity.

1.9. This Safety Guide together with Ref. [4] supersedes IAEA Safety Series No. 118, Safety Assessment for Spent Fuel Storage Facilities⁴.

1.10. Assessment and demonstration of the safety of nuclear power plants, decommissioning of facilities using radioactive material and disposal of radioactive waste are not covered in this Safety Guide. The reader is referred to companion Safety Guides [5–7].

1.11. This Safety Guide applies to the predisposal management of radioactive waste of all types and covers all steps in the management of radioactive waste, from its generation up to disposal, including its processing (pretreatment, treatment and conditioning), storage and transport. A classification scheme for radioactive waste and recommendations on the application of the scheme to the various types of radioactive waste are provided in Ref. [8].

1.12. The transport of radioactive waste is managed in the same way as the transport of any radioactive material. The safe transport of radioactive waste is ensured by complying with the requirements established in Ref. [9].

1.13. This Safety Guide applies to the predisposal management of radioactive waste 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 Safety Guide, the term ‘facility’ is used to refer to either of these possibilities.

⁴ INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Spent Fuel Storage Facilities: A Safety Practice, IAEA Safety Series No. 118, IAEA, Vienna (1995).

1.14. The Safety Guide applies to radioactive waste storage facilities, including long term storage facilities, spent fuel storage facilities (see Ref. [4]) and storage facilities for radioactive sources.

1.15. In addition to the processing, storage and transport of waste, predisposal waste management activities include:

- The remediation of areas on which waste facilities had been located;
- Retrieval of waste;
- Characterization of waste;
- Clearance of waste from regulatory control;
- Discharge of effluents to the environment.

1.16. 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 radionuclides of natural origin;
- The remediation of contaminated areas.

1.17. Clearance from regulatory control and control of discharges are addressed in Refs [10, 11], respectively.

1.18. Facilities or activities that deal with radioactive material may have impacts of both a radiological and non-radiological nature, but the primary focus of this Safety Guide is on the radiological impacts. However, the radiological consequences of non-radiological events or hazards, such as fire, are addressed. Furthermore, although the assessment of non-radiological hazards is outside the scope of this Safety Guide, it is important that due consideration be given to such hazards, as required in national legislation.

STRUCTURE

1.19. This Safety Guide is structured as follows: Section 2 discusses the overall process of demonstrating the safety of a radioactive waste management facility or activity, while Section 3 summarizes the main safety principles and safety requirements to be met in the preparation of the safety case. The overall goal of the subsequent sections is to provide guidance on how to meet these principles and requirements. Section 4 elaborates on the concept of the safety case. The

components of the safety case and its role in the development, operation and decommissioning of a waste management facility or activity are described, and possibilities for building confidence in the safety case are discussed. Section 5 addresses methodology for the safety assessment, which forms the core element of the safety case described in Section 4. Various steps in this process are outlined and discussed in detail. In particular, guidance and recommendations are provided on the management of uncertainties within the safety assessment, as well as on the use of the outcomes of assessments for comparison with assessment criteria. Section 6 discusses specific issues that arise in the preparation of a safety case, and Section 7 addresses the documentation of the safety case and indicates possible uses of the safety case in the development of the waste management facility or activity. Section 8 provides guidance and recommendations on the regulatory review of the safety case. Annex I provides examples of hazards and initiating events, Annex II provides a list of topical issues for the regulatory review of the safety case, Annex III provides a template for the regulatory review report and Annex IV provides a framework for the overall safety assessment work.

2. DEMONSTRATING THE SAFETY OF THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

2.1. Assessment and demonstration of safety for radioactive waste management facilities and activities has been widely undertaken in the past. However, until recently only limited efforts had been made to develop an international consensus on approaches to such assessment and demonstration. The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [12] in 2001 placed increasing emphasis on the demonstration of safety and on supporting safety assessment. Consequently, the IAEA established an international intercomparison and harmonization project on the subject called the International Safety Assessment Driving Radioactive Waste Management Solutions (SADRWMS). This project has contributed significantly to the development of an international consensus on the methodology for demonstration and assessment of safety, and to the content of this Safety Guide. The framework for the work carried out within the SADRWMS project was developed at an early stage of the project and is included in this Safety Guide as Annex IV.

2.2. In the broader context of safety demonstration, the concept of the ‘safety case’ is used. The safety case is the collection of arguments and evidence, including the outcome of safety assessment, in support of the safety of a facility or activity. The safety case will normally include the findings of a safety assessment, together with consideration of the level of confidence in these findings, the adequacy of the assessment work for the decisions to be taken and the need for any further work to reduce uncertainties. The safety case provides the basis for safety decisions with respect to siting and location, design, construction, operation and decommissioning of a facility, including for the justification of changes with a significant impact on safety. It also serves as a basis for interaction and dialogue between the operator and the regulatory body, since it comprises the main body of documents in support of applications for the authorizations necessary under national legislation.

2.3. The safety assessment conducted in support of the safety case should employ a systematic methodology to demonstrate compliance with the applicable safety requirements. Criteria should be developed to be met at the various stages of the lifetime of the facility, and these criteria should include the periodic review of the safety case and supporting assessment. This should help ensure that interested parties are confident in the safety of the facility or activity. Once developed by the operator, the safety case is reviewed by the regulatory body to verify compliance with relevant safety requirements and criteria.

2.4. A number of related IAEA Safety Requirements and Guides have been established [2, 3, 13–19] and these should be read in conjunction with this Safety Guide.

3. SAFETY PRINCIPLES AND SAFETY REQUIREMENTS

3.1. This section lists the fundamental safety principles and the main requirements that have to be met when preparing the safety case and supporting safety assessment for a predisposal waste management facility or activity.

SAFETY PRINCIPLES

3.2. The safety principles to be applied in all radioactive waste management facilities and activities are established in the IAEA Fundamental Safety Principles [1]:

- Principle 1: Responsibility for safety
- Principle 2: Role of government
- Principle 3: Leadership and management for safety
- Principle 4: Justification of facilities and activities
- Principle 5: Optimization of protection
- Principle 6: Limitation of risks to individuals
- Principle 7: Protection of present and future generations
- Principle 8: Prevention of accidents
- Principle 9: Emergency preparedness and response
- Principle 10: Protective actions to reduce existing or unregulated radiation risks

3.3. The principles established in Ref. [1] form the technical basis for the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management⁵ [12]. The relevant requirements for radiation protection are established in the IAEA's General Safety Requirements publication, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (BSS) [13]. Many of the concepts of protection adopted in Ref. [13] and in the Joint Convention are derived from the recommendations of the International Commission on Radiological Protection [20–23].

REQUIREMENTS FOR THE SAFETY CASE AND SAFETY ASSESSMENT

3.4. The following paragraphs set out the main requirements in Refs [2, 3] that are relevant for the preparation, updating and maintenance and use of the safety case and supporting safety assessment. Recommendations on meeting other requirements in Refs [2, 3] are provided in later sections of this Safety Guide. For remediation situations, the requirements established in Ref. [13] are applicable.

⁵ The Joint Convention made use of the principles established in Principles of Radioactive Waste Management, IAEA Safety Series No. 111-F, IAEA, Vienna (1995), which were subsequently integrated into Ref. [1].

RESPONSIBILITIES FOR DEVELOPING THE SAFETY CASE AND SAFETY ASSESSMENT

3.5. For predisposal waste management facilities and activities:

“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” (Requirement 13, Ref. [2]).

3.6. “The responsibility for carrying out the safety assessment shall rest with the responsible legal person; that is, the person or organization responsible for the facility or activity” (Requirement 3, Ref. [3]). This responsibility relates to the conduct of the assessment and the quality of the results.

3.7. “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” (para. 5.2 of Ref. [2]).

These regulatory requirements and conditions will have to be addressed by the operator when undertaking safety assessment and preparing the safety case.

CONTENT OF THE SAFETY CASE AND SAFETY ASSESSMENT

3.8. The following requirements apply for the safety case and supporting safety assessment to be prepared for a predisposal waste management facility or activity:

- “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” (Requirement 14, Ref. [2]).

- “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” (para. 5.5 of Ref. [2]).
- “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” (para. 5.6 of Ref. [2]).

3.9. The following requirement applies for all facilities and activities, including waste management facilities and activities: “It shall be determined in the assessment of defence in depth whether adequate provisions have been made at each of the levels of defence in depth” (Requirement 13, Ref. [3]). This requirement is further developed in the following statement:

“It has to be determined in the safety assessment whether adequate defence in depth has been provided, as appropriate, through a combination of several layers of protection (i.e. physical barriers, systems to protect the barriers, and administrative procedures) that would have to fail or to be bypassed before there could be any consequences for people or the environment” (para. 4.12 of Ref. [3]).

3.10. In accordance with Ref. [3], it is required to carry out a safety assessment to ensure adequate levels of safety that addresses all radiation risks, ensures adequate measures are taken and provides quantitative analysis for assessing risk challenges. Detailed requirements are established in paras 4.5, 4.6, 4.9 and 4.10 of Ref. [3].

MAINTENANCE OF THE SAFETY CASE AND SAFETY ASSESSMENT

3.11. More specifically, for predisposal waste management facilities:

“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” (para. 5.3 of Ref. [2]).

3.12. Furthermore:

“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” (Requirement 16, Ref. [2]).

3.13. With regard to the process of such reviews:

“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” (para. 5.11 of Ref. [2]).

3.14. The timing of reviews is required to be defined by the following considerations:

“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” (para. 5.12 of Ref. [2]).

DOCUMENTATION OF THE SAFETY CASE AND SAFETY ASSESSMENT

3.15. “The results and findings of the safety assessment are to be documented, as appropriate, in the form of a safety report that reflects the complexity of the facility or activity and the radiation risks associated with it. The safety report presents the assessments and the analyses that have been carried out for the purpose of demonstrating that the facility or activity is in compliance with the fundamental safety principles and the requirements established in [Ref. [3]], and any other safety requirements as established in national laws and regulations” (para. 4.62, Ref. [3]).

3.16. The following detailed requirements on documentation of the safety case apply:

- “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” (Requirement 15, Ref. [2]).
- “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” (para. 5.8 of Ref. [2]).
- “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” (para. 5.9 of Ref. [2]).
- “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” (para. 5.10 of Ref. [2]).

USE OF THE SAFETY CASE AND SAFETY ASSESSMENT

3.17. “The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity and to make decisions in an integrated, risk informed approach” (Requirement 23, Ref. [3]).

4. THE SAFETY CASE FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

4.1. This section identifies and provides recommendations on the components of the safety case, its development and its role during the development and operation of a predisposal waste management facility or activity.

4.2. The components of the safety case are indicated in Fig. 1 and should include the following: the context; the safety strategy; the facility description; safety assessment; limits, controls and conditions; iteration and design optimization; uncertainty management; and integration of safety arguments.

4.3. The safety case should be developed from the conceptualization of the facility and should be maintained throughout its lifetime, up to decommissioning and licence termination. Management systems for ensuring the quality of all safety related work should be applied throughout and the regulatory process applied as illustrated in Fig. 2. Arrangements to facilitate the involvement of all interested parties in the development and use of the safety case should be in place.

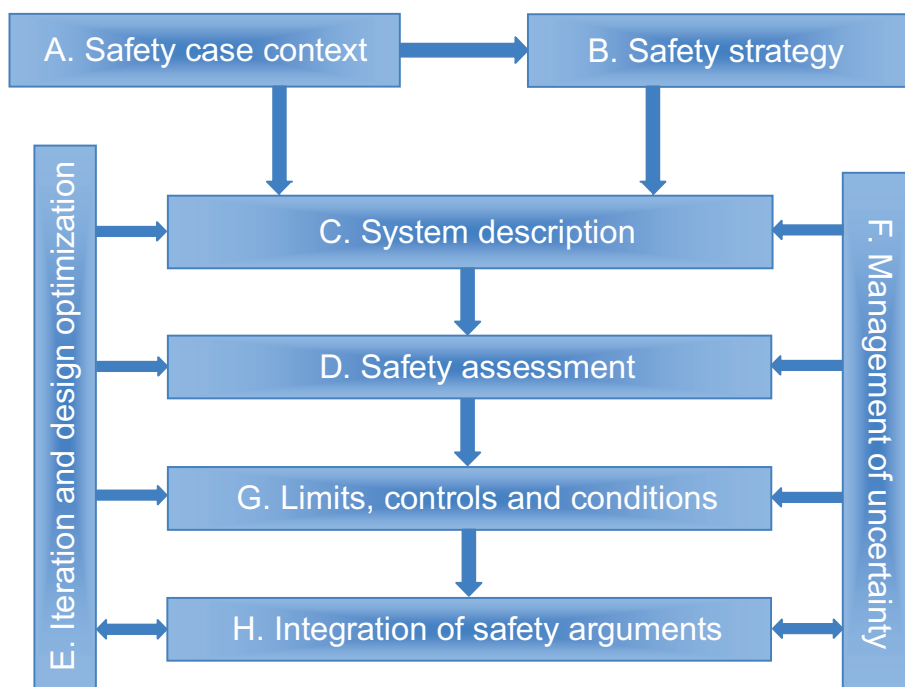


FIG. 1. Components of the safety case.

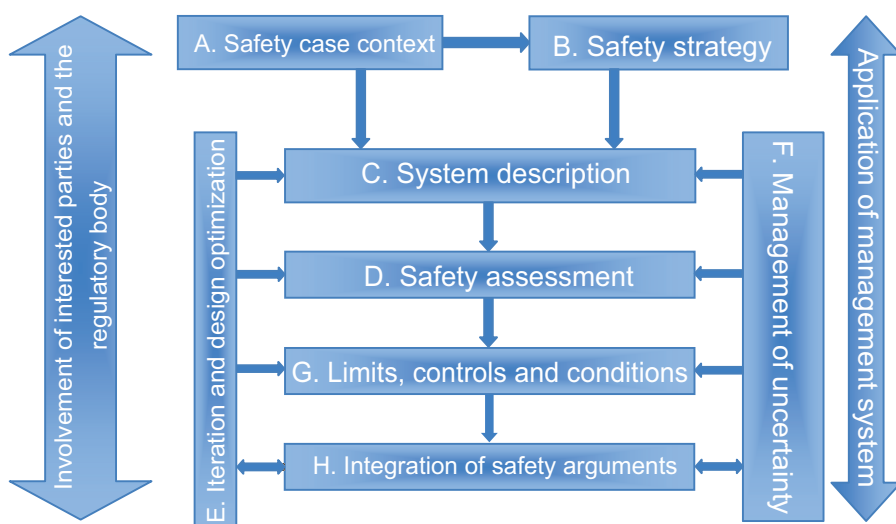


FIG. 2. Application of the management system and the process for interaction with the regulatory body and interested parties.

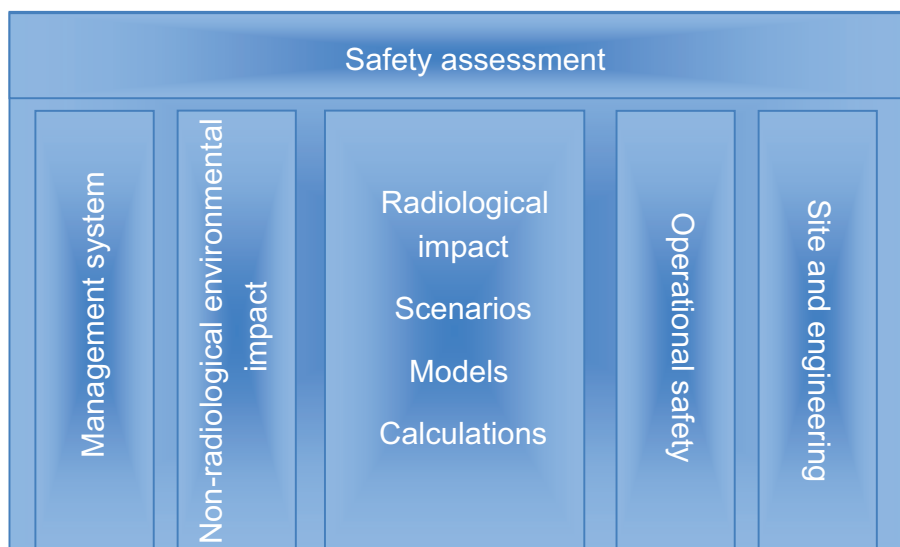


FIG. 3. Aspects included in safety assessment.

4.4. Safety assessment is the main component of the safety case and involves assessment of a number of aspects as illustrated in Fig. 3. The fundamental element of the safety assessment is the assessment of the radiological impact on humans and the environment in terms of both radiation dose and radiation risks. The other important aspects subject to safety assessment are site and engineering aspects, operational safety, non-radiological impacts and the management system. Paragraphs 4.6–4.28 provide guidance on the various components of the safety case.

4.5. The safety case is of particular importance and benefit for large predisposal waste management facilities, such as centralized facilities for the processing and storage of radioactive waste in States that have a nuclear power programme. For smaller scale facilities, such as storage facilities for disused sealed sources, the components of the safety case described in this section are still relevant; however, the level of detail and the complexity and depth of the safety assessment are required to be commensurate with the potential hazard (Requirement 1, Ref. [3]). In addition, the actual process of developing the safety case and conducting safety assessment will be commensurately less demanding, and several of the aspects discussed below, such as development of the safety case in stages, will be less relevant for some types and sizes of facilities. This is an expression of the graded approach described in para. 4.26 and Section 6. IAEA Safety Reports

setting out examples of safety cases are under development to provide additional guidance on the level of depth and detail warranted for safety cases prepared for smaller facilities.

ROLE AND DEVELOPMENT OF THE SAFETY CASE

4.6. The role of the safety case for a predisposal waste management facility or activity should be to provide:

- All the safety arguments and supporting evidence that demonstrate the safety of the waste management facility or activity.
- A basis for and an aid in decision making on the licensing or other authorization process for the facility or activity.
- An integration of relevant scientific (and other) information in a structured, traceable and transparent way that demonstrates an understanding of the anticipated behaviour and performance of the facility or activity.
- A demonstration that consideration has been given to all steps in the management of the waste under consideration, from its generation to its disposal, and to their overall compatibility. Short term, medium term and long term aspects of waste management should be considered, as well as the possible need for future handling and treatment of the waste and the risks and doses that may be associated with these activities. Compatibility of the waste packages and unpackaged waste with a disposal option should be demonstrated; however, in the event that a disposal option has not been identified at a certain stage, assumptions should be made about the likely disposal options and these should be set down clearly.
- Identification of uncertainties in the performance of the facility, analysis of the significance of the uncertainties, and identification of approaches for the management of significant uncertainties.
- Facilitation of communication between interested parties on issues relating to the facility or activity.

4.7. A specific role of the safety case in aiding decision making about treatment options is to ensure that suitable waste forms are produced. The safety case should provide an integrated consideration of safety for all waste management steps, and should address both the safety of operations at the individual facility and the interdependences with other waste management steps. The adequacy of waste forms produced should be judged on the basis of waste acceptance criteria for all subsequent waste management activities, in particular processing, storage, transport and eventual disposal of the waste. There are many aspects connected to

these decisions, some of which will be based on quantitative assessments while others will be more qualitative in nature. A more detailed discussion of relevant considerations and the implications for development of the safety case is provided in Section 6.

4.8. Development of the safety case should commence at the inception of the project and should be continued throughout all of the steps in the development and operation of the facility, through to its decommissioning. The safety case should also be used throughout all steps to guide the site selection, facility design, construction, operation of the facility and its decommissioning. It should be used to identify research and development needs, and to identify and establish limits, controls and conditions at the various steps, and as a basis for the process of regulatory decision making and approval.

4.9. The safety case may be developed in various ways and its content and structure will be greatly influenced by State specific legislative and regulatory requirements and local concerns. Although some States do not use the term ‘safety case’, the approaches and processes used to demonstrate safety are compatible with and, in essence, similar to the safety case concept.

4.10. In accordance with the requirements of Refs [2, 3], the development of a safety case is required to cover all the stages in the lifetime of the facility and, as such, is an iterative process that evolves with the development of the facility. The formality and level of technical detail of the safety case will depend on the stage of development of the project, the decision in hand and specific national requirements. This approach provides a basis for decision making relating to the development, site selection, design, construction, operation and decommissioning of the facility, and should allow the identification of issues that require further attention in order to improve the understanding of aspects influencing the safety of the facility or activity.

4.11. When developing the safety case, the needs of the key parties that will review, use and approve the safety case (e.g. government, the regulatory body and interested parties) should be identified and should be well understood; such needs will depend on the local and national situation. The preparation of the safety case, including the supporting safety assessment, is the responsibility of the facility operator, and it will need to be presented in a manner that meets the needs of the different interested parties. As far as possible, prior agreement should be achieved through communication with those parties, on what is to be included, assessed and calculated, as appropriate for each step of facility development and for the relative level of hazard associated with the facility or activity. For

example, the expectations of interested parties with regard to presentation and interpretation of the results of safety assessment may increase as licensing decision points are approached.

4.12. The early development and adoption of a strategy for safety is a key point in the development of the safety case. The safety strategy should comprise an overall management strategy for the various activities required in planning, operation and decommissioning of a waste management facility, including siting and design, development of the safety case, safety assessment, site characterization, waste form characterization, and research and development. More recommendations on developing a strategy for safety are provided in paras 4.27–4.32.

4.13. As outlined in para. 3.11, predisposal waste management facilities or activities can be developed in a step by step manner. The step by step approach adopted should enable:

- The systematic collection, analysis and interpretation of the necessary scientific and technical data;
- The evaluation of possible sites, radioactive waste management options, long term strategy and available technology;
- The development of plans for design and operation;
- Iterative studies for design and safety assessment with progressively improving data;
- The incorporation of comments from technical and regulatory reviews;
- Consultation with the public concerning specific decision points;
- Political involvement.

The exact process followed should be determined on the basis of the type of facility and national practices.

4.14. The step by step approach, together with the consideration of a range of options for the design and operation of a predisposal waste management facility, should be such as to provide flexibility for responding to new scientific or technical information and advances in waste management and materials technologies. It should also be carried out in a manner that enables social, economic and political aspects to be addressed.

4.15. In accordance with the requirements of Refs [2, 3], the safety case and supporting safety assessment are to be reviewed and updated periodically as necessary to reflect actual experience and increasing knowledge and

understanding (e.g. knowledge gained from scientific research), with account taken of any relevant operational experience feedback or other aspects that are relevant for safety. Following commencement of facility operation, revisions or updates to the safety case and supporting assessment have to be carried out when there are significant changes that may affect the safety of the facility or activity, e.g. changes to operational practices, waste forms and design. The regulatory body should consider the types and/or magnitude of changes and the time frames for which an update would be required. Typical periods range between five and ten years, with account taken of factors such as the availability of new information, significant design or operational modifications, improvements in knowledge and advances in assessment techniques.

4.16. In the site selection process, some assumptions will have to be made regarding the detailed characteristics of the site and the design of the facility and, therefore, the safety assessment will only provide preliminary estimates of how the facility will perform. This is acceptable because the role of the safety case at this stage is only to determine whether a site is, in principle, suitable for a predisposal waste management facility. In some situations, the site will have been selected for other facilities with which the waste management facility is collocated and, as such, the location and design should be compatible with the prevailing conditions. At later stages, more site specific data will be necessary and details of the proposed design will have been developed, which will allow operational issues to be addressed in more detail in the safety case. Throughout this process, the safety case prepared for individual stages of the process should provide sufficient depth of information and assessment to support the decisions required.

4.17. Principle 3 in Ref. [1] states that “Safety has to be assessed for all facilities and activities, consistent with a graded approach” (para. 3.15). This is further detailed by the following recognition in Principle 5 in Ref. [1]:

“The resources devoted to safety by the licensee, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the radiation risks and their amenability to control” (para. 3.24).

In accordance with this, Refs [2, 3] state that the extent and complexity of safety assessment are required to vary with facility type and to be related to the potential hazard. Furthermore, the level of detail of the safety assessment performed for each step of the development and operation of a facility will vary depending on the magnitude of the risks.

4.18. As a consequence of the iterative approach to the development of the safety case, the relative importance of the arguments that are included in the safety case, and the level of scrutiny that they are subjected to by the regulatory body and interested parties may vary over time. Further guidance on the application of the graded approach to the development of the safety case is provided in Section 6.

COMPONENTS OF THE SAFETY CASE

Context for the safety case

Purpose of the safety case

4.19. As stated in para. 4.10, the safety case will be developed as the project progresses and will be used as a basis for decision making, for both regulatory decisions and other decisions relating to, for example, the design, supporting research work or site characterization activities. The context for each revision of the safety case should be set out clearly and should be updated as necessary and appropriate for subsequent revisions of the safety case.

4.20. The purpose of each revision of the safety case will depend on a number of factors, such as the programmatic framework, the stage of development of the facility, and whether the safety case is being submitted to the regulatory body as part of a formal licensing procedure or to obtain directions from the regulatory body. For each revision of the safety case, the operator should provide a clear description of its purpose, which, depending on the stage of development of the facility, could include:

- Testing of initial ideas for safety concepts;
- Site or location selection;
- Demonstration of the safety of the facility or activity;
- Optimization of the facility design or activity arrangements;
- Evaluation of clearance and discharge activities;
- Determination and justification of the expected lifetime of the facility;
- Assessment of the maximum inventory of waste that can be accepted (the ‘radiological capacity’ of the facility);
- Definition or revision of limits, controls and conditions;
- Input to monitoring and data acquisition programmes;
- Periodic reassessment as required by law or regulation;
- Application to modify the facility or activity or to collocate new facilities;

- Shutdown and decommissioning of the facility, either at the planned end of the life of the facility or as a consequence of non-compliance with regulations;
- Determination of whether remedial action is necessary;
- Demonstration of compatibility with a disposal option.

The process of determining the purpose of the safety assessment is also addressed in the SADRWMS project and is included as Annex IV of this Safety Guide.

Scope of the safety case

4.21. The scope of the safety case should be clearly defined. It should identify whether the safety case considers an entire facility or a single activity within a larger facility. It should also consider site boundaries and interfaces with neighbouring activities and facilities.

4.22. In the case of step by step development of the facility, the scope of the safety case should provide a clear definition of the relevant stage in the facility's lifetime, how the safety case has changed from previous versions, and how it will support future revisions. For example, it should be explained how the safety case for the commissioning stage has progressed from the safety case for the construction stage, and how this will justify the operation of the facility once commissioning is complete.

Demonstration of safety

4.23. The approach to demonstration of safety refers to the safety objectives and safety principles that must be applied and the regulatory requirements that must be met. The safety objectives and safety principles may be established by the regulatory body. The regulatory framework that governs how the safety case is to be developed should be documented as part of the context for the safety case, and the safety case should be developed in a manner consistent with that framework. The safety criteria may vary in different countries and are required to be specified in the context for the safety case [2].

4.24. Safety requirements other than safety criteria, as well as other requirements relating to the safety case, should be specified in the context for the safety case (e.g. industrial safety criteria, environmental criteria, clearance criteria and criteria for release of the site from regulatory control).

4.25. The approach to demonstration of safety should also set out explicitly how the management of uncertainties will be addressed in the safety case. This should

cover, as a minimum, how uncertainties will be identified, how they will be characterized and what the approach will be to their management. Specific recommendations on the management of uncertainties are provided in Section 5.

Graded approach

4.26. A graded approach is required to be taken in determining the scope, extent and level of detail of the safety case and supporting safety assessment to be carried out [3]. The graded approach adopted should be explained and justified and should be such that the scope, extent and level of detail of the safety case and supporting safety assessment are commensurate with the hazards, the complexity of the facility or activity and the characteristics of the waste to be managed. The safety case should provide a justification for the extent and depth of the safety arguments and supporting safety assessment. For example, in the case of a step by step approach, the safety assessment for generic storage concepts being considered prior to site selection might be conducted in less detail than the safety assessment for facility commissioning. Factors relevant to the graded approach for a safety assessment are given in Ref. [3]. Section 6 provides further recommendations on the application of a graded approach to safety assessment for predisposal waste management facilities and activities.

Strategy for safety

4.27. The strategy for safety refers to the approach that will be taken in site selection, facility location, and facility design and operation to comply with the safety objectives, principles and criteria, to comply with regulatory requirements and to ensure that good engineering practice has been adopted and that safety and protection are optimized. The strategy should be established at the early stage of conceptualization of the facility. At later stages, the strategy may develop and mature, but should be defined at as early a stage as possible, so that by the time the site and the location of the facility are selected, the design concept to implement the strategy will be sufficiently well developed to provide assurance that the facility or activity will provide the requisite safety functions. As the project develops, the strategy for safety should be continually validated and any changes should be justified in the safety case. Any evolution of the strategy for safety should be carefully recorded and the records should be preserved for use in the future.

4.28. The strategy for safety should address a number of key elements, namely the provision of multiple safety functions and defence in depth, shielding and confinement, and the selection of appropriate approaches to waste processing. It

should address how the amount of waste generated is to be minimized, how waste management will be optimized with regard to reuse, recycling and clearance of materials and discharge of effluents, and how interdependences with other steps in the predisposal management and with the disposal of the waste will be taken into account. It should also address the approach that will be taken to management of uncertainties, with a view to ensuring that the approach to demonstration of safety set down in paras 4.23–4.25 will be respected.

4.29. Consideration should be given to the interdependences between waste generating processes and subsequent waste management processes. Such consideration should also address the possibility of different regulatory bodies having responsibilities for these different activities.

4.30. Reference [3] requires that defence in depth be provided such that safety does not depend unduly on any single layer of protections or any single physical barrier and to ensure that if one barrier does not perform as intended, there are further barriers to compensate for it. For example, if the integrity of waste packaging would be compromised under certain accident conditions, the facility building itself is assigned a confinement function. The strategy for safety should identify the intended safety functions and the time frames over which they will be available. It should also demonstrate how degraded performance of one barrier would be compensated for by another mechanism or component, or should demonstrate that those risks associated with degraded performance will meet appropriate regulatory limits. The strategy for safety should also address how the adequacy of the various safety functions will be demonstrated (e.g. by assessment, analogy and testing). The strategy should indicate how an adequate level of defence in depth will be provided. The adequacy of the defence in depth may be expressed in quantitative and qualitative terms.

4.31. The approach that will be taken to demonstrate compatibility of the processed waste with the acceptance criteria of disposal facilities should be included in the strategy for safety.

4.32. In addition, the strategy for safety should set out the following:

- The degree of caution that will be exercised when making decisions;
- The rationale for selecting the assessment methodology and time frame and time windows for assessment, including a discussion of the various approaches to assessment and tools that will be used to verify, confirm and compare assessment findings;
- How peer reviews will be conducted;

- How consistency with international guidance and practices will be demonstrated;
- Other high level arguments as appropriate.

Description of the facility or activity and the waste

4.33. The description of the waste management facility or activity should record all the information and knowledge about the facility and the activities to be carried out, and should provide the basis on which all safety assessments are carried out. Information will be obtained and knowledge about the facility and activities should evolve and mature as the project progresses and assessment is carried out in an iterative manner. As knowledge is developed, it should be used to determine future needs for information about the design of the facility and the activities to be undertaken. The description should contain, depending on the type of facility, information on the aspects outlined below.

Site conditions

4.34. Site conditions and the associated events, both natural and human induced, that could influence safety, and thus could impose demands on the facility or activities and the facility's equipment and components, should be identified and described. The site characteristics form part of the input to the design and may refer to the range of conditions under which the facility is operated or the activity performed, such as meteorological conditions, or to the hazards to which the facility might be exposed, such as seismic hazards. Therefore, all site conditions, processes and events having relevance in this regard should be identified and considered in accordance with a graded approach. The normal or average situation should be determined and any more extreme but credible events that need to be considered should be identified.

System description (description of the facilities and activities and of the waste)

4.35. The safety of a predisposal waste management facility, as other engineered systems, depends in part on robust and proven design and construction. The most important design features are those that provide the necessary assurances that the radioactive waste can be handled (processed, stored, retrieved, etc.) without undue risk to workers, the public or the environment.

4.36. Therefore, the facility design and the fundamental assumptions upon which the design is based should be addressed in depth in the safety case. The safety case should include: a full description of the structures, systems and components

of the facility and their importance for safety; the quantity and characteristics of the waste to be handled at the facility; the range of conditions under which the facility may operate; the hazards to which the facility may be exposed; and the required performance criteria.

4.37. The fundamental design requirements that have been applied and how the resulting design reflects these requirements should also be considered in the safety case. Typically, the fundamental design requirements will address such considerations as the need to ensure an adequate degree of redundancy, diversity, reliability and tolerance of faults, and the need to ensure that any failures that might occur are limited in scope and, to the extent possible, limited in consequence. For spent fuel, verification of subcriticality and heat removal should be addressed. The design must also implement the concept of defence in depth [1].

4.38. As appropriate, the design should be examined in the light of safety requirements to determine whether the design, in conjunction with operation at the facility, incorporates adequate measures to prevent accidents and to limit the consequences of an accident if one were to occur. For example, for facilities or activities that handle fissile material, issues associated with criticality should be adequately addressed in the design.

4.39. The flexibility of the design to accommodate changes in operating conditions, technology used and plans for decommissioning should be examined.

4.40. If national and/or international systems for accounting and control of nuclear material [24] are applicable to the facility or activity, any provisions that are put in place for this purpose should be assessed from a safety point of view and any conflicts (such as access restrictions to areas or material) should be resolved.

4.41. In addition to issues relating to the design and construction, the safety of a facility or activity also depends on operational aspects such as operating and maintenance procedures, controls and monitoring. The organizational structure and staffing of the operator, particularly those aspects of safety culture, required personnel competencies, safety measures and the quality of training, have often been linked to the frequency of human induced events.

4.42. Although operational aspects of the facility or activity are difficult to quantify, their consideration forms an important part of the safety case. Their importance to the overall safety of a facility or activity requires that they be given

appropriate consideration in the safety assessment and within the broader context of the safety case for the facility or activity. In the context of addressing operational aspects, emergency planning and security measures should also be addressed.

4.43. For each safety related operational issue, the safety case should provide an explanation of how the operator intends to address the particular issue (both in terms of preventing accidents and responding to them if they arise) with policies, procedures, controls and monitoring. The explanation should demonstrate the adequacy of the response from the operator to the underlying safety concern.

Waste

4.44. Data on the type of radioactive waste to be processed (i.e. pretreated, treated and conditioned) or stored, as well as on material that is to be cleared or discharged at the facility or within the activity, should be collected with respect to the volume and form of the waste, the radionuclides of concern, the radioactive content, the presence of fissile materials, and other physical, chemical and pathogenic properties. Secondary waste streams that may arise from waste processing should be included.

4.45. Account should be taken of any non-radioactive hazardous constituents that may be present in the waste or introduced as process chemicals or by other means. These may be covered by other legislation, but the potential for any interaction with or influences on treatment of the waste should be considered.

4.46. Variations in the expected characteristics of input materials (feedstock, source materials, receipts, etc.) should be considered, particularly with respect to their influence on the potential for anticipated operational occurrences and design basis accidents at the facility.

Safety assessment

General

4.47. The term ‘safety assessment’ is used in this Safety Guide to refer to all assessments performed as part of the safety case (see Fig. 3). This encompasses all aspects that are relevant for the safety of the facility. Thus, the safety assessment also addresses qualitative aspects, such as good engineering practice, and the management of non-radiological issues, such as conventional safety.

4.48. The term ‘safety assessment’ is used differently in two respects:

- (a) ‘Safety assessment’ was defined in earlier publications (e.g. Ref. [26]) as the overall process of performing quantitative assessments of radiological safety. This included the development of the context for the assessment and the description of the facility and its environment, as well as the interpretation of the results. However, in terms of the broader context for the safety case, as illustrated in Fig. 1, these elements are considered part of the overall safety case and are not only part of the quantitative safety assessment. Addressing these elements in a broader context, as in this Safety Guide, therefore, does not represent a change in the actual methodology for the performance of quantitative assessments (as discussed for disposal facilities in Ref. [26]); the approaches developed in those publications are now integrated into the broader context of the safety case.
- (b) ‘Safety assessment’ in this Safety Guide relates to aspects relevant for safety beyond the quantitative assessment of radiation risks. This broadening of the term ‘safety assessment’ is a logical consequence of the adoption of the broader concept for the safety case as a basis for this Safety Guide.

4.49. The following sections provide an overview of the key elements of the safety assessment as shown in Fig. 3.

Radiological impact assessment

4.50. Assessment of radiological impacts forms the core of the safety case for a predisposal waste management facility or activity. In addition to qualitative assessments, this involves a comprehensive quantitative analysis of possible challenges to the safety functions and the resulting potential radiological impacts. In this approach, scenarios are used to describe possible conditions or events at the facility or during the activity and the resulting radiation risks are quantitatively analysed by means of conceptual and mathematical models. A detailed description of this approach is provided in Section 5.

Site and engineering aspects

4.51. Quantitative assessment of potential radiological impacts should result in conclusions on the adequacy of the chosen or proposed site, as well as on the intended design of the predisposal waste management facility or activity. The conclusions drawn from quantitative assessment should be supplemented by qualitative arguments and assessments. The integrated set of qualitative and

quantitative assessment results should be sufficient to demonstrate the adequacy of the site and engineering aspects, compliance of the site and engineering aspects with the relevant safety requirements set out in Section 3 and that the safety strategy set out for the facility is fulfilled.

Engineering analysis

4.52. The engineering analysis should identify where changes to the design could eliminate a hazard or reduce the frequency of occurrence or consequences of an event. The value of making the changes identified should be evaluated using the principle of optimization of protection.

4.53. The safety assessment should be used to identify the safety functions and associated structures, systems and components that are relied on for preventing accidents and for mitigating the consequences of initiating events. This should be done by applying appropriate engineering codes and standards, commensurate with the importance of the safety functions (e.g. the consequences of their failure to perform).

4.54. The safety assessment should be used to determine whether the existing structures, systems and components are suitable and sufficient to perform their functions during normal operation, anticipated operational occurrences and accident conditions, and whether they will achieve the required control of doses and risks. The safety assessment should also be used to verify that existing structures, systems and components will continue to perform their safety functions for as long as is required by the stage in the lifetime of the facility, with account taken of ageing, other degradation mechanisms and invasive maintenance activities (e.g. demolition of supporting walls or creation of dusty environmental conditions).

4.55. The safety assessment should be used to identify any safety functions that require new engineered structures, systems and components, and should verify that these will be suitable and sufficient to meet relevant safety requirements and criteria. The safety assessment should also be used to identify any ongoing engineering requirements that need to be applied during operation (e.g. requirements relating to inspection, maintenance and testing of structures, systems and components) and services that need to be maintained, including those at other related facilities.

Passive safety

4.56. The operator should demonstrate that passive safety features are applied both to the extent possible and as soon as possible; for example, when long storage periods are involved. This is, according to Ref. [2], of particular relevance for the storage of waste. This topic is discussed in more detail in Section 6.

Defence in depth

4.57. The term ‘defence in depth’ means the hierarchical deployment of diverse equipment and procedures in order to maintain the effectiveness of physical barriers placed between radioactive material and workers, the public or the environment, in normal operation, anticipated operational occurrences and, for some barriers, in accident conditions at the facility. According to Ref. [3], an assessment of defence in depth is required, which should comprise an evaluation of the levels of defence provided by the facility or activity.

4.58. Application of the concept of defence in depth to predisposal waste management facilities or activities requires the operator to demonstrate that several safety functions have been taken into account in the design of the facility. Application of this concept should ensure that safety is not unduly dependent on a single component or control procedure, or on the fulfilment of a single safety function. This topic is discussed further in Section 6.

Scientific and engineering principles

4.59. Elements of good scientific practice include, among other things, making observations, developing and testing hypotheses, assessing reproducibility and peer review. The application of good scientific principles in the development of a safety case can be illustrated by considering, for example, work aimed at understanding the effectiveness of a proposed activity processing chemical waste. Such work might involve taking waste measurements, putting forward hypotheses as to the effect of additives on the physical and chemical behaviour of the waste, testing these hypotheses with models using the data collected, using more than one approach or team in the modelling work to examine alternative conceptual models and reproducibility, and subjecting the work to independent peer review (see paras 4.97–4.99).

4.60. Good technical and engineering principles should be applied in order to avoid complex or insufficiently characterized situations, and procedures should be put in place to ensure application of these principles and to address

unanticipated conditions. The safety case should address how the principles of good engineering practice have been applied, and the operator should demonstrate in the safety case that the materials, equipment and processes foreseen for the facility or activity are well understood and that knowledge gained from similar applications confirms that these materials, equipment and processes are well suited for the intended use. Wherever possible, the operator should use well established techniques and should give due consideration to feedback from experience gained in the use of these techniques.

Quality of the site characterization

4.61. The safety case should contain a clear description of the approach and criteria used in site selection and should demonstrate that the site selected is in accordance with the strategy for safety and any criteria that have been established. The safety case should integrate knowledge of the site and its surroundings and its proximity to other facilities or population centres, and modelling should be employed to help understand the possible behaviour of the facility or activity.

4.62. Confidence in the results of the assessment will be enhanced when the site characterization and safety assessment programmes are of high quality; site data collected by the operator are consistent with other existing data in terms of parameter values and the measurement methodology applied; the safety assessment models developed are consistent with the properties of the site and the conceptual understanding of the site based on scientific principles; and the conceptual understanding of the site and the safety assessment models continue to be compatible with and appropriate for any new information about the site that may become available, subject to only minor refinement.

Operational safety aspects

4.63. The assessment of non-radiological operational safety lies outside the scope of this Safety Guide; however, there will be interactions and possible synergies with the assessment of operational safety (e.g. fires, explosions or the presence of toxic material). How requirements relating to non-radiological risks should be applied will depend on the type of facility, the legal and regulatory framework and the stage of facility development. Since the origin of radiation risks and non-radiological risks may be the same, an integrated assessment of such risks and the necessary countermeasures may be beneficial.

Non-radiological environmental impact

4.64. The assessment of non-radiological impacts arising from the predisposal waste management facility or activity (e.g. transport of material to and from the site, effluent releases and noise) will be required and governed by environmental protection legislation, its associated regulations and transport related regulations. This lies outside the scope of this Safety Guide. Nevertheless, the approaches to assessment described in this Safety Guide may also be of use in the assessment of hazards posed by non-radioactive waste components and in optimization of protection and safety against all potential hazards.

4.65. Environmental protection legislation and its associated regulations will result in several requirements on the construction, operation and decommissioning of a predisposal waste management facility or on the implementation of a waste management activity. Examples are restrictions in terms of traffic or noise pollution, which may limit the construction and operation of the facility. Other examples are limits, controls and conditions required for the water management at the facility in construction. Such requirements arising from environmental protection legislation should be adequately considered in the facility design. Thus, the integration of safety arguments (see Fig. 3) should also take into account non-radiological impacts and should demonstrate the overall safety of the facility or activity and its overall compliance with all relevant legislative and regulatory requirements.

Management system

4.66. Requirement 7 of Ref. [2] states that “Management systems shall be applied for all steps and elements of the predisposal management of radioactive waste.” General requirements for the management system are established in Ref. [19], and recommendations on how to meet these requirements are provided in Ref. [27]. Application of a suitable management system will contribute to confidence in the safety case and an assessment should be carried out as to the adequacy of the management system governing all safety related work.

4.67. The requirements on the management system influence the development of the safety case in two ways. First, the description of the management system that applies to the various stages of facility development should represent an important element of the safety case, contributing to the confidence that the relevant requirements and criteria for site selection, design, construction, operation and decommissioning safety are met. Second, programmes should be set up to ensure the quality of all activities associated with the safety case and

safety assessment, such as data collection and modelling. This aspect is discussed in paras 4.100–4.105.

Management of uncertainties

4.68. The importance of addressing uncertainties in safety assessment is reflected in Ref. [3], which states that “Uncertainties in the safety analysis have to be characterized with respect to their source, nature and degree, using quantitative methods, professional judgement or both.” Reference [3] further requires that “Uncertainties that may have implications for the outcome of the safety analysis and for decisions made on that basis are to be addressed in uncertainty and sensitivity analyses.” Approaches to the management of uncertainties are discussed in Section 5.

Iteration and design optimization

4.69. The process of making decisions on design options is multifaceted in that several varied and sometimes competing factors have to be brought together and reconciled to reach a decision. The decision making process will be iterative in most practical cases. The amount of iteration will depend on the stage of development of the facility and the nature of the decision to be made as well as on the availability of data and models.

4.70. Early iteration in the decision making process should be undertaken with the available data and capability for conducting assessment. The iteration needs to proceed only until the assessment is judged to be adequate for its purpose. Furthermore, additional knowledge needs to be acquired only to the extent necessary to improve the basis on which the decisions will be made. Iterations may only affect one specific aspect of the safety case (e.g. the improvement of the data requirements for a specific model). More extensive iterations may involve revisions of all components of the safety case, such as:

- The context for the safety case may be adjusted to, for example, treat uncertainties more realistically or to broaden the range of receptors (see para. 5.19) considered.
- The strategy for safety may be improved and refined.
- New data about the site may become available and/or the design may have been developed further.

Triggered by such changes or by other factors (e.g. the results of peer reviews), the components of the safety case and supporting safety assessment may be revised and developed further.

4.71. The optimization of protection for a predisposal waste management facility or activity is a judgemental process that is applied to the decisions made in the development of the facility design. Good engineering and technical solutions should be adopted and the principles of quality management should be applied throughout the development, operation and decommissioning of the facility.

4.72. For some decisions on the optimization of protection and safety, a qualitative approach based on expert judgement and on the utilization of the best available and proven technology may be sufficient. The more complex an issue is and the more interconnections it has with other aspects of the facility, the more stringent the application of the requirements on optimization of protection to demonstrate optimization of protection. In order to demonstrate that protection can be considered optimized, the following important arguments should be shown to be valid:

- Due attention has been paid to the safety implications of various design options at each stage in the development, construction and operation of the facility;
- The likelihood of events that might disturb the performance of the facility or activity so as to give rise to higher doses or risks has been reduced as far as is reasonably possible by siting or design.

4.73. It should be demonstrated that the selected design option has been chosen by a well defined, rational procedure. Confidence in the selected design option may be increased if alternative design options are presented in the safety case with an assessment of their advantages and disadvantages, and a justification is provided for the preferred option. Consideration of alternatives is a regulatory requirement in some States (e.g. Ref. [29]).

4.74. Substantially different options for a project are generally considered at the project design stage. However, the possibility of adopting alternative means to carry out a project should be kept open at each stage of the decision making process. The safety case should describe the process used to select the most appropriate options on the basis of a set of predetermined criteria or considerations. The criteria used for the comparison of alternatives should include, in addition to safety criteria, environmental and socioeconomic factors (e.g. costs, public acceptance of certain options).