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
International Atomic Energy Agency

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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

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

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

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.

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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

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

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

Safety Fundamentals

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

Safety Requirements

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

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

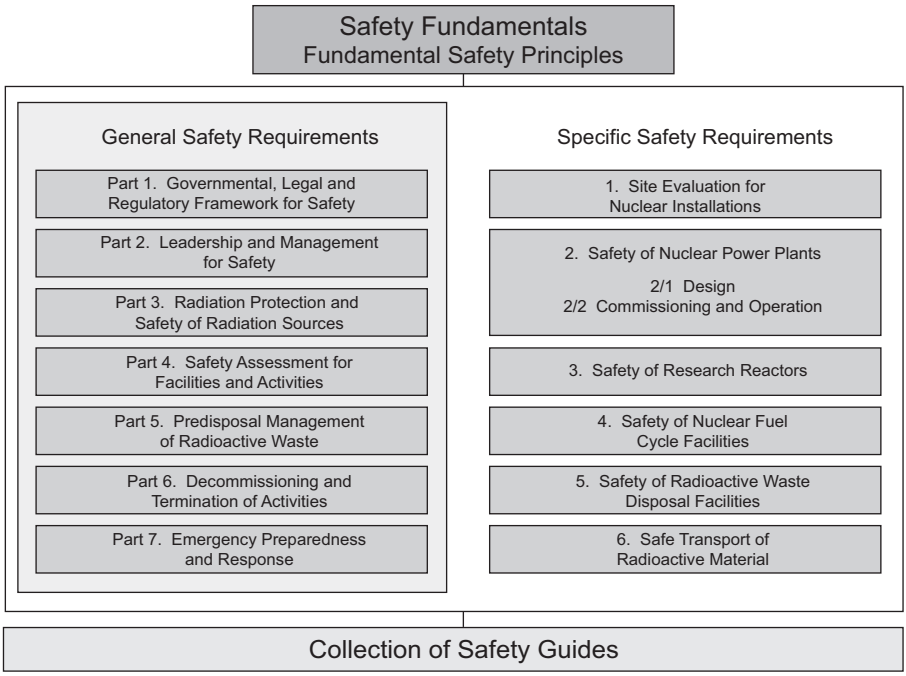

FIG. 1. The long term structure of the IAEA Safety Standards Series.

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).

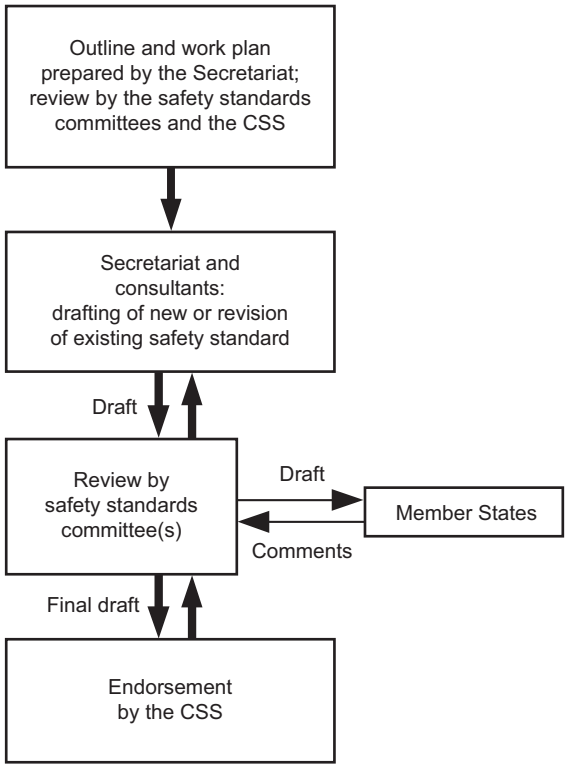

FIG. 2. The process for developing a new safety standard or revising an existing stand-

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.

CONTENTS

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 case[1], together with the necessary supporting safety assessment, be developed and undertaken for each facility[2] 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 activity[3], 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.

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[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 Facilities[4].

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.

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[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 Management[5] [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.

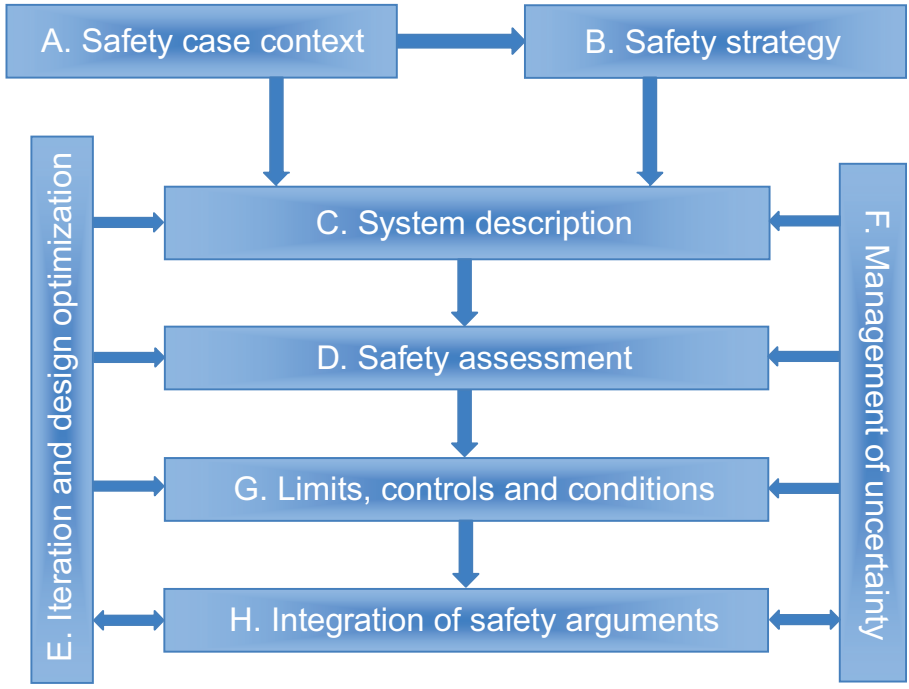

FIG. 1. Components of the safety case.

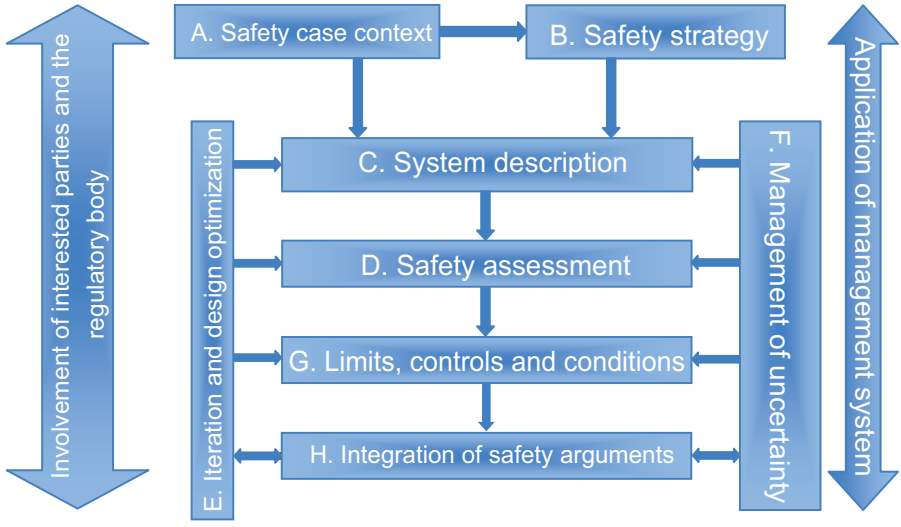

FIG. 2. Application of the management system and the process for interaction with the regulatory body and interested parties.

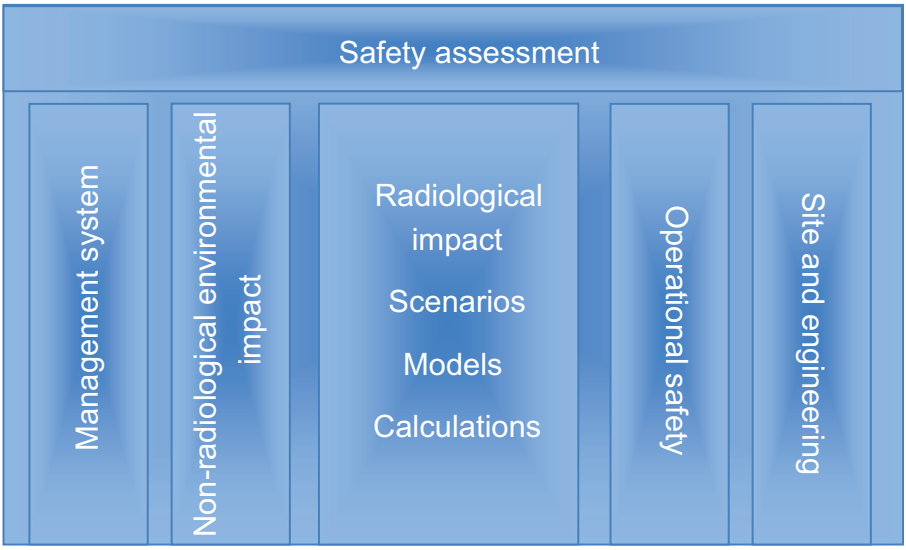

FIG. 3. Aspects included in safety assessment.

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).

4.75. Examination of alternative means of carrying out a project involves answering the following three questions:

(a) What are the alternatives?
(b) What are the impacts, in particular the advantages and disadvantages, associated with each alternative?
(c) What is the rationale for selecting the preferred alternative?

4.76. Alternatives should be identified and described in sufficient detail to provide clear answers to these questions. For example, if alternative design options are being considered, then each alternative option should be described and the potential radiological effects, costs and benefits of each alternative should be determined. The criteria and analysis of the different options should then be fully documented to support the proposed design. Further recommendations on decision making and appraisal of alternative options are provided in Section 6. Records should be made of the design evolution and the basis for design related decisions, and these records should be maintained throughout the evolution of the safety case.

Identification of safety measures

4.77. The results of safety assessment should serve to demonstrate compliance with the regulatory requirements and criteria expressed in terms of effective dose (e.g. individual annual effective doses for normal operation, individual effective doses for single incidents, including accidents) or in terms of risk. To achieve this, the results of safety assessment should be expressed in the same units as the associated safety criteria.

4.78. Sensitivity analyses should be performed in order to identify and assess the parameters and values with the greatest impact on the assessment results. If the results of safety assessment are particularly sensitive to an input parameter or assumption, the operator should direct efforts towards reducing the uncertainties and repeating that part of the safety assessment.

4.79. The safety case should demonstrate that there are adequate safety measures in place to meet the safety criteria, commensurate with the likelihood of occurrence of each event and the associated radiological consequences. Such measures may include:

— Engineered measures: Technical or physical measures in place during operation, such as the provision of shielding.

— Procedural measures: In the event that engineered measures cannot fully eliminate a hazard, administrative measures may have to be used, such as restriction of access to areas with high levels of radiation.

Further aspects of the use of the safety assessment for addressing the adequacy of the facility design and safety provisions are described in Section 6.

Limits, controls and conditions

4.80. The safety case should be used to assist in the establishment of licence conditions and other controls and requirements on the facility or activity.

4.81. The specifications within which the facility can operate safely or the activity can be carried out safely should be identified, and limits and operational restrictions should be derived from this envelope. Examples include site specific or process specific limits on the types, activities and quantities of waste that may be accepted or processed in order to ensure operational safety and, in the case of long term storage of waste, long term safety.

4.82. Specifications for safe operation should also be used as an input to the development of operational programmes and procedures, including maintenance, inspection and testing requirements. A formal mechanism should be established to link these various operational programmes and procedures to the safety assessment and a process should be put in place to track the actions necessary to give effect to this linkage.

4.83. Limits and conditions of particular importance for a facility or activity are the acceptable waste inventory and/or the concentration levels for specific radionuclides in the waste. These should be defined on the basis of the results of the safety assessment.

4.84. Waste acceptance criteria for the facility may be established both for individual waste packages and for the facility as a whole. Acceptable inventory levels are usually dependent on the assessment of various scenarios, as well as on criteria associated with discharge, clearance and predisposal waste management activities. In addition, the safety case should be used to assess the properties and levels of substances (e.g. chemicals) in the facility that may cause degradation of key safety features.

Integration of safety arguments

4.85. The safety case should provide a synthesis of the available evidence, arguments and analyses. The synthesis should explain how relevant data and information have been considered, how models have been tested, and how a rational and systematic assessment procedure has been followed. The safety case should also acknowledge any limitations of currently available evidence, arguments and analyses, and should highlight the principal grounds on which a judgement has been made that the planning and development of the facility or activity should nevertheless be continued. The safety case should include the approach by which any open questions and uncertainties with the potential to undermine safety will be addressed and managed. If the evidence, arguments and analyses do not provide sufficient confidence to support a positive decision, then the safety case or the facility design may need to be revised.

4.86. In general, the safety case for each stage of planning and development of the facility will include all of the different lines of evidence, arguments and analyses that are available to support the assessment of the quality and performance of the facility. Findings that are in contradiction to arguments made in the safety case and uncertainties should also be discussed and analysed. This necessitates a detailed discussion of the following:

— The treatment of uncertainties in the safety case and supporting assessment;
— The quality and reliability of the science and the design work that form the basis for the safety case;
— The quality and reliability of the safety assessment, including the development of scenarios, the adequacy of the range of scenarios considered, assessments of their likelihood, and the adequacy of the methods, models, computer codes and databases used;
— Management system requirements on the performance of safety assessment calculations to provide assurance of their quality.

4.87. The emphasis placed on different lines of argument when presenting the safety case can vary, however, depending on:

— The concerns and requirements of the intended audience;
— The timescale for which safety is to be demonstrated, and the variation of the hazard with time;
— The stage of project development;
— The possible evolution of the facility or activity;

— The associated uncertainties and their implications for the safety of the facility.

4.88. One important use of quantitative assessment results is for comparison with safety criteria, in particular with dose and risk limits or constraints. In addition, complementary safety and performance indicators can be used for the evaluation and appraisal of the results of calculations. Quantitative analysis should be complemented by other lines of reasoning that also consider semi-quantitative and qualitative arguments.

Comparison with safety criteria

4.89. A clear distinction needs to be made between objectives and criteria for safety and the indicators used to demonstrate that these criteria are met and the objectives are fulfilled. While objectives for safety are expressed in general terms (international agreements exist as to these objectives), criteria for safety (established in national regulations) relating to specific indicators (e.g. dose or risk indicators) are often expressed as targets, constraints or limits. Such indicators may differ from State to State.

4.90. If several facilities or activities exist or are planned at the same site, the impact of all of the facilities and activities should be taken into account in establishing which criteria to consider according to the scope of the assessment and when comparing the results of the safety assessment with these criteria. This may not be straightforward if a mixture of existing and new facilities or activities is present at a site, or if different predisposal waste management facilities exist or different types of activity take place at the site. In such situations, consultation between the operator and the regulatory body will usually be required in order to define the criteria to be used in the safety assessment.

4.91. One of the aims of safety assessment is to compare the end points for the safety assessment with the safety criteria. However, an indication that calculated doses or risks are less than a particular dose or risk constraint is not in itself sufficient for the acceptability of the safety case for a predisposal waste management facility, since other requirements have to be fulfilled, such as the provision of multiple safety functions and the optimization of protection.

Plans for addressing unresolved issues

4.92. The safety case for a predisposal waste management facility or activity is required to be developed and progressively updated throughout the lifetime of the

facility or activity [2]. Confidence in the safety case at any stage will be enhanced if each revision of the safety case includes a plan for further work as necessary to address remaining issues and/or, where possible, to reduce significant remaining uncertainties or to reduce their relevance or avoid them entirely by, for example, changes in the design of system components.

4.93. At the earliest stages of development of a facility, there may be many open questions and uncertainties, and the safety case should include clear plans for dealing with these at future stages (e.g. by site characterization or by optimization of system design), and should set out the strategy by which these plans will be achieved. This strategy should group unresolved issues in terms of their significance, with unresolved issues of high importance to safety being given the highest priority for resolution. The operator and the regulatory body should make a judgement as to whether development of the facility should be halted until key safety issues are resolved. In the later stages and certainly by the time the safety case is presented as part of a licence application, uncertainties and open questions with the potential to undermine safety should have been addressed in a manner appropriate for the decision at hand. The manner in which this has been done should be reflected in the safety case.

INTERACTING PROCESSES

4.94. As indicated in Fig. 3, there are a number of external processes that interact with the development of the safety case to ensure its quality and adequacy. The most important of these is the regulatory process through which standards to be complied with are established and regulatory guidance to meet the standards is provided. It should also involve a process of structured interaction and communication to ensure that all of the expectations of the regulatory body for the safety case have been met and that issues needing resolution are identified and managed. Section 8 provides guidance on how the regulatory review process should be structured and implemented to provide additional confidence in the safety case.

4.95. These interacting processes should also encompass the involvement of independent experts and interested parties. In addition, the development of the safety case should be carried out with a comprehensive management system that ensures the quality of the safety case and its documentation.

Involvement of interested parties

4.96. Early involvement of interested parties should be part of the process of building confidence in the safety of the facility. A range of different models for involvement of interested parties has been applied in different States, and extensive research has been conducted on the methods of engaging interested parties in both national and international research programmes. A key consideration is that interested party involvement should take place within an open and transparent framework for consultation, with clearly defined rules of procedure. The process for involvement of interested parties should be set out in the safety case.

Independent review

4.97. Independent peer review should play an important role in building confidence in the safety case. Peer review should entail a formally documented examination of a technical programme or specific aspect of work by a suitably qualified expert or group of experts who have not been directly involved in the development of the safety case and have no direct interest (e.g. financial or political) in the outcome of the work.

4.98. Independent peer review should be an active and ongoing part of the work leading to development of the safety case, and should begin at an early stage in the project. Peer reviews should be fully documented, including the scope and terms of reference for the review, the basis for selection of reviewers, the findings of the peer review, responses of the operator to comments made by reviewers and reviewers' evaluations of the responses.

4.99. In certain circumstances, international peer review teams should be established to focus on one or more specific topics or to evaluate an entire safety case and/or supporting safety assessment.

Management system

4.100. The regulatory body and the operator are required to put in place appropriate management systems to ensure the quality of all safety related work [19]. The following aspects should be taken into account in developing an appropriate management system, which should be designed to provide an adequate basis for the development and review of the safety case:

— The need for well defined, consistent and transparent criteria according to which the safety case is evaluated and decisions are made;

— The need for internal and external audits, as appropriate, to determine the adequacy of the management system and its implementation;
— The need to document and enhance the qualifications, competence and credibility of assessors and reviewers, for example, through the provision of training programmes and participation in international projects;
— The need for transparency and public involvement in the processes for development and review of the safety case;
— The need to ensure consideration of international perspectives (e.g. recommendations, safety objectives, safety assessment methodologies, time frames and disposal concepts);
— The need to develop and maintain the competence and knowledge of the operator and the regulatory body over the entire time frame of the project.

4.101. Development of the safety case and supporting safety assessment should be conducted within a management system that can ensure an adequate level of quality. The management system should involve a planned and systematic set of procedures for carrying out and documenting the various steps in the process for providing confidence that the input data, models and results are of good quality. The need to build confidence in the results of safety assessment necessitates the application of programmes to ensure the quality of the various elements of the assessment from the earliest stage of development of the facility.

4.102. Confidence in the safety case will be reduced if it is perceived not to have addressed relevant issues. Completeness is one of the first things that the regulatory body is likely to consider in its review of the safety case (see Section 8). Other interested parties may also wish to verify that issues important to them have been addressed. It is, therefore, advisable to use various methods to demonstrate that the safety case addresses all relevant issues, including the relevant uncertainties. The range of issues to be addressed will depend on the stage of development of the facility and may derive from several sources, including legislation, regulations and concerns of interested parties. Methods for demonstrating completeness may, therefore, include structured cross-references or mappings that provide a link from these sources to the safety case.

4.103. Traceability requires a clear and complete record of the decisions and assumptions made, and of the models, parameters and data used in arriving at a given set of results. Traceability also encompasses the possibility to trace back to the origin of data and other information used in the safety case. Thus, a coherent referencing system supporting the safety case should be established. The records should include structured information on when, on what basis and by whom various decisions and assumptions were made, how these decisions and

assumptions were implemented, what versions of modelling tools were used, and what the ultimate sources are for the data.

4.104. Transparency requires openness, communication and accountability. This implies that the safety case and safety assessment should be documented in a clear, open and unbiased way that, for example, recognizes both the features of the facility that provide safety benefits and the uncertainties. The aim should be to provide a clear picture of what has been done in the assessment, what the results and uncertainties are, why the results are what they are, and what the key issues are, that can be used to inform decision makers. To increase transparency, the documentation of the safety case should be made available to the public and should be prepared in a manner and at a level of detail that is suitable for the intended audience.

4.105. Further recommendations on the documentation of the safety case are provided in Section 7.

5. SAFETY ASSESSMENT

INTRODUCTION

5.1. Safety assessment is the systematic process of evaluating the safety of a predisposal waste management facility or activity and quantifying its potential impact on human health and the environment. Safety assessment should be performed in a systematic manner using a graded approach, commensurate with the hazards, the complexity of the facility or activity and the characteristics of the waste.

5.2. Safety assessment includes both the quantification of the overall level of safety of the facility or activity and the analysis of the associated uncertainties. The methodology used for the safety assessment should be systematic and the assessment should adequately address all of the aspects relevant to protection and safety.

5.3. The safety assessment will not necessarily be performed at the same level of detail at all stages in the lifetime of the facility or activity (e.g. there may be a lack of design information at the site selection stage). The safety assessment should be

updated at appropriate intervals (e.g. at least before the beginning of each stage, or as required by the regulatory body), with account taken of new information, such as feedback from operating experience.

OVERALL APPROACH

5.4. The recommended approach to safety assessment includes the following key components:

- Specification of the context for the assessment;
- Description of the predisposal waste management facility or activity and the waste;
- Development and justification of scenarios;
- Formulation of models and identification of data needs;
- Performance of calculations and evaluation of results;
- Analysis of safety measures and engineering aspects, and comparison with safety criteria;
- Independent verification of the results;
- Review and modification of the assessment, if necessary (i.e. iteration).

5.5. Some of these components (context for the assessment, description of the facility or activity, evaluation of results) overlap with the respective components of the safety case described in Section 4. This is a natural consequence of considering the safety assessment as one aspect of the broader safety case. The respective discussions in this section relate specifically to the quantitative assessment and supplement the more general presentation of these components in Section 4.

ASSESSMENT CONTEXT

5.6. The context for the assessment involves the following key aspects: the purpose of the assessment, the philosophy underlying the assessment, the regulatory framework, the assessment end points and the time frame for the assessment. In addition to the general aspects discussed in Section 4, the following guidance is relevant for quantitative assessments of the radiological safety of the facility or activity.

Philosophy underlying the assessment

5.7. The philosophy underlying the assessment, i.e. the choice of approach taken in conducting the assessment, has already been discussed in general terms in Section 4. With regard to quantitative assessment, some specific aspects are relevant.

Use of different approaches to assessment

5.8. The safety assessment should be performed using an appropriate selection of approaches that, when used in a complementary manner, can increase confidence in the safety of the facility or activity. The different approaches that can be considered include: reasoned arguments, the use of simple conservative models, probabilistic and deterministic approaches, and the use of more complex and more realistic models.

Probabilistic and deterministic approaches

5.9. Reference [3] establishes requirements on the use of probabilistic and deterministic approaches. Complex or hazardous facilities are required to meet these requirements, but simple facilities may only need qualitative analysis, in accordance with a graded approach. A combination of probabilistic and deterministic approaches in the safety assessment may contribute to increased confidence in the outcomes of the assessment. It is, however, important to be aware of the benefits and limitations associated with these two approaches.

5.10. A deterministic approach is easier to implement and might be more easily explained to a range of audiences. Limitations of the deterministic approach include the inability to directly take probabilities and variability into account, and the difficulty in justifying the choice of best estimate or conservative values for the parameters.

5.11. A strength of the probabilistic approach lies in its ability to provide a more comprehensive and explicit representation of the facility or activity under consideration and of the remaining uncertainties. Such approaches also provide for more thorough and systematic sensitivity analyses, and can be used to derive risk estimates. Challenges associated with a probabilistic approach include difficulties in obtaining or specifying appropriate probability distributions for the parameters, the possibility that the statistical sampling method applied may result in a choice of parameter combinations outside the range of validity of the

sampling method, the difficulty in communicating probabilistic assumptions and results, and the additional resources necessary.

Conservative assessments and realistic assessments

5.12. Reference [3] provides a discussion of the role of conservatism and realism in relation to the use of deterministic and probabilistic analyses. A realistic assessment is aimed at providing an indication of the most likely behaviour of the facility or activity. In general, this requires complex conceptual and mathematical models. A conservative assessment, on the other hand, is aimed at simplicity by deliberately overestimating the likelihood and magnitude of exposures and/or underestimating the ability of the engineering and safety measures to provide protection.

5.13. Both conservative and realistic calculations might be necessary in a safety assessment and both approaches can be used to increase confidence in the safety of the facility or activity. For example, conservative models can be used, especially in the early phases of assessment, to quickly assess the performance of part of the facility or of the entire facility. Simple conservative models may also be used to increase confidence in the results obtained with more complex models.

5.14. The decision to use a conservative approach, a realistic approach or both approaches will depend on a number of factors, such as the nature and objective of the assessment, regulatory requirements, the availability and reliability of data, the complexity of the site and the facility or activity, and available resources.

5.15. If the safety assessment is to be used for optimizing the design of the facility or demonstrating a detailed understanding of its behaviour, the safety assessment should be as realistic as possible, given the availability of data with which to parameterize the models. Undertaking a realistic assessment may, however, require complex calculations involving a large number of parameters, and significant resources may be necessary to demonstrate that the data and models used lead to a realistic representation of the facility. Realistic assessment necessitates the use of relevant and reliable available data, including radiological and environmental monitoring results, operating experience and information on historical events relevant to safety (e.g. at the facility or at similar facilities within the State or in other States).

5.16. If the safety assessment is to be used for demonstrating compliance with a numerical measure or standard of performance, it may be appropriate to undertake a conservative analysis based on relatively simple models. Such an

approach will be feasible if there is a large margin of safety. Caution is necessary, however, because, if misused, results from overly conservative or worst case representations of the facility or activity may lead to poor decision making that is based on assessment results that bear little resemblance to the actual facility or activity.

End points for the assessment

5.17. A clear description and justification of the end points for the assessment corresponding to the associated regulatory safety requirements and criteria should be provided, with account taken of assumptions used in the assessment such as time frame and the receptors used. Assessment end points can include:

— The assessment end points considered for radiological impact such as dose or risk: These will usually relate to the regulations applicable to the facility or activity, and it will be necessary to demonstrate that the selected assessment end points are consistent with the purpose of the assessment and with relevant regulatory requirements and guidance.
— Other safety indicators such as dose rates, radionuclide releases, concentrations of radionuclides in the environment, concentrations and releases of non-radiological contaminants and impacts on non-human species.
— A description of how the assessment end points will be used, for example, to determine compliance with radiological or environmental standards.

5.18. The time frame for the assessment is the longest period considered in the calculations for the safety assessment. The rationale for selecting the assessment time frame should be explained and justified, and the rationale should be consistent with the regulatory framework.

Receptors

5.19. The receptors (persons or groups receiving a radiation dose from the facility or with a risk of exposure, or, in the case of species other than humans, members of that species receiving a radiation dose or with a risk of exposure) associated with each of the various end points should be clearly specified and described. The use of a range of potential receptors should be considered, which may include individuals, populations and other species.

5.20. The International Commission on Radiological Protection recommends the use of the concept of a ‘representative person’ for the assessment of public

exposure [20]. Either the dose or the risk to a representative person of a potentially exposed group can be used as an end point for the assessment, depending on regulatory requirements.

5.21. The ability of the environment to support or sustain a potentially exposed group of which the representative person is a member should be considered. It should also be ensured that the assumed characteristics of this group are consistent with the capability of the biosphere to support such a group. For example, the assumed environmental conditions (location, climate, land use, etc.) may limit the type or size of the group that can reasonably be expected to be present.

DESCRIPTION OF THE FACILITY OR ACTIVITY AND OF THE WASTE

5.22. The descriptions of the waste and of the facility or activity and its surroundings were discussed in paras 4.33–4.46 as this is necessary, to a certain extent, for all elements of the safety case. The quantitative analysis of risks will pose many additional data requirements. These are determined by the scenarios defined and the models used. The collection of these additional data needed for the quantitative analysis should proceed within an iterative process in parallel with the development and refinement of scenarios and models.

DEVELOPMENT AND JUSTIFICATION OF SCENARIOS

5.23. The term ‘scenario’ means a postulated or assumed set of conditions and/or events [3] that can lead to human exposure or environmental contamination.

5.24. Each scenario may represent or bound a range of broadly similar situations reflecting certain conditions arising either during the normal operation of a facility or as a consequence of a specific event leading to a deviation from normal operation conditions. The choice and the rationale for the choice of an appropriate range of scenarios and associated assessment cases are vital, and the scenarios selected will strongly influence the subsequent assessment of the safety of waste management.

5.25. The set of safety assessment scenarios should take account of existing and potential hazards arising for the facility or activity, and their interrelation and evolution over the lifetime of the facility or activity according to the safety case and the context for the assessment.

5.26. As a basis for the development and justification of scenarios, a systematic approach to identification and screening of hazards should be taken on the basis of the description of the facility and activities. The following steps should be applied in an iterative manner in order to identify scenarios for normal operation and anticipated operational occurrences and accident conditions that could lead to the exposure of workers and members of the public, or adversely impact the environment:

(a) Identification of hazards and initiating events: This should consider the inventory, activity, physical conditions and location of the waste and other radioactive material, together with any additional hazards arising from activities or processes for its management, and should identify where initiating events create the potential for causing harm to human health and/or the environment.
(b) Screening of hazards: The hazards identified should be quantified and screened in order to direct efforts towards all significant and relevant hazards and initiating events for the facility or activity.
(c) Identification of scenarios: The safety analysis should identify all relevant scenarios arising from either processes or accident situations in which the screened hazards could be realized.

5.27. The process of identification and screening of hazards should consider the complexity of the facility or activity, as well as the evolution of hazards and risks over the lifetime of the facility or activity, and should be consistent with the regulatory framework.

Identification of hazards

5.28. When identifying hazards, consideration should be given to the performance of each process during normal operation, maintenance and recovery from failure. Consideration should also be given to how the failure of one process can affect associated processes. For example, in identifying hazards associated with the emplacement of waste by crane, consideration should be given to faults that could occur in normal operation of the crane, during maintenance of the crane and during recovery of the crane for maintenance following a failure during emplacement, and to the effect of an outage of the crane on upstream processes.

5.29. The set of identified hazards should include those that could occur as a consequence of human error. This could range from incorrect or incomplete maintenance operations to incorrect settings of limits on control equipment or wrong operator actions. Such hazards will not necessarily be the same as the

hazards identified as being caused by equipment failure because they could involve common cause failures in addition to the initiating event.

5.30. Many remotely operated components depend on computer codes. Software reliability should be covered in the hazard identification process.

5.31. Although the focus of this Safety Guide is on radiological safety, non-radiological hazards (e.g. chemo-toxic, industrial) should also be addressed as specified in national requirements or as they may affect radiological safety (e.g. fires). Non-radiological hazards for which safety criteria exist can be assessed and modelled along with radiological hazards.

5.32. The hazards identified should be quantified and screened in order to direct efforts towards all significant and relevant hazards for the facility or activity. Hazards lacking the potential to cause harm to human health and/or the environment to a degree that exceeds relevant safety requirements or criteria, or which cannot be realized given the scope of the facility or activity being assessed, can be screened out from the subsequent hazard analysis. In the re-evaluation of a safety assessment, such screening arguments should be reviewed to check that they remain valid.

Screening of hazards

5.33. The hazards should be quantified, with no credit taken for any protective or mitigatory safety measures to be used. However, credit should be taken for intrinsic (passive) features of the facility (e.g. walls for shielding, engineered safety features) that are not affected by the initiating event. Hazards with the potential to cause significant harm through any identified pathway or events with a high probability of occurrence when compared to relevant criteria should be considered further.

5.34. Hazards that lie outside the scope and/or objectives of the safety assessment or that cannot lead to consequences in excess of relevant criteria should be screened out. This will lead to a reduced list of hazards to which the effort of the safety assessment should be directed. Furthermore, it may be possible to simplify the safety assessment by grouping these hazards, so that one bounding assessment of their consequences can be undertaken for each group.

5.35. Where hazards are eliminated or grouped, a justification for the approach should be included within the safety assessment. In the re-evaluation or

subsequent iterations/development of the safety assessment, such justifications should be reviewed to check that they remain valid.

5.36. The hazard screening process should involve consideration of all relevant exposure pathways to workers and the public. This aspect of the process should take into account releases of radioactive material and exposures in normal operation and anticipated operational occurrences (as such releases and exposures may occur continuously over a relatively long time interval) and those in accident conditions, which are typically single events.

5.37. The screening process should consider all potential exposure pathways through which the identified hazards could cause harm to workers, for example:

- External exposure from contamination and/or activation of the structures, components, buildings, surfaces, etc. in the facility or from radioactive material (e.g. sealed sources, radioactive waste packages, direct radiation from gamma emitting radionuclides);
- Inhalation or ingestion of airborne releases (particularly gases, aerosols and particulates) during operation of the facility or activity, or following an accident such as a fire;
- Dose to the skin arising from radioactive material deposited on skin or clothing;
- A combination of contamination and mechanical injuries (e.g. contamination of wounds).

5.38. Exposure pathways to members of the public and releases to the environment should be considered wherever applicable (e.g. a lack of containment or a fire could lead to the inadvertent dispersion of radioactive material beyond the site). In addition to the pathways listed above for workers, the potential for off-site exposure pathways through water, via airborne releases and/or via the food chain should be considered.

Identification of scenarios

5.39. Assessment scenarios for screened hazards should be generated in a systematic manner (e.g. by the identification of postulated initiating events).

5.40. Consideration should be given to all postulated initiating events through which harm could be realized, in particular:

— External initiating events: (i) natural events, such as adverse meteorological conditions (e.g. wind, snow, rain, ice, temperature, flood, lightning), earthquakes or biological intrusion; and (ii) human induced events, such as aircraft crashes (with or without subsequent fire), explosions, fire, loss of electrical power or other services, and unauthorized access.
— Internal initiating events at the facility or the site, e.g. fire, explosions, collapse of structures, leakages or spillages, failure of ventilation, drops of heavy loads, failure of protective measures (e.g. shielding, personal protective equipment).
— Human induced initiating events, such as operator errors and violations, misidentifications, and the performance of incompatible activities. Consideration should also be given to the potential for new initiating events to be caused by actions taken during the evolution of an accident to mitigate the consequences of the accident.

5.41. Particular consideration should be given to human factors and technological procedures, as these often represent a main contributor to the generation of scenarios.

5.42. The identification of initiating events and their evolution should be carried out using an appropriate technique (e.g. hazard and operability analysis, event tree analysis or fault tree analysis) and sources of information, such as checklists, expected dose rates for the facility or activity, inventories of radioactive waste and feedback from other facilities or activities. Annex I includes a list of postulated initiating events and examples of the development of an exposure scenario (developed within the SADRWMS project).

5.43. Scenarios should be developed for normal operation (including startup and shutdown where appropriate), anticipated operational occurrences and accident conditions. The safety analysis should address the consequences of normal operation and the frequencies and consequences associated with all anticipated operational occurrences and accident conditions. The degree of detail of the analysis should depend on the magnitude of the radiation risks associated with the facility or activity, the frequency of occurrence of the events included in the analysis, the complexity of the facility or activity and the uncertainties inherent in the processes that are included in the analysis.

Scenarios for normal operation

5.44. Scenarios for normal operation should address all conditions under which the systems and equipment of the facility will be operated or the activity carried

out as expected, with no internal or external challenges. This includes all of the aspects of operation for which the facility is designed to operate in the course of normal operation and maintenance over the lifetime of the facility, and all stages of the activity. The effects of variations in the input materials (feedstock, source material, receipts, etc.) on normal operation should be considered.

5.45. Scenarios for normal operation should be defined with the goal to assess whether the activity can be carried out safely or the facility operated safely under normal operation. This includes assessment of whether radiation doses to workers and members of the public and planned discharges will be within prescribed limits and constraints and will be maintained as low as reasonably achievable. It also includes verification that the elements of defence in depth will be maintained and that adequate safety margins will remain at all times.

Scenarios for anticipated operational occurrences and design basis accidents

5.46. The facility conditions considered in the design basis assessment are typically divided into two categories: anticipated operational occurrences and design basis accidents. The division between the two categories of scenarios is based on the frequency of occurrence and the extent of the challenge to safety from the initiating events that created the fault condition.

5.47. Anticipated operational occurrences are operational processes deviating from normal operation that are expected to occur at least once during the operating lifetime of the facility, but which, in view of appropriate design provisions, do not cause any significant damage to items important to safety or lead to accident conditions [30]. Scenarios for anticipated occurrences should also be considered for waste management activities.

5.48. A design basis accident is an accident condition against which a facility is designed according to established design criteria, and for which the damage to the radioactive waste inventory and the release of radioactive material are kept within authorized limits [30]. Design basis accidents have a lower frequency than anticipated operational occurrences. Design basis accidents are not expected to occur during the lifetime of the facility but are considered in the design of the facility.

5.49. The safety analysis should identify the anticipated operational occurrences and accident conditions. This should include all internal and external events and processes that may impact physical barriers that confine the radioactive material or otherwise give rise to radiation risks. The selection of events and processes

considered in the safety analysis should be based on a systematic, logical and structured approach, and justification should be provided that the identification of scenarios is sufficiently comprehensive. The analysis should be based on an appropriate grouping and bounding of the events and processes, and partial failures of components or barriers as well as complete failures should be considered.

5.50. The assessment of anticipated operational occurrences and design basis accidents should provide a demonstration that the design of the facility or the rules of procedure of the activity are such that:

— The potential for release of radioactive material or loss of shielding is controlled and the safety requirements will be met.
— Any operational discharges of effluents will remain below prescribed limits.
— Limiting criteria for design basis accident conditions will be met.
— Radiological limits applied will not be exceeded.
— Some or all of the barriers put in place to limit exposures and to limit the release of radioactive material from the facility will maintain their integrity to the extent required.

5.51. In addition, the aim of the design basis assessment should be to provide a robust demonstration of the fault tolerance of the engineering design and the effectiveness of the safety features and protective measures. This should be achieved by means of a conservative assessment that should take account of the uncertainties associated with the assessment. Furthermore, the analysis of scenarios addressing design basis accidents should be used as a basis for design specifications relating to reactivity control of fissile material, the safety features (e.g. the confinement boundary, the fire protection system, the ventilation system, the cooling system) and the electric power system (if necessary for safety).

5.52. For new facilities or activities, a comprehensive identification and assessment of all design basis accidents should be carried out. For modifications of existing facilities or activities, the assessment should focus on those design basis accidents that could affect the modification, either directly or indirectly.

5.53. For modifications to, or reassessment of, an existing facility or activity, the methodology and assumptions used in the original design may need to be changed, for example, because:

— The original design basis and the acceptance criteria may no longer be adequate;

— The safety assessment tools previously used may have been superseded by more sophisticated methods; or
— The original design basis may no longer be met.

5.54. The assessment carried out for anticipated operational occurrences is essentially the same as that for design basis accidents and also requires many of the same conservative assumptions, especially those that relate to the structures, systems and components important to safety. However, in the assessment for anticipated operational occurrences, it is not necessary to assume that all non-safety structures, systems and components are unavailable and that credit cannot be taken for these features in mitigating the effects of the initiating event unless the hazard would make these systems unavailable.

Scenarios for beyond design basis accidents

5.55. Accidents beyond the design basis are those that are not considered for design basis accidents, but that are considered in the design process of the plant in accordance with best estimate methodology, and for which releases of radioactive material are kept within acceptable limits [30]. Design extension conditions may be considered in two general groups:

(a) Those that have a high enough probability of occurrence and severe enough consequences that it is advisable to give some prior consideration to possible corrective or remedial actions that could be taken if such an event were to occur. This may be appropriate even though the probability of occurrence is lower than that of design basis accidents.
(b) Those that have a low enough probability of occurrence not to warrant such consideration, even though the potential consequences could be severe.

5.56. The distinction between design basis accidents and accidents beyond design basis is based upon consideration of the probabilities of occurrence and the consequences. The distinction is facility or activity dependent and site dependent to a great degree. If the probability of occurrence of an accident is considered to be unacceptably high, the design should be able to accommodate the accident without significant consequences. If the probability of occurrence of an accident is much lower but the consequences would be significant, it may be advisable to incorporate features into the design to accommodate this eventuality.

5.57. Accidents that are beyond the design basis can have a range of consequences as follows:

(a) Those that fall within the envelope of the conservative acceptance criteria for the design basis accidents (an assessment may be necessary to demonstrate this);
(b) Those that exceed the conservative acceptance criteria for the design basis accidents but would not result in significant facility damage or releases beyond discharge limits;
(c) Those in which there is significant facility damage, the safety features malfunction and some of the barriers to the release of radioactive material fail or are bypassed.

5.58. The accidents described in para. 5.57(c) above are severe accidents in the context of the facility or activity. However, the term 'severe accident' has acquired a particular meaning relating to core damage and other effects in an accident at a nuclear reactor. The term will not be used in this Safety Guide; instead, reference will be made below to the term 'serious accident' to denote such accidents.

5.59. In the case of accidents described in para. 5.57(a) and (b) above, the assessment should aim to quantify a safety margin for the facility or activity and should demonstrate that a degree of defence in depth is provided for this class of accidents. This would mean that the facility design and operation includes, where reasonably achievable, the following:

— Measures to prevent the escalation of events into serious accidents, to control the progression of serious accidents and to limit releases of radioactive material, by provision of additional equipment and accident management procedures;
— Measures to mitigate the potential radiological consequences, by provision of plans for on-site and off-site emergency response.

5.60. The set of representative fault sequences chosen for assessment of accidents beyond design basis should be selected by including additional failures or incorrect operator responses in the scenarios for design basis accidents and in the dominant accident sequences originating in the probabilistic assessment. The important event sequences that could lead to serious accidents should be identified using a combination of probabilistic and deterministic methods, and sound engineering judgement. The details of the serious accident sequences that need to be analysed are dependent on the design of the facility.

5.61. The assessment should generally be carried out using best estimate assumptions, data, methods and decision criteria. Where this is not possible, reasonably conservative assumptions should be made that take account of the uncertainties in the understanding of the physical processes being modelled. This is important since overly conservative assumptions can lead to design or operational provisions that are overly conservative or unnecessary and can mislead operators trying to diagnose an accident and track its cause.

5.62. The accident assessment should model the wide range of physical processes that could lead to a release of radioactive material to the environment.

5.63. The assessment of beyond design basis accidents should take account of the full design capabilities of the facility, including the use of some safety and non-safety features beyond their originally intended function, to return the accident to a controlled state and/or to mitigate its consequences. If credit is taken for the extraordinary use of certain systems, there should be a reasonable basis to assume such systems can and will be used as analysed.

FORMULATION AND IMPLEMENTATION OF ASSESSMENT MODELS

5.64. Once the scenarios have been developed, the corresponding assessments should be carried out. This is commonly undertaken using assessment models. An assessment model will be developed from the following components:

— A conceptual model, which is a representation of the waste management system under consideration: In predisposal waste management facilities or activities, this model can represent a certain component or process during normal operation (e.g. when evaluating the effectiveness of shielding) or during and after an accident (e.g. to estimate releases from waste forms during a fire). The model may also represent other parts of the facility (e.g. structures acting as barriers) or parts of the biosphere (e.g. if the modelling is used to assess the consequences of releases over atmospheric or aquatic pathways). In all of these cases, the conceptual model provides a description of the components and the interactions between these components. It also includes a set of assumptions concerning the geometry of the facility or activity and the chemical, physical, biological and mechanical behaviour of the facility or activity, consistent with the available information and knowledge.

— A mathematical model, which is a representation of the features and processes included in the conceptual model using mathematical equations: The mathematical model can be used for performing quantitative analyses.
— A computer code, which is a software implementation of the mathematical model that facilitates performance of the assessment calculations: The computer code may include numerical schemes for solving the equations in the mathematical model.

5.65. Specific models may have to be developed for particular processes and/or system components. For the purposes of safety assessment, these models will need to be linked in such a way that it is possible to assess the potential radiological impacts of the facility or activity as a whole. The model linking and the use of more detailed models to support simplifications made for safety assessment purposes should be properly managed in accordance with relevant quality assurance measures.

5.66. In developing assessment models, it should be ensured, as far as possible, that:

— The level of detail and the balance between realism and conservatism in modelling is fit for purpose, given the status of the context for the assessment and existing knowledge of the waste management system.
— The conceptual model provides a reasonable representation of the waste management system under consideration, and the mathematical model adequately represents the conceptual model.
— Any alternative conceptual and mathematical models that have been considered or evaluated are documented in order to provide supporting arguments as to the adequacy of the selected models.
— Appropriate exercises for model verification and validation are conducted and documented to build confidence in the suitability of the model for its intended purpose [3].

5.67. Once the models have been developed, it is necessary to assign values to the different parameters, a process that is called model parameterization. In this process, the following should be ensured:

— Parameter values used as inputs to the models and codes used in assessment calculations should be documented. The process of model parameterization should be traceable to source data.

— Records should be kept of how site specific and system specific characterization data have been used to derive parameter values used in the assessment calculations.
— Where a probabilistic approach has been used in the assessments, a justification of the selected probability distributions should be provided.
— Where a deterministic approach has been applied, a justification for the conservatism or realism of selected parameter values used in the calculations should be provided.

PERFORMANCE OF CALCULATIONS AND ANALYSIS OF RESULTS

5.68. Once the models have been parameterized, they can be used for performing deterministic and/or probabilistic calculations for the assessment cases corresponding to the different scenarios.

5.69. The assessment cases should adequately address the appropriate scenarios using the conceptual models and site and facility or activity design information. A sufficient range of sensitivity and uncertainty analyses should be performed to contribute to understanding the system and to identify parameter correlations that have not been treated in an appropriate way.

5.70. When presenting the output from safety assessment calculations, sufficient results should be provided: those that are necessary for comparison with both the ultimate assessment end points and any alternative or subsystem safety or performance criteria. Guidance on the use of the safety assessment results should be provided. For example, it should be explained whether the safety assessment results (end points) will be compared directly with regulatory criteria (e.g. safety targets) or whether they will be used for illustrative or other purposes.

Management of uncertainties

5.71. In view of the complexity of certain waste management systems, efforts should be undertaken in the assessment to understand the significance of the uncertainties and to reduce or bound uncertainties.

5.72. The analysis of uncertainties should be an integral part of the dose or risk calculation process and, whenever possible, reported results should include ranges of possible values (indicating what each range represents) rather than single point values. The analysis of uncertainties should be adequate for the purpose of the assessment.

Sources of uncertainty

5.73. In the safety assessment of a facility or activity, there are several sources of uncertainty, which can be broadly categorized as: (i) modelling uncertainty and (ii) data and/or parameter uncertainty.

5.74. Modelling uncertainty arises from imperfect knowledge of the processes, which leads to an imperfect conceptual model (e.g. when estimating the amount of radioactive material released from a waste form during a fire). The mathematical representation of the conceptual model may be approximate or oversimplified, which may also contribute to modelling uncertainty. Imprecision in the numerical solution of mathematical models is another source of uncertainty falling into this category.

5.75. Data and/or parameter uncertainty refers to the uncertainty in the values of the parameters used in the safety assessment models. This category often includes uncertainty in the intrinsic characteristics of the components, such as:

— Waste characteristics, e.g. radionuclide inventory, physical and chemical form, content of chemical substances, such as complexing agents, hazardous substances;
— Waste package characteristics, e.g. mechanical and chemical performance of the container and the matrix, composition of the waste form;
— Process characteristics, e.g. chemical and physical characteristics during processing, additive to waste ratio;
— Measurement procedures, e.g. clearance procedures, discharge measurement procedures;
— Receptor characteristics, e.g. exposure times.

Uncertainty and sensitivity analyses

5.76. Some uncertainty has to do with events or phenomena that occur in a random manner such as random failures of equipment (aleatory uncertainties). These aspects of uncertainty are inherent in the logic structure of the probabilistic model. Other uncertainties are associated with the state of knowledge relating to the problem under consideration (epistemic uncertainties). In any analysis or analytical model of a physical phenomenon, simplifications and assumptions are made. Even for relatively simple problems, a model may not include some aspects that are deemed unimportant to the solution. Additionally, the state of knowledge within the scientific and engineering disciplines may be incomplete.

Simplifications and lack of knowledge lead to uncertainties in the prediction of outcomes for a specified problem.

5.77. Uncertainty analysis is the estimation of the uncertainties in the assessment end points from the uncertainties in the input data and model parameters. Sensitivity analysis is used to identify the relative importance of each uncertain input parameter to the results of the assessment.

5.78. Probability distributions provide a convenient means of representing uncertainty in the values of parameters, and facilitate the application of probabilistic techniques for uncertainty and sensitivity analyses.

5.79. When defining an approach for the treatment of uncertainties, it is convenient to differentiate between scenario uncertainties, modelling uncertainties, and data and/or parameter uncertainties. Possible approaches for their treatment are outlined below.

Treatment of modelling uncertainties and data and parameter uncertainties

5.80. For each scenario, it is necessary to deal with uncertainties in the models and parameter values used. Although actions can be undertaken to reduce some uncertainties, there are always remaining uncertainties that have to be dealt with in such a way that it is possible to draw conclusions from the results of the assessment and make decisions.

5.81. A commonly used approach to address modelling uncertainties is to perform inter-comparisons between alternative models, and, in some cases, also between model predictions and empirical observations.

5.82. Sometimes it is possible to demonstrate by sensitivity and/or uncertainty analyses that a given uncertainty is not significant to the safety of the facility or activity. For example, the sensitivity study may show that the model is not sensitive to some parameters, even when these are varied over the whole range of possible values. In addition, the uncertainty analysis may show that some parameters, even those with high sensitivity, have a small contribution to the overall uncertainty of the model predictions.

5.83. The graded approach to safety assessment also applies to the treatment of uncertainties. For example, a commonly used approach to treat uncertainties is to use conservative (cautious) assumptions (e.g. when simplifying the models used, a conservative view can be taken). Another example is to assign conservative

values to model parameters. This approach has several advantages, in particular for the demonstration of compliance with regulatory criteria. However, it should be taken into account that in some cases such conservative assumptions may lead to assessments representing situations that are extremely unrealistic or impossible and, therefore, difficult to interpret and communicate. Furthermore, when conservative values are assigned to several parameters, the results of the calculations might be overly conservative, owing to magnification of errors, and would provide a poor basis for decision making. Another important consideration is that an assumption that is conservative in one scenario, or for one nuclide, might not be so for another. The conservatism of the assumptions should be justified in relation to their impact on the assessment end points.

5.84. Probabilistic safety assessments can be used to quantify the risks associated with each scenario. Probabilistic assessments should avoid realizations with impossible combinations of the parameters or combinations of parameters corresponding to very unlikely states of the facility or activity. Impossible combinations may be generated, for example, in Monte Carlo simulations, when sampling from the probability distributions of the different variables, if correlations are not taken into account. Probabilistic safety assessments should also be conducted so as to avoid undue 'risk dilution', i.e. masking of the impact of a very significant event at some point in the lifetime of the facility by rendering its consequences of little significance in the overall assessment of risk when multiplied by the probability of occurrence of the event.

ANALYSIS OF ASSESSMENT RESULTS

Comparison with assessment criteria

5.85. One of the aims of the safety assessment is to compare the assessment end points with specific indicators. This is significantly aided by adopting a systematic approach, such as that reflected in the SADRWMS project (see Annex IV).

5.86. However, the achievement of a level of protection such that calculated doses are less than a dose constraint is not in itself sufficient for acceptance of a safety case for a facility or activity, since protection is also required to be optimized. Conversely, an indication that calculated doses could, in some unlikely circumstances, exceed the dose constraint need not necessarily result in rejection of a safety case. Recommendations relating to optimization of protection are provided in paras 4.69–4.76.

5.87. If the safety assessment results do not demonstrate compliance with safety requirements or criteria, the assessment should be revised in accordance with the framework shown in Fig. 2. The results of the revised assessment should be used to identify proposed amendments to the existing safety case, or to identify activities, engineering and protective safety measures, and, where appropriate, additional safety measures to ensure compliance with the requirements and criteria. The treatment or reduction of uncertainties in the safety assessment should be reviewed and, where necessary, revised.

Review and modification of the assessment models

5.88. In site selection, assumptions will have to be made regarding the design and relevant location of the facility or activity and, therefore, the safety assessment will only provide preliminary estimates of the safety of the facility or activity. This is acceptable because the role of safety assessment at this stage is only to determine whether a site is, in principle, suitable for a predisposal waste management facility or activity. At later stages, details of the proposed design will be defined, allowing operational issues to be addressed in more detail. Throughout this process, the safety assessments prepared for each stage of the process should provide sufficient depth and robustness to support the decisions required.

5.89. In accordance with the graded approach, the extent and complexity of the safety assessment will vary with facility or activity type and is required to be commensurate with the magnitude of the associated hazards [2, 3]. In addition, the depth of the safety assessments performed at the different stages of the development of a facility or activity will vary.

5.90. The level of detail to which the models are developed and the associated amount of data required will be a function not only of the assessment context but also of the stage of iteration of the assessment process (see Section 3). For example, in early iterations (such as for site selection or in initial investigations), it might be sufficient to generate relatively simple models for screening purposes that can be implemented using simple computer tools such as spreadsheets and data that are readily available. Following the review of the results, it might be appropriate to collect further data and improve certain models and implement them using more sophisticated computer codes. Models and data for later iterations, especially for the final safety case, may need to be even more comprehensive.

5.91. Any lessons learned in applying the models and interpreting the results should be used to revisit assumptions and decisions made during the course of model development. It is likely that such information can be used to refine the model, perhaps by identifying particularly important processes or particularly sensitive parameters.

6. SPECIFIC ISSUES

6.1. This section provides recommendations on several issues that may need particular consideration when undertaking safety assessments for a radioactive waste predisposal management facility or activity. The issues considered are:

— Evolution of the safety case;
— The graded approach;
— Defence in depth;
— Reliability;
— Lifetime of the facility or activity;
— Long term storage of waste;
— Waste acceptance criteria and interdependences;
— Comparison of options.

EVOLUTION OF THE SAFETY CASE

6.2. Annex IV illustrates a framework developed within the SADRWMS project for the overall process of assessment of predisposal waste management. This framework can be used to identify those facilities and activities requiring safety assessment and provides an overview of the scope and objectives of these safety assessments.

6.3. In the pre-operational period, the safety case will evolve in five main steps:

(a) Concept development and siting;
(b) Design and construction;
(c) Commissioning, both inactive and active;
(d) Operation;
(e) Shutdown and decommissioning.

6.4. This section provides an overview of the role and content of a safety case in each of these steps. A safety assessment should be carried out at the design stage of a new facility or activity or as early as possible in the lifetime of an existing facility or activity, and should be updated as necessary as the facility or activity passes through the stages of its lifetime. Updating of the safety assessment should take account of any changes in circumstances (such as the application of new standards or scientific and technological developments), changes in the site characteristics, modifications in the design or operation and the effects of ageing. A safety case may also be required for modifications to facilities that are already in operation or modifications to activities; depending upon the scale and type of modification any or all of the above steps may have to be addressed. Such a step by step approach is demonstrated in the SADRWMS project (Annex IV).

Concept development and siting

6.5. For a proposed facility, the safety case may conclude that there is sufficient confidence in the possibility of achieving safety to justify a positive decision to proceed to the next stage of planning or implementation. This is a statement of confidence on the part of the author of the safety case based on the analyses and arguments developed and the evidence gathered. If the evidence, arguments and analyses do not give the author sufficient confidence to support a positive decision, then the safety assessment or the facility design may need to be revised.

6.6. The first step in the pre-operational phase addresses concept development and design. The safety case for this step should present the strategy for safety and the way it will be met. At this stage, it will generally not be possible to provide a detailed description and assessment of the facility or activity. However, key aspects relating to the strategy for safety and to the description of the design concept should be addressed. In the absence of any quantitative demonstration, qualitative justifications for the strategy for safety adopted will have to be provided in the safety case. In addition, the approach to radiological impact assessment, the management system and management of uncertainties should be set out and explained, even though these aspects will evolve significantly in subsequent steps of the project.

6.7. In accordance with the application of the strategy for safety to the facility or activity and its components, the safety case should address specifically how, individually and in combination, the components will ensure implementation of all safety requirements. In general, the safety case should include a description of the safety functions assigned to each component and should provide an assessment of the ability of these components to fulfil their given role. The safety

case should also address the feasibility of construction and reliability. In all of these respects, statements about the performance of the facility or activity should be justified and the uncertainties remaining at the particular stage of the project should be identified.

6.8. The safety case should explain how it is intended that the characteristics and properties of each component will meet their allocated safety functions and how this will evolve with time. This explanation should be supported by the following:

— An overview of the technical feasibility of the proposed design options, identifying aspects that rely on already proven techniques and those that are new and need future confirmation through experimental tests;
— An overview of the level of knowledge on the ability of each component to fulfil its expected role under anticipated conditions and disturbing events that have already been identified as possible perturbations;
— An assessment of how the components will function together in a complementary manner to ensure that there is adequate defence in depth and that safety is not unduly dependent on a single safety function.

6.9. The radiological impact assessment can only be very preliminary at the stage of concept development. Nevertheless, such a preliminary assessment should be carried out in order to provide a broad estimate of the order of magnitude of possible impacts, on the basis of generic considerations of the performance of the site, and to begin to identify the features of the facility and environment that are likely to be important to safety.

6.10. One of the key considerations at this stage of the project is the siting of the facility or activity. This should consider the effect the facility or activity will have on:

— Other activities at the site;
— Any neighbouring populations.

6.11. Consideration should also be given to:

— The effect of other activities or facilities on the proposed facility or activity;
— The management of any primary and secondary waste generated by other activities and facilities at the site and the discharge or clearance of any radioactive material.

6.12. The safety case should also contain information about the management system. Among the topics relating to the management system, at this early step, the safety case should address the organizational structure and the resources necessary for the project, the programme for the project planning and the system that will be in place for the management of information. At this stage, arrangements for communication with the regulatory body and interested parties should be developed and put in place.

6.13. The anticipated output of this stage of development of the safety case is justification that construction of the facility or the activity can, in principle, be undertaken and that it appears safe to do so.

Design and construction

6.14. At the stage of design and construction, the safety case should be further developed, so that it can be demonstrated whether the following conditions are met:

— There is a need for the facility or activity;
— The adopted design will meet all safety requirements;
— The facility can be safely constructed or the activity can be safely carried out.

6.15. It should also be demonstrated in the safety case that the likelihood of a component failing is low and that, in the event of degradation, the loss of a safety function of one component will not jeopardize the safety of the whole system. Thus, the safety case should provide a mature assessment of the engineering aspects and of the impact of the facility or activity.

6.16. The output of the safety case at this stage is justification that the facility or activity, as designed, can be safely constructed and operated.

Commissioning

6.17. In commissioning, specific attention should be paid to the performance of structures, systems and components important to safety. The safety case should be capable of demonstrating that the as-built facility meets the safety requirements specified in the final design. This should include the impact of any modifications to the design that have been implemented during the construction period.

6.18. A schedule should be prepared for commissioning that details the tests to be undertaken and the expected results, to ensure that all aspects of the facility important to safety are adequately tested.

6.19. The safety case should provide updated information about the management system, with particular emphasis on:

— The organization and procedures that will be put in place to ensure the quality of the work performed;
— The linkage of design to the outcome of research and development activities and safety assessment work;
— The keeping of records on the basis of decisions made during design or operations;
— Design basis information, including information on design modifications;
— The expertise available to carry out tests and operate the facility or activity.

6.20. Operations and events and occurrences in other comparable facilities or activities should also be used to identify the potential need for a re-examination of the safety case or structures, systems and components important to safety. All appropriate information should be made available in order to support decision making, including references to outputs from other projects, results of tests and substantiations of assumptions made.

6.21. It is possible that separate safety cases and commissioning schedules will be required for inactive commissioning and active commissioning. The aim of the safety case for inactive (cold) commissioning is to justify the decision that the as-built facility is safe to operate. The aim of the safety case for active commissioning is to justify the decision that the facility can accept radioactive material safely.

Operation

6.22. In the initial safety case for operation, evidence should be provided that the facility has been constructed in accordance with the design and that commissioning demonstrates that the facility can be operated safely. Information acquired during commissioning should be used to verify the validity of the safety assessment conducted for the previous stages, particularly regarding key assumptions and predictions. Any significant differences between the actual performance and predicted performance of the facility or activity should be identified and the reasons for these differences should be investigated. All discrepancies should be justified. If there are safety implications, then a

re-examination of the related structures, systems and components important to safety should be carried out.

6.23. The safety case should provide updated information about the management system, with particular emphasis on:

— The organization and procedures that are in place to ensure the safety of operations;
— The record keeping and tracking system covering data, information and records of decisions made;
— The adequacy of the expertise available to operate the facility or activity;
— Interdependences.

6.24. Operations and events and occurrences in other comparable facilities or activities should also be reviewed to identify any changes necessary before the plant can be operated. The safety case should be capable of demonstrating that the as-built facility complies with the expectations of the operator and regulatory body.

6.25. The safety case should provide evidence that the facility can be safely decommissioned. Where a treatment facility is developed for all decommissioning waste, it should be recognized that the treatment facility itself will also generate decommissioning waste in the future that will need some sort of appropriate treatment.

6.26. The aim of the safety case for operation is to justify the decision that the facility can be operated safely for a specific period and can then be safely decommissioned.

Shutdown and decommissioning

6.27. Every waste management facility will eventually be closed and decommissioned. From the very earliest stage of the development of the safety case, this must be addressed to justify decisions on its safety. The justification should be based upon techniques that are currently available and should take into account the level of resources that are likely to be available at the time of closure.

Review of the safety assessment

6.28. During the operational life of a facility or activity, there may be a need to modify some part of the facility or aspect of the activity. Where a modification

could have an impact on safety, an appropriate safety assessment should be conducted or the current assessment should be updated before implementation to ensure that established safety requirements will continue to be met. The results of the safety assessment should be compared with the safety case for operation and the approved documentation should be appended to the safety case.

6.29. There may be time dependent processes and events, both internal and external to the facility or activity, that could lead to the need to modify certain assumptions, parameters and boundary conditions. As the processes and events may be gradual or may occur at unpredictable times, the safety case for operation should be reviewed periodically in order to detect significant changes in the underlying assumptions, parameters and boundary conditions. If necessary, the safety case should be revised accordingly. This periodic review should be mandatory and should be conducted at intervals determined by the regulatory body.

6.30. A periodic review of the safety case may also be required to justify decisions to extend the life of the facility beyond its original design life; to change the ownership or management of a facility; or to change regulations.

6.31. The updating of the safety assessment should take into account operating experience, including data relating to anticipated operational occurrences, accident conditions and accident precursors, both from the facility or activity itself and from other similar facilities or activities.

GRADED APPROACH

6.32. This Safety Guide applies to a wide range of facilities or activities, and to a wide range of wastes, which may pose different degrees of hazard and risk. A graded approach to safety assessment has to be considered to take account of the different levels of hazard and risk. Thus, it could be expected that greater levels of effort should be put into developing the safety case and safety assessment for a large waste treatment facility than for a small, low level waste storage facility. The degree of detail necessary in the safety case and safety assessment should be determined by first undertaking a relatively simple safety assessment that provides an indication of the levels of possible risk associated with the facility or activity.

6.33. According to Ref. [3], when undertaking a safety assessment, it is necessary to ensure that the assessment is based on an appropriate level of understanding of

the facility or activity and its potential behaviour, and that all safety relevant issues are considered and addressed. Various criteria may be used to help in determining the amount of effort that should be expended on the safety case and safety assessment for a particular facility or activity. Reference [3] identifies the following criteria to be taken into consideration in the application of a graded approach: the safety significance, complexity and maturity of the facility or activity. The use of these criteria in safety assessment for predisposal waste management facilities or activities is discussed in paras 6.34–6.36.

6.34. According to Ref. [3], safety significance will usually be the most important criterion to be taken into consideration. Use of this criterion will necessitate consideration of the performance of the facility or activity in terms of releases of radioactive material in normal operation, potential consequences of anticipated operational occurrences and reasonably foreseeable accidents, and the potential significance of low probability events with potentially severe consequences.

6.35. Complexity may also be used as a guide to help inform decisions regarding the level of effort to be applied in assessing or reviewing a particular facility or activity. A complex design for a facility or activity might suggest the need for a correspondingly complex representation of the design in safety assessment.

6.36. Maturity of the facility or activity, as well as of the technologies employed, may also be used to inform decisions regarding the amount of effort that should be expended on the assessment or review of a particular predisposal waste management facility or activity. In this sense, consideration of maturity may refer to: (i) the use of well established practices, procedures and designs; (ii) the availability of knowledge of the operational performance of similar facilities or activities (and the associated uncertainties); and (iii) the availability of experienced manufacturers and constructors. The process of applying a graded approach is fostered by the systematic hierarchy set out in the SADRWMS project (see Annex IV).

6.37. In accordance with a graded approach, it might be determined that the development of a safety case for a comparatively simple waste management facility, such as a storage facility in a hospital, requires only a few weeks and can be conducted using a checklist approach. The development of a safety case for a large, centralized waste processing facility, on the other hand, may require a large team of experts with several different specializations and may require several years of work.

6.38. A specific example of the application of the graded approach concept is the decision about when to undertake probabilistic modelling as opposed to conservative deterministic assessment, which is conceptually simpler. Three main decisive factors can be identified in determining the need to conduct a probabilistic assessment:

— Complex situations, with many influencing factors, that could lead to exposure of workers or the public usually require adequate treatment of possible evolution paths of each relevant component and each internal or external factor of influence. In most cases, this is only possible by setting up an appropriate probabilistic model that adequately addresses and combines the individual probabilities to arrive at an overall probability distribution for the possible consequences.
— Large spreads of parameter values that determine the likelihood and/or magnitude of exposure usually require probabilistic treatment because setting each parameter conservatively may result in grossly overestimating doses and, thus, may not yield an adequate basis for the assessment of the facility or activity and of the required safety provisions.
— An accident with potentially severe consequences usually requires a thorough analysis in order to achieve sufficient confidence in the results.

6.39. While these aspects determine the need to conduct probabilistic assessments from the point of view of the graded approach, there may be other situations in which probabilistic assessments are conducted, for example, for reasons of convenience or because of the preference of the safety assessor.

6.40. Probabilistic assessments vary in complexity and detail. Determination of the appropriate level of complexity and detail will depend on the factors indicated in para. 6.36 and, thus, is also driven by the graded approach.

DEFENCE IN DEPTH

6.41. According to Ref. [3], an assessment of defence in depth is required, comprising an evaluation of the levels of defence provided by the facility or activity. The concept of defence in depth is based on the application of several levels of protection, including successive barriers and other safety functions that prevent the release of radioactive material to the environment and minimize exposures. The concept includes protection of the barriers by averting damage to the facility and to the barriers themselves. It includes further measures to protect workers, the public and the environment from harm in the case of unexpected

malfunction or degradation of these barriers. The use of physical barriers and administrative controls should be combined into an effective defence in depth strategy.

6.42. The most important safety functions are usually fulfilled by means of passive barriers, such as the physical or chemical properties of conditioned waste, the waste package itself or process piping. Active controls can also provide safety functions or contribute to the confidence in passive barriers and safety functions but these should not be relied on wholly to ensure defence in depth.

6.43. Safety assessment should take into account existing levels of defence in depth or should provide evidence of the adequacy of projected levels of defence in depth. This can be made clear by:

(a) Identification of barriers and other safety functions;
(b) Explanation of the diversity of such barriers and other safety functions;
(c) Explanation of the resilience of such barriers and other safety functions under normal and abnormal conditions;
(d) If appropriate, making a quantitative estimate of their contribution to the margin of safety;
(e) Demonstration that if any single safety barrier were to fail then the safety of the facility would not be unacceptably compromised.

6.44. In the safety assessment, particular consideration should be given to internal and external hazards that could have the potential to adversely affect more than one barrier.

RELIABILITY

6.45. When selecting components for use in a facility, it is important to know their reliability. The safety case should provide evidence for the level of reliability demanded of any component. The necessary reliability will depend on the demands for safety made of the component and the defence offered by other components in the system (i.e. redundancy).

6.46. In the safety assessment, consideration should also be given to the reliability of components over the lifetime of the facility. Components should be designed to have a lifetime commensurate with the demands that will be placed upon them. The appropriate design of components should be complemented by an appropriate maintenance regime to ensure the continued reliability of the

component. Older components may well have lower levels of reliability, unless they have been well maintained.

EXPECTED LIFETIME OF THE FACILITY

6.47. The safety case should provide evidence for the expected lifetime of the facility. The expected lifetime of the facility needs to be sufficient for the activity being undertaken. For storage of waste, the expected lifetime of the facility may need to include some contingency, such as for delays owing to unloading of the waste or for delays in the availability of a disposal facility.

6.48. For facilities or activities with long lifetimes, it will be necessary to use well proven and well documented materials, so that there is confidence that they will last for the lifetime of the facility or activity. Particular consideration should be given to long term storage of waste, on which recommendations are provided in paras 6.50–6.68.

6.49. In the case of planned extension of the lifetime of a facility beyond its original planned lifetime, the safety case (including the safety assessment) should be updated to address the potential impacts on safety. The update should take into account the degradation of barriers or components, and should be performed well in advance of the end of the original licence term to facilitate regulatory review.

LONG TERM STORAGE

6.50. Long term storage of waste, by definition, involves a period of time that will exceed the normal design lifetime of civil structures, including those used in short term storage facilities. This will have implications for the selection of materials, operating methods, quality assurance and quality control requirements, etc. Specific issues that should be given special consideration in the safety case for long term storage of waste include the time frame for the assessment of the storage facility or activity, the importance of passive safety features, retrievability, and the management system. An ageing management programme should be established to deal with ageing related degradation. The monitoring necessary for early detection of any deficiency should be specified in the ageing management programme.

6.51. In the context of this Safety Guide, long term storage is considered to be storage beyond approximately fifty years, and with a defined end point. The

storage end point is important since it provides the basis for the design lifetime of the facility, packaging requirements and financial guarantees, and the planning basis for subsequent disposal facilities. Long term storage is not expected to last more than approximately one hundred years. This time frame is based on technical experience with civil construction methods and structures.

Time frame

6.52. The time frame for the assessment is the period covered by safety assessment calculations. The rationale for selecting the assessment time frame should be explained and justified. Depending on the purposes of the assessment for long term storage, it might be convenient, for modelling or presentational reasons, to divide the overall time frame for the safety assessment into shorter time windows with different end points.

6.53. The assessment time frame should be defined by taking account of national regulations and regulatory guidance, as well as the characteristics of the particular long term storage facility or activity, the site and the waste to be stored. Other factors that should be considered when deciding on time frame and time windows for the assessment include the following:

— For most long term storage systems (including waste packages, engineered constructions and surrounding environment) and waste types, impacts on people and the environment will rise for a period of time after commissioning of the facility. In the longer term, depending on the nature of the waste, impacts may decrease, in particular through decay of the radioactive inventory of the storage facility. Usually, the safety assessment calculations should cover a period that is sufficient to determine the maximum, or peak, dose or risk associated with the facility or activity.
— Another consideration that may influence decisions on time frames or time windows for the assessment is the return period of natural external hazards such as extreme meteorological events or earthquakes; however, the design of the facility against the hazards posed should take precedence over this consideration.
— Several factors that can significantly affect safety assessment results may change with time. The assessment should consider these changes. As a means to assess the possible evolution of the long term storage facility, the assessment may consider one or more scenarios to reflect different evolution paths. The assessment time frame and time windows should be defined as appropriate to reflect the possible changes that could affect the storage facility.

— The habits and characteristics of the group of receptors, as well as the conditions in which they are located, may change over time. Consequently, receptors should be considered hypothetical, but receptors and populations in the future have to be afforded at least the same level of protection as is required at present [1]. The habits and characteristics assumed for the group should be chosen on the basis of reasonably conservative and plausible assumptions, considering current lifestyles as well as the available information on site conditions and regional environmental conditions.

Passive safety

6.54. The operator should demonstrate that, to the extent possible, safety of the facility is ensured by passive safety features for the anticipated lifetime of the facility or activity. According to Ref. [2], this is of particular relevance for the storage of waste. The assessment of long term safety should take account of the degradation of passive barriers over time.

6.55. The complementary performance of the various safety functions should be assessed over different time periods. Each safety function should be as independent as possible of the others to ensure that they are complementary and cannot fail through a single failure mode. The safety case should explain and provide evidence for the safety functions provided by each barrier and should identify the time periods over which the barriers are expected to perform their various safety functions. The safety case should also identify the alternative or additional safety functions that will operate if a barrier does not perform as expected.

Retrievability

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

6.57. A plan for safe handling of the waste following long term storage should be considered in the safety case and the potential effects of degradation of waste packages on the ability to retrieve and handle the waste should be assessed.

Management system

6.58. As long term storage is an interim measure, the safety case should describe the provisions for the regular surveillance, inspection and maintenance of the waste and the storage facility to ensure their continued integrity over the anticipated lifetime of the facility.

6.59. Owing to the long time frames potentially involved with long term storage, a plan for adequate record keeping over the expected time frame for storage should be considered in the safety case.

6.60. The safety case should be reviewed periodically to verify the continuing adequacy of the storage capacity, with account taken of the predicted waste arising, both for normal operation and for possible incidents, the expected lifetime of the storage facility and the availability of disposal options.

Waste acceptance criteria and interdependences

6.61. It is important to note that there are interdependences among and between the various steps of radioactive waste management. Decisions made at one step may affect subsequent steps or foreclose viable alternatives. Such interdependences should be identified in the safety assessments for each predisposal waste management activity and it should be ensured that no conflicting requirements arise that could compromise safety.

6.62. As the last step in the management of radioactive waste, disposal of the waste should also be taken into account when any other upstream radioactive waste management activity is being considered. However, in many States, disposal facilities are not yet generally available, or only for specific types of waste. Irrespective of this, all radioactive waste arisings must be dealt with. This means that decisions on waste forms to be produced might have to be made before all radioactive waste management activities are fully established.

6.63. Such circumstances emphasize the importance of preparing adequate specifications on waste forms, for waste to be accepted by a facility (e.g. a storage facility) as well as for waste forms to be produced by a facility (e.g. a waste processing facility). Waste form specifications must consider radiological, mechanical, physical, chemical and biological properties of a broad range of different types of waste, or may be established for particular waste types.

6.64. The specifications for acceptable waste forms are required to be consistent with the safety case for the facility or activity. In the development of specifications, focus should be placed on the assessment or control of the radiological, mechanical, physical, chemical and biological properties of waste packages in order for these to be acceptable for transport, storage and disposal. In order to achieve this objective, the specifications should consider the intended storage facility and the IAEA's Regulations for the Safe Transport of Radioactive Material [9], and should incorporate any relevant parameters from waste acceptance requirements, if available.

6.65. Various methods are applied for processing the different types of radioactive waste. Consideration is given to identifying suitable options and to assessing the appropriateness of their application. Decisions are taken within the overall approach to radioactive waste predisposal management as to what extent the waste has to be processed, with account taken of the quantities, activities and physical and/or chemical nature of the radioactive waste to be treated, the technologies available, the storage capacity and the availability of a disposal facility. When the unpackaged waste and waste package concept has been decided upon, all relevant parameters should be quantified in terms of ranges that might be achieved in producing the waste package. Maximum values for each parameter can then be determined, together with transport, storage and disposal factors relevant for safety (such as safety margins).

6.66. When deriving the specifications on waste forms within a safety assessment, the situation can arise in which a comparison of different waste treatment options is needed to find a balance between possible improvements in safety and higher financial costs. In such situations, methodologies for the comparison of options should be utilized.

6.67. Another example of the need to balance options against each other relates to decisions on the treatment of waste in situations in which final acceptance criteria for disposal of the waste are not yet available. Conditioning the existing waste form (e.g. conditioning of liquid waste) may turn out to be inappropriate if the eventual waste acceptance criteria of the disposal facility are different from what was expected. On the other hand, storage of the waste in liquid form, to avoid conditioning as long as final waste acceptance criteria are not known, may be less safe than storing the waste in a conditioned form. Decisions on such issues can be made only on the basis of a thorough evaluation of the different options, with account taken of the existing or planned storage facility as well as of the status of development of the disposal route (and the remaining prevailing uncertainties with regard to eventual waste acceptance criteria).

6.68. All decisions discussed in this section should be seen as integral parts of the safety case developed for the facility or activity in question. As discussed above, there may also be a need to take safety cases for other facilities and activities into account. The basis for the decisions made should be recorded thoroughly and sufficient justification should be provided in the safety case. The need for a thorough review of the assumptions made and arguments used within the regulatory review process (see Section 8), as well as in other internal and external review processes, is greater, the more complex the situation and the interdependences are.

7. DOCUMENTATION AND USE OF THE SAFETY CASE

7.1. This section discusses how to compile and draw together all of the different information comprising the safety case. The section elaborates on how to document the safety case and discusses its possible uses.

DOCUMENTATION OF THE SAFETY CASE

7.2. Compliance with the requirements on the documentation of a safety case (see Section 3) presents a number of challenges because the target audience is composed of a wide range of interested parties with different needs, expectations and concerns. Another challenge is related to situations where there are complex legal and regulatory requirements involving multiple regulatory agencies with different regulatory processes and where multiple levels of documentation are required throughout the stages of development of a predisposal waste management facility or activity. Given these challenges, there is no universal structure for the documentation of the safety case.

7.3. The structure and the documentation process are influenced by the expectations of the intended audience, the decision that is under consideration, the stage of development of the facility as well as the type and complexity of the facility or activity being considered, and the associated risks. More detailed recommendations on the use of the graded approach in determining the level of documentation are provided in Section 5.

7.4. The required content of the safety case for a facility or activity may vary among States; however, the documentation of the safety case should cover, at a minimum, the safety assessment and the operating limits and conditions. There are many possible ways of structuring and documenting a safety case. Nevertheless, there are a number of common elements that should be considered irrespective of the documentation structure or process adopted. The main elements should be clearly documented and presented, and should include: the executive summary; the introduction and context for the safety case (or safety assessment); the strategy for safety; the safety assessment (including all of the aspects discussed in Section 4), synthesis and conclusions; a statement of confidence; and a plan for follow-up programmes and actions; as well as a summary of public involvement in development of the safety case. Important issues with regard to some of these components of the safety case are briefly described in the following paragraphs.

Executive summary

7.5. At the highest level, the documentation of the safety case should contain an executive summary that briefly describes the project, the main safety related issues associated with the project, the evidence, arguments and main assessment results, the proposed follow-up and options for mitigation that would address the safety issues identified, and any uncertainties and concerns of interested parties.

7.6. For most interested parties, the summary will provide the first and most lasting impression of the project. This might be all that individual interested parties will read. Consequently, this section should be clear, complete and concise. The use of summary tables, graphics and flow charts should be considered as these are effective ways to present information clearly and accurately. The use of complicated technical terminology should be avoided, to the extent possible. The executive summary can be presented under a separate cover and may be more widely distributed than the rest of the documentation. It may also be presented in different languages to meet the needs of local communities.

Introduction and context for the safety case

7.7. The documentation of the safety case should be introduced by clear presentation of the purpose and context for the safety case, in order to provide the reader with a clear understanding of the project, the decisions to be made and the

decision making process, and of the various issues that are to be considered. In the introduction, the following main aspects should be outlined:

— A brief description of the project that provides its specific objectives, background, various stages involved and its current status;
— The policy and regulatory contexts under which the safety case has been prepared and presented;
— The roles and responsibilities of the various organizations involved in the decision making process, including the framework for public consultation and involvement;
— A clear guide to the decision making process;
— A comparison with other similar projects (national and international);
— A discussion of the status and maturity of development of the technologies that will be used;
— A statement on the need for and importance of the project, in order to support and justify the safety case;
— A discussion of alternatives that have been considered and reasons for the preferred alternative;
— The key decisions that have been and will have to be made during the course of the proposed project;
— A description of critical timing considerations associated with the project;
— An overview of how compliance with regulatory requirements will be ensured by the operator and how compliance will be verified by the regulatory body;
— An overview of the operator's management system and its ability to address the challenges associated with the project adequately.

Strategy for safety

7.8. Following the presentation of the purpose and context for the safety case, the documentation of the safety case should provide an overview of the high level approach that will be used to achieve safety. The objective of the section on strategy for safety is to demonstrate that the overall approach and methods adopted to design, assess, construct, operate, shut down and decommission the predisposal waste management facility or activity are adequate to ensure safety. The section should also include confidence building arguments that are relevant to the strategy for safety. The main aspects to be considered include the following:

— Strategy and approach to manage the different stages of development of the facility or activity (e.g. site evaluation, construction, operation, shutdown, decommissioning);

— How the adopted strategies apply good engineering principles and practices;
— Management and reduction of uncertainties;
— The basis for making decisions;
— Safety features embedded in the design of the facility and the levels of defence in depth used;
— The rationale for selecting the assessment methodology and the time frame and time windows for the assessment, including a discussion of the various assessment approaches and the tools used to verify, confirm and compare assessment findings;
— Peer reviews conducted and consistency with international guidance and practices;
— Other high level arguments as appropriate.

Safety assessment

7.9. The section on safety assessment should document the details of the safety assessment, which forms the scientific and technical basis for the safety case (including all of the aspects discussed in Section 4 of this Safety Guide). This is the section that will be scrutinized by technical reviewers and the regulatory body. Documenting the safety assessment involves a detailed description of the context for the safety assessment, each step of the assessment, the assessment findings and the conclusions. Owing to the large amount of detail involved, it could be more practical and traceable to document detailed descriptions, modelling and calculations in annexes or in separate supporting documents. The main document should focus on the assumptions, approaches and methodologies used in assessment; discussion of the most relevant features that affect safety; the assessment findings; and arguments in support of the conclusions. Confidence building arguments should be documented at each step of the safety assessment as well as for the overall safety assessment.

7.10. All relevant assumptions and the results of the assessment should be adequately documented. This includes uncertainties and assumptions that have been made where no site specific data were available. In particular, it should be made clear in the documentation where assumptions have been made that rely on the provision of new safety measures or on the continuation of existing safety measures. The level of confidence in the evaluation results or safety margin and future actions should be identified if necessary.

7.11. The quantitative and qualitative outcomes of the safety assessment form the basis for the safety case. These should be supplemented by supporting evidence

for and reasoning about the robustness and reliability of the safety assessment and its assumptions, including information on the performance of individual system components as appropriate.

Synthesis and conclusions

7.12. Following the details of all supporting evidence for the safety case, a section should be developed to set out evidence in support of conclusions and recommendations. This section on synthesis and conclusions should:

— Draw together the key findings from the safety assessment;
— Highlight the main evidence, analysis and arguments that quantify and support the claim that the facility or activity is safe;
— Present an evaluation of uncertainties and unresolved issues and discuss planned steps to resolve them;
— Present statements of confidence that take account of additional evidence and arguments that complement the findings of the safety assessment.

Follow-up programmes and actions

7.13. In particular when the safety case is developed in a step by step approach, it is important to put each revision of the safety case into the context of the overall development process. Necessary activities for the subsequent stage of development of the safety case should be described, such as acquisition of additional data or planned improvement in modelling. If certain activities can only proceed after decision points or milestones have been reached (e.g. decisions on the site of the facility or activity), these should be identified.

Traceability and transparency of the documentation of the safety case and safety assessment

7.14. Irrespective of the documentation structure adopted, there are key attributes and considerations that should be considered throughout the process of developing the documentation. These include the following:

— All documents produced in the context of the safety case, whether for regulatory approval, for information or promotion, should convey a consistent message about safety issues. In other words, the message should remain the same and not be changed to suit the expectations of a particular audience. The messages contained in annexed documents and promotional

material should always be consistent with the main documentation of the safety case.[6]

— The main documentation of the safety case should provide sufficient information for the key safety arguments and the evidence supporting them to be clearly understandable.
— The documentation should show that the safety case is based on sound scientific evidence and arguments using established technical experience and analyses.
— The documentation should be clearly written and uncertainties and limitations as well as their implications for safety should be acknowledged.
— The documentation should be well structured, transparent and traceable.
— The documentation should be transparent such that the information is readily available to interested parties, by being clear and understandable and by clearly presenting the justification and rationale behind key assumptions.
— The documentation should be such that the procedures followed and the key decisions taken in the development of the facility or activity and of the safety case are traceable. This should include showing how follow-up actions and programmes are put forward at early stages to confirm assumptions made or how unresolved uncertainties have been addressed and/or will continue to be addressed. It should also be shown how key decisions have been documented and recorded by including a clear referencing system.
— The safety assessment methodology should be well structured, transparent and traceable. It should enable the regulatory body and other technical reviewers to follow the logic and understand the assumptions used in the assessment easily and, where desired, to reproduce the assessment results. The assessment should provide a full description of the practical methods used in order to identify and reduce uncertainties and to identify the assumptions and uncertainties that impact the most on safety.

7.15. The documentation of the safety case should be updated periodically in accordance with a systematic plan. The operator should implement proper controls over the process for approval of the documentation of the safety case and over updates to the set of data and parameter values, models, scenarios and computer codes on which the safety case is based and that are used in safety

[6] The need for consistency does not preclude emphasizing different arguments depending on the audience, as people with different backgrounds may be convinced by different arguments.

assessment. Documents should be made subject to formal review processes only when they have reached the necessary maturity.

7.16. The following observations are relevant to the transparency and traceability of safety assessment:

— The assessment methodology should be clearly structured and presented, and the assumptions and basis for the assumptions should be clearly presented. Well defined and documented methods should be used in identifying features and processes, in designing tests and experiments and determining the necessary instruments, in interpreting test results, in constructing conceptual models, and in analysing and evaluating the models.
— Consistency between assumptions should be sought, along with consistency in the range of parameter values over which the assumptions are appropriate.
— Consistency should be achieved between all stages of safety assessment, and with the main objectives and approach at each stage of safety assessment.
— The evolution of the assessment from one iteration to the next should be transparent to interested parties (e.g. explanation of new data or reasons for changing components of the conceptual or mathematical model should be provided), in order to avoid giving an impression that the assessment is being manipulated to give more favourable results.
— Confidence should be built by selection of an assessment methodology that is compatible with international experience and guidance.
— A formal set of management system procedures should be developed, and evidence should be provided that these procedures have been applied.
— As part of the management system procedures, a comprehensive system for the recording of detailed information on all aspects of the facility or activity and its safety case, including safety assessment, should be established and maintained.
— Accurate and direct references to the appropriate literature should be provided.

7.17. The various interested parties will have different interests and will scrutinize the arguments provided in the safety case that are more related to their interests and concerns. The necessary levels of traceability and transparency may, therefore, depend on the expectations of the interested parties. For example, technical reviewers will pay close attention to the aspects of the safety case addressing safety assessment, whereas members of the general public may be

more interested in the other more qualitative arguments such as the managerial aspects. For this reason, a simplified version of the safety assessment documentation could be sufficient for the public, whereas more complete information would be expected by the regulatory body.

7.18. Traceability necessitates a clear and complete record of the decisions and assumptions made, and of the models, parameters and data used in arriving at the results. The record should include information on when and by whom various decisions and assumptions were made, how these decisions and assumptions were implemented, what versions of modelling tools were used, and what the ultimate sources of the data are, etc. Traceability necessitates the highest standards of quality assurance. Traceability further implies that the regulatory body or other technical reviewers should be able to reproduce part or all of the assessment results from the documentation of the safety assessment. Traceability will be greatly increased by presenting the safety case in a hierarchically structured set of documents.

7.19. To ensure traceability of the safety assessment, the following issues should be considered:

— All information comprising the safety case and safety assessment should be traceable to its source. Such information sources may include records of observations, measurements, research work, modelling studies as well as decisions and assumptions made during development of the safety case. Such decisions and assumptions may rely on expert judgement or expert elicitation processes, for which appropriate procedures and documentation are necessary.
— Expectations relating to traceability depend on the individual or organization using the safety case. Traceability in the safety case intended for scrutiny by the regulatory body should be more rigorously presented than in a document intended for internal use by the operator organization.
— If safety assessment is undertaken iteratively, there may be a tendency for the references simply to refer to decisions made in a prior iteration of the safety assessment (i.e. ‘self-citations’). The reviewer may need to trace through a chain of documents before finding the origin of an assumption, parameter value or decision, which may be time consuming. Further, caveats and limitations to the work included in the primary references may become lost or diluted with subsequent repetition. This can lead to a reduction in confidence in the operator and, consequently, confidence in the safety of the facility or activity by the reviewer. Primary references should

be cited directly and each iteration of the documentation should permit straightforward evaluation of its traceability.

— Referencing of reports from the 'grey literature' or proprietary or classified documents should be avoided. Self-citations should be avoided, except where the self-citation is to an accessible primary reference. If referenced documents are unavailable to the reviewer, their use as a reference would break the chain of traceability.
— The need to keep the chain of traceability intact back to primary sources of information tends to make documents large and difficult to read. Consequently, a trade-off may need to be made between traceability and transparency. The optimum balance between the two can only be decided upon in each particular situation.

USES OF THE SAFETY CASE

7.20. The safety case may be used for several purposes depending on the stage of the design, construction, operation, shutdown and decommissioning of the facility or activity. For example, at an early stage, safety assessments should be used to compare and assess the feasibility of different options. Later, the safety case should be used to inform the licensing process and to provide for the establishment of suitable limits and conditions on operation. The safety case should, at all times, be consistent with the current stage in the lifetime of the facility (see Section 5). The following paragraphs discuss primary uses of the safety case in more detail.

Licensing

7.21. A principal function of the safety case is in the licence application and approval process. The regulatory body may require that the safety case be revised at various stages in the licensing process, including for approval to construct, operate and shut down the facility, and whenever there are significant changes in the facility or activity. In other cases, the licence could cover all of the life cycle stages of the facility. The safety case should also be updated periodically to reflect new information acquired according to regulatory requirements.

7.22. For predisposal waste management facilities and activities located within other facilities operated for other purposes, such as nuclear power plants or spent fuel reprocessing plants, the licence for the predisposal waste management facility or activity may be granted within the framework of the licensing procedure of the other facility.

Construction and commissioning

7.23. In conducting the safety assessment, a number of assumptions will be made in relation to the design, construction, commissioning, operation and decommissioning of the facility. It is important that these assumptions be realized in practice. The plant should be built according to the assessed design, and the structures, systems and components that are important to safety should undergo commissioning tests to demonstrate that they perform as expected.

Operation

7.24. The operating procedures for the facility should be drawn up to ensure that the facility will be operated in accordance with design specifications. Such procedures should be assessed for adequacy as part of the overall safety assessment process.

7.25. A formal procedure for control of modifications should be established and maintained that will ensure that any proposed changes to the facility or its proposed operations remain within the assessed envelope. Alternatively, additional assessment should be carried out to demonstrate the acceptability of a modification.

Monitoring

7.26. The safety case should be used when evaluating potential exposure pathways and in establishing and reviewing the environmental monitoring programme for the site and the surrounding area. Surveillance environmental monitoring programmes should be established to verify that the facility or activity is performing as expected and that each component is achieving its safety function.

Management controls

7.27. The safety case should be used to establish the necessary combination of management controls (covering, for example, quality assurance, maintenance, surveillance testing, staff education and training, emergency preparedness, radiation protection, record keeping and industrial safety) to ensure that the facility is designed, constructed, operated, shut down and decommissioned safely or that the activity is carried out safely. Management controls should also address the clearance and discharge of materials.

8. REGULATORY REVIEW PROCESS

8.1. The regulatory decision making process may involve one or several regulatory bodies and may also be scrutinized by the public and other interested parties. The credibility of the process is enhanced if the regulatory body takes a coordinated approach in order for interested parties to observe that regulatory decisions are based on a careful and comprehensive examination of the safety case that has been prepared by the operator and submitted to the regulatory body for approval. The review should be undertaken in accordance with plans for the regulatory review process and in accordance with requirements established in Ref. [14] and the recommendations provided in Ref. [31]. Some important elements of the process of regulatory review of the safety case and safety assessment for predisposal waste management facilities and activities are discussed in the following sections.

OBJECTIVES AND ATTRIBUTES OF THE REGULATORY REVIEW PROCESS

8.2. In establishing the objectives for a review by the regulatory body of the safety case and safety assessment, account should be taken of the status of the facility (e.g. whether the facility is proposed, under development, operational, undergoing reassessment or closed) and the associated context for the safety assessment.

8.3. The overall goal of the regulatory review is to verify that the facility or activity will not cause an unacceptable adverse impact on human health or safety, or on the environment, both now and in the future. To achieve this goal, the regulatory review process will typically have the following objectives:

— To determine whether safety assessment has been developed to an acceptable level (in terms of its quality and the detail and depth of understanding displayed) and whether it is fit for purpose;
— To verify that the safety case and the assumptions on which it is based comply with, or are in accordance with, accepted principles for radioactive waste management and regulatory requirements and expectations;
— To determine whether the safety case provides an appropriate basis to demonstrate that the proposed facility will be operated safely or the proposed activity will be conducted safely, in particular by identifying any

limits, conditions and controls that will need to be applied to support safe operation of the facility or safe conduct of the activity;
— To verify that relevant measures for mitigating unlikely potential effects have been identified and addressed, and that adequate follow-up plans for implementing these measures have been developed;
— To determine whether issues required by the regulatory body to be addressed by the operator have been clearly identified;
— To identify any unresolved issues and to verify that plans for resolving these issues have been developed.

8.4. In order to facilitate the evaluation of the safety case against the primary objectives of the regulatory review, it is common for a number of secondary objectives to be specified. These should include evaluation of whether the safety case:

— Has been developed within an appropriate context;
— Is sufficiently complete, given the status of the waste management programme and the facility or activity under consideration, and is consistent with the planned activities;
— Is sufficiently transparent in its presentation of data and information, and has been prepared by competent personnel applying a suitable management system that provides confidence in the quality of the operator's safety assessment;
— Is based on appropriate assumptions and makes use of adequate assessment techniques and models, and contains satisfactory arguments supporting the adoption of those assumptions and parameter values and the use of the models;
— Demonstrates an adequate understanding of the facility or activity that includes identification and screening of hazards and related scenarios, such that all relevant safety functions and all potential safety concerns are adequately addressed;
— Clearly describes how the identification, establishment, justification and optimization of (procedural or engineered) safety measures, limits, controls and conditions were performed and that adequate defence in depth is provided;
— Clearly identifies the uncertainties associated with the understanding of the operation and performance of the facility or activity, as well as with input data and models used in the assessments, and addresses them adequately;
— Provides an adequate assessment and supporting justification that protection is optimized and risks are as low as reasonably achievable, and

that accidents are prevented, appropriate protective measures are identified and the consequences of accidents will be mitigated appropriately;
— Includes adequate consideration of the justification and optimization of remedial measures for existing facilities, if applicable;
— Appropriately applies the graded approach to the requirements applied to the safety case for the facility or activity;
— Addresses all relevant factors of the management system to be applied for the siting, construction, commissioning, operation and shutdown of the facility, as appropriate (e.g. internal and external audits, verification and validation; use of suitably qualified and experienced personnel; training; control of processes outsourced to subcontractors; implementation of conclusions and recommendations);
— Provides for adequate planning of emergency preparedness measures;
— Provides for adequate planning of surveillance and maintenance measures;
— Demonstrates that good engineering practices with adequate defence in depth have been used in developing the design of the facility or activity;
— Defines a programme for future development of the safety case for the facility or activity.

8.5. When defining the objectives and scope of the review, relevant points that should be considered include the following:

— The important safety issues for the site;
— The extent of the safety information provided by the developer or operator, and the resources available to the regulatory body to evaluate the information;
— Whether the review will consider only radiological impacts on humans or will consider other impacts as well, for example, impacts relating to hazardous waste materials;
— Whether the review will consider impacts on the public, workers and non-human species in addition to the overall impact of the facility or activity on the environment;
— Which parts of the safety case documentation should be the focus of the review;
— The use to be made of the results of regulatory review, for example, whether they will be used as part of communication on licensing between the operator and other interested parties, for facility licensing or to establish conditions for an existing facility.

8.6. There are a number of key attributes that influence the quality and success of a regulatory review. These include the following:

— The requirements and expectations of the regulatory body, as well as the criteria against which safety will be judged, should be clearly defined early in the process. The completeness and quality of the safety case and safety assessment often depend on the clarity of the regulatory requirements, and the expectations and approach of the regulatory body. Annex II contains an example checklist of aspects that are likely to be of importance in the regulatory review.
— The regulatory review process should be free of conflicting interests, and the team of reviewers should not allow themselves to become unduly influenced during the review process by internal and external considerations that are outside the scope and terms of reference of the review. Any such considerations should be taken into account in the broader context for the safety case by the decision makers, along with the findings from the regulatory review.
— The regulatory review process should be structured and traceable, with clearly defined roles and responsibilities and decision making processes.
— The regulatory body should have personnel with expertise and hands-on experience in safety assessment of radioactive waste management facilities and either should have in-house expertise or should have access to specialists in all of the necessary disciplines involved in such assessment (see Ref. [14]).
— The regulatory review should be conducted using a level of resources that is commensurate with the level of complexity of the safety case and the potential risks associated with the facility or activity under consideration.
— Communication between the operator and the regulatory body should be maintained throughout the regulatory review processes.
— The regulatory review process should include a framework for consultation with interested parties with well defined consultation steps, rules of procedure and decision making processes. The credibility of this process can be enhanced by including means for discussion of progress and the outcome of the review process within this framework.
— In the review process, it should be ensured that the rationale and judgements are documented as to whether or not the arguments presented in the safety case and safety assessment are adequately supported by the underlying science and technology, and whether these arguments are in accordance with regulatory requirements and expectations.

MANAGING THE REVIEW PROCESS

8.7. The management of the review of a safety case should be treated as a project in itself, to which the standard principles of good project management apply (see Section 3). Depending on the scale of the review, it may be necessary to establish a dedicated team of personnel to conduct the review. The regulatory review may be conducted by the regulatory body with or without support from external organizations but the results of the review are the responsibility of the regulatory body, which should take 'ownership' of the results.

8.8. The regulatory body should establish clear and consistent regulatory requirements, guidance and expectations on safety assessments early in the process. A well defined regulatory process including appropriate decision points should exist and independence of the regulatory review process should be ensured. The regulatory body should have in place well established and documented procedures for the review process.

8.9. Management of the review process should include the following aspects:

— Definition of the objectives and scope of the review, as well as identification of all national and international regulations, guidance and recommendations that apply to the development of the safety case;
— Development of a review plan that identifies the review tasks and addresses other relevant topics;
— Assembling a review team of competent personnel possessing the necessary expertise and experience to undertake the review;
— Definition of a project schedule and allocation of resources for the conduct of project tasks, including consideration of the conduct of the review if resources become limited at a later stage;
— Identification of the responsibilities of review team members and ensuring that they receive adequate training and guidance in the review methods;
— Coordination of the conduct of the review tasks, and ensuring sufficient communication between review team members;
— Identification, at an early stage of the review, of any areas of regulatory guidance that are important to regulatory decision making but that may be unclear or could be interpreted in different ways;
— Establishment of a formal process to identify issues for which resolution is necessary by the operator, and a mechanism to track the further consideration and resolution of the issues;
— Coordination of communication with the operator of the facility, and with other interested parties during the review process;

— Review and integration of documents generated in the review process;
— Synthesis, documentation and communication of the findings from the review.

8.10. The review procedures applied should allow the regulatory body to verify that the review of the safety case has been performed by competent reviewers, and has been recorded in a traceable and auditable manner. Project specific procedures should include structured approaches for documenting review comments, for specifying required competence, for specifying responsibilities and tasks in the review, for recording the status of review comments and for dealing with instances where differing or opposing views or review comments on the safety case arise. Further procedures may be necessary if the review includes tasks, such as audits or independent calculations, performed by the regulatory body.

8.11. For each regulatory review, a review plan will be necessary to guide the procedural and technical aspects of the review. Procedural guidance should include the means of documenting the review findings. Technical guidance should include the criteria against which to judge specific aspects of the safety case. The review plan can serve as a template from which a project specific review plan can be developed.

8.12. To the extent practicable, the regulatory review team should have the following characteristics:

— A range of expertise appropriate to the review, including practical experience in areas that are most important to the particular safety case under review;
— Experience of conducting reviews relevant to safety cases;
— Understanding of the context for the review to be conducted (e.g. they should have knowledge of the facility or activity and of the regulations governing its authorization);
— A broad knowledge of waste management practices and programmes, both nationally and in other States;
— Be made up of individuals whose findings will be viewed by interested parties as being credible;
— Be independent of the operator;
— Be made up of individuals who have not had involvement in the development of the safety case to be reviewed or in any supporting work, and have not been directly involved in the management, financing or operation of the facility or activity.

THE USE OF A GRADED APPROACH BY THE REGULATORY BODY

8.13. The level of scrutiny and scope of the regulatory review of a safety case should follow a graded approach. Decisions about the depth and extent of the review process should take into account the following:

— The likelihood and magnitude of exposures of workers and/or members of the public arising from planned processes, or from anticipated operational occurrences or accidents;
— The complexity, safety significance and maturity of the proposed processes;
— Operator aspects (e.g. the operator's record of performance and their relevant experience in the design or operation of the facility or activity or other similar facilities or activities; in the development of safety cases; and the complexity of the organization);
— Relevant experience from similar facilities or activities (national and international);
— The scope of the facility or activity being assessed (e.g. a stage of a larger project, a single large project or a modification);
— Technical or safety concerns of other competent authorities.

8.14. To facilitate the application of the graded approach, the regulatory body should consider establishing a set of deterministic screening criteria to categorize facilities or activities according to their safety significance on the basis of the criteria listed in para. 8.13.

CONDUCT OF THE REVIEW AND REPORTING OF REVIEW FINDINGS

8.15. A regulatory review may have up to four phases, depending on the complexity of the safety case and the pre-existing circumstances:

(a) An inception phase, prior to the receipt of any documents from the developer or operator, in which initial planning for the review should be carried out: This should normally involve meetings with the developer or operator with a view to developing an understanding of the extent of the information that will be provided.
(b) An initial review phase, during which the regulatory body will make an initial evaluation of the submitted documents to assess the completeness of the safety case and the availability of supporting documents, and to make a preliminary identification of those issues that are most important to safety (e.g. to 'risk-inform' the review): Evaluation of the completeness of the

safety case should include checking that the information submitted addresses all of the expectations of the regulatory body for the safety case. This checking will be documented and a series of detailed review comments should be prepared, which may require additional information. The regulatory body should review and assess any additional information provided by the developer or operator in response to the review comments.

(c) A main technical review phase in which the bulk of the effort will be expended: This should include the development of detailed review comments, and may include evaluation of additional information provided by the developer or operator in response to comments.

(d) A completion phase, in which the main conclusions of the review should be identified and used to inform the decision making process.

8.16. In addition to the evaluation of documentation submitted by the operator, the regulatory review of the safety case may require inspection of the facility or activity, if this already exists, in order to verify the accuracy of the safety case as a description of the facility and its operational features.

8.17. The completion phase of the review will include the development of a final review report. There is no single correct way in which the final review report should be organized and presented, and each such report will inevitably need to be customized to the particular review conducted. The regulatory body should consider including the following in the final review report:

— Background to the review, including summary information about the site, the regulatory framework in which the review was conducted, the purpose of the review, the approach to the review and the review process followed;
— Key review findings concerning high level issues, such as the safety strategy, the context, approach and results for the safety case and safety assessment, the treatment of uncertainty (in scenarios, models, parameters), risk management and optimization, appropriate limits and conditions, and the programme for the future development of the safety case;
— Key review findings concerning the main technical areas of review, such as the characterization and modelling of waste inventories and waste streams, with consideration given to aspects of engineering, chemistry, geology, hydrogeology, climate and biosphere;
— Key review findings concerning compliance with the main regulatory criteria and guidance;
— Conclusions of the review with regard to issues to be considered in licensing or authorization, such as further information to be provided by the developer or operator, revised safety assessment work, monitoring and

other controls on the site or the waste, restrictions on the waste inventory, risk management and waste acceptance criteria;
— A list of unresolved issues and uncertainties;
— A list of references, including reference to documents considered in the review, and underlying review reports that support the final review report;
— Appropriate information to demonstrate the credibility of the individuals on the review team.

A sample template for the regulatory review report is provided in Annex III.

8.18. When documenting review comments and assessments, the following should be ensured:

— The approach taken in safety assessment and the results of that approach should be briefly summarized and specific references to the information should be provided.
— Any significant comments and the basis for the comments should be clearly stated using a standard format, and each comment should be given a unique identifier for ease of cross-reference.
— The relevance of the comment to safety, understanding of systems and/or control of the facility should be noted.
— Recommendations regarding actions necessary to resolve the issues identified in the review comments should be stated clearly, and justification should be provided for each recommendation.

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Annex I

EXAMPLES OF HAZARDS AND INITIATING EVENTS

I–1. The purpose of this annex is to identify postulated initiating events for predisposal waste management facilities and to demonstrate, through two examples, the development of an exposure scenario. Owing to the uniqueness of each facility and the difference in operating conditions and levels of competency of operators, exposure scenarios need to be tailored for each facility.

IDENTIFICATION OF POSTULATED INITIATING EVENTS IN SAFETY ASSESSMENT

I–2. A safety assessment consists of different process steps in order to evaluate the hazards associated with the operation of a facility. The various controls in place to manage the risk associated with operation of the facility in normal operating conditions as well as in accident conditions need to be identified to demonstrate protection of workers and members of the public.

I–3. The safety assessment for normal operation needs to address all of the facility conditions under which systems and equipment are being operated as expected. This includes all of the phases of operation for which the facility was designed to operate in the course of normal operation and maintenance over the lifetime of the facility but it also includes the effects of deviations or variations in the inputs (feed material, source material, etc.) on normal operations. The deviations or variations can give rise to a postulated initiating event, which can be identified using various methods. Methods such as ‘what if’ analysis, hazard and operability studies (HAZOP), and failure mode and effects analysis (FMEA) are widely used to identify possible accident sequences. Fault tree analysis, event tree analysis, cause–consequence analysis and human reliability analysis can then be applied to provide in depth analysis of specific accidents that have been identified through the use of the other methods mentioned above.

I–4. Postulated initiating events are generally grouped, and the postulated initiating events in each group have to be evaluated to identify the limiting events. The events selected for further analysis can then be indicated. Such events include those having potential consequences that bound all other postulated initiating events in the group.

I–5. Safety requirements (design and operational) have to be more stringently applied for facilities posing a greater hazard, and vice versa. In accordance with this graded approach, fuel cycle facilities and radioactive waste treatment facilities are not required to comply with defence in depth requirements to the same extent as a nuclear power plant.

DEFINITIONS

I–6. External event: an event unconnected with the operation of a facility or activity that could have an effect on the safety of the facility or activity. Typical examples of external events for nuclear facilities include earthquakes, tornadoes, tsunamis and aircraft crashes [I–1].

I–7. Postulated initiating event: an event identified during design as capable of leading to anticipated operational occurrences or accident conditions. The primary causes of postulated initiating events may be credible equipment failures and operator errors (both within and external to the facility), or human induced or natural events [I–1].

EVALUATION OF INDIVIDUAL EVENT SEQUENCES

I–8. Detailed information needs to be provided for each selected postulated initiating event. This information can be organized under the following headings:

(a) Identification of causes;
(b) Sequence of events and operation of systems;
(c) Transient analysis and accident analysis;
(d) Classification of damage states;
(e) Derivation of the source term;
(f) Evaluation of radiological consequences.

I–9. The extent of the quantitative information to be included under these topics will differ for the various initiating events and is dependent on the facility. For those situations where a particular postulated initiating event is not limiting, only the qualitative reasoning that led to that conclusion needs to be presented, along with a reference to the section that presents an evaluation of the limiting postulated initiating event. Furthermore, for those postulated initiating events that require a quantitative analysis, such an analysis may not be necessary for each

topic; for example, there are a number of postulated initiating events that result in no or minimal radiological consequences.

I–10. For each event evaluated, a description of the occurrences that led to the postulated initiating event under consideration needs to be included.

SCOPE

I–11. The conduct of safety assessments and the identification of a postulated initiating event for nuclear power plants have been covered in detail in the scientific literature. The identification of possible postulated initiating events for nuclear power plants is excluded from this annex. Examples of possible postulated initiating events are provided for the following facilities:

— Storage facilities (for liquid and solid waste);
— Processing or conditioning facilities (e.g. for cementation, immobilization, petrifying, compacting, incineration, melting);
— Long term storage facilities;
— Decommissioning facilities;
— Nuclear fuel cycle facilities;
— Laboratories;
— Facilities processing radioactive material of natural origin.

POSTULATED INITIATING EVENTS

I–12. Postulated initiating events are listed below in the following groupings: external natural factors, external human factors and internal operational factors, including general factors that are relevant for all types of facility and factors specific to one type of facility.

External natural factors

(1) Extreme meteorological conditions:
  (i) Strong winds, dust, sand storms (causing abrasive effects, damage to roofs or structures);
  (ii) Cyclones (causing damage and flying objects);
  (iii) Tornadoes;
  (iv) Hurricanes;
  (v) Tsunamis;

(vi) Lightning;
(vii) Snow;
(viii) Rain;
(ix) Drought;
(x) Extreme temperatures (causing heating or freezing);
(xi) Floods;
(xii) Extremely high or low tides;
(xiii) Humidity and high salt content;
(xiv) Hail;
(xv) Frost;
(xvi) Fog.

(2) Seismic conditions;
(3) Ground instability;
(4) Landslides (e.g. due to ice melting);
(5) Erosion;
(6) Natural fires;
(7) Volcanism;
(8) Biological phenomena (e.g. algae or marine growth, fauna and flora invasion, and biological contamination).

External human factors

(1) Explosions;
(2) Fire from:
(i) The sea after oil spill from a vessel;
(ii) Uncontrolled bush or veld fires.
(3) Mining activities;
(4) Projectiles, sources of high energy from machines and flying objects;
(5) Aircraft crashes and other unpredicted mobile sources;
(6) Sabotage;
(7) Theft;
(8) Nearby industrial activities (toxic gases, corrosion, smoke);
(9) Transport infrastructure;
(10) Nearby military activities;
(11) Civil strife and war;
(12) Electromagnetic interference (e.g. caused by a power station close by);
(13) Floods due to dam failures.

General and specific internal operational factors

Generally applicable to most facilities and activities

(1) Loss of power;
(2) Loss of ventilation;
(3) Loss of containment;
(4) Loss of confinement;
(5) Loss of instrument control;
(6) Lack of maintenance;
(7) Failure of emergency equipment (e.g. malfunction of fire extinguishers);
(8) Loss of utilities (e.g. cooling water, steam, compressed air).

Storage facilities (e.g. liquid and solid waste storage facilities)

(1) Accepting material not in compliance with waste acceptance criteria or requirements: This could result in workers being exposed to unacceptable levels of radiation, in inadvertent criticality or in chemical reactions between incompatible materials placed close together;
(2) Incorrect determination or no determination of chemical characteristics and other characteristics of waste in containers: This could result in:
    (i) Liquids being present in a location where only a solid matrix is permitted;
    (ii) The degradation or corrosion of containers faster than their anticipated loss of integrity;
    (iii) Generation and release of toxic gases;
    (iv) Generation of gases (hydrolysis) leading to damage to the matrix;
    (v) Variation of pressure due to chemical reaction inside containers;
    (vi) Fire due to vapours on surface of matrix material (e.g. bitumen);
    (vii) Biological contamination.
(3) Loss of power, which could lead to various issues such as lack of ventilation or interruption in transport of containers leading to long exposure times;
(4) Vehicle collision (e.g. fork-lift trucks damaging shielding, safety equipment or containers);
(5) Loss or malfunction of instrumentation, which, specifically with regard to storage, could result in loss of temperature control and failure of effective air monitoring;
(6) Ineffective personal monitoring;
(7) Faulty or ineffective security monitoring;
(8) Faulty calibration instruments, leading to quality assurance and safety issues;

(9) Maintenance activities not well managed;
(10) Malfunction of lifting equipment leading to falling or dropping of waste packages;
(11) Loss of shielding (leading to overexposure of workers);
(12) Criticality due to violation of storage arrangements;
(13) Fire (due to, for example, sparks, cigarette smoking);
(14) Improper inspection or inappropriate inspection frequency;
(15) Failure of emergency equipment (e.g. malfunction of fire extinguishers);
(16) Spontaneous combustion of materials;
(17) Failure to control natural phenomena, such as a rising water table;
(18) Loss of or insufficient ventilation, which could lead to internal contamination and surface contamination.

Processing or conditioning facilities (e.g. cementation, immobilization, petrifying, compacting, incineration or melting facilities)

(1) Insufficient or incorrect mixing between wastes and conditioning material;
(2) Wrong classification or characterization of waste, which could lead to:
    (i) Wrong processing method applied (e.g. compacting waste that is not compactable);
    (ii) Moisture or liquid present in compactable waste;
    (iii) Moisture or liquid present in a melting batch, which could lead to an explosion.
(3) Chemical hazards present in waste to be processed (e.g. pH not neutralized prior to processing);
(4) Wrong measurement of level or pressure, resulting in overfilling or overpressurizing of waste containers or equipment;
(5) Wrong processing method applied (compressing material that is not compressible);
(6) Incompatibility of process material and material of construction;
(7) Addition of chemicals in wrong sequence, causing damage to equipment (e.g. through hot spots or corrosion);
(8) Addition of wrong chemicals (leading to, for example, pH swing to wrong direction, wrong flux or chemical, ineffective decontamination, settling or separation);
(9) Accumulation of fissile material in equipment (e.g. as sediment at bottom of tank, in evaporator), which could lead to criticality;
(10) Incorrect setting on process control equipment;
(11) Malfunction of instrumentation or equipment, leading to:
    (i) Overfilling or underfilling of containers;
    (ii) Inability to monitor.

(12) Failure of process control equipment (e.g. heating, cooling, pressure control);
(13) Wrong selection of waste (e.g. wrong identification of waste for packaging and waste for conditioning);
(14) Wrong composition of raw material or solidification material, or wrong relation between mixing materials;
(15) Internal missiles (e.g. from explosions, ruptures, collapses, dropping of loads, high energy rotating machinery);
(16) Failure of safety systems, alarms and early warning systems;
(17) Failure of emergency equipment (e.g. malfunction of fire extinguishers);
(18) Fire;
(19) Dust explosions;
(20) Sparks from operating equipment;
(21) Collision of transport vehicles (e.g. fork-lift trucks);
(22) Failure of critical process equipment (e.g. liners in smelter);
(23) Failure of equipment (e.g. overhead cranes) during handling of equipment;
(24) Loss of water supply;
(25) Ageing of equipment not properly monitored or managed;
(26) Internal flooding due to pipe rupture, which could lead to criticality or other failure of equipment;
(27) Voids in metal pipe to be melted leading to pressure buildup when melted, and then causing explosions.

Long term storage facilities

(1) Waste accepted that is not in compliance with facility acceptance criteria, leading to exposure scenarios of workers and the public no longer being valid;
(2) Dropping or damage of waste containers during handling or loss of content, which could compromise the containment or shielding;
(3) Waste containers not in compliance with requirements;
(4) Loss of or compromise or deterioration of engineering controls;
(5) Inspections being neglected;
(6) Collapse or damage of structures (e.g. trenches) during offload of waste packages;
(7) Leaking of waste containers;
(8) Loss of shielding (e.g. damage to concrete drums during transport);
(9) Effects due to natural weather conditions not managed (e.g. erosion after heavy rain);
(10) Intrusion of animals, such as rabbits or rats, not controlled.

Nuclear fuel cycle facilities (e.g. uranium conversion, uranium enrichment or fuel reprocessing facilities)

(1) Criticality during maintenance due to rearrangement of fissile material to an unsafe geometry;
(2) Overpressure and possible rupture of equipment due to addition of material in the wrong sequence;
(3) Solidification of material in process lines (e.g. blockages);
(4) Internal flooding due to pipe rupture, which could lead to criticality or other failure of equipment;
(5) Insufficient or incorrect mixing of materials;
(6) Chemical incompatibility of process material and construction material;
(7) Accumulation of fissile material in equipment (e.g. as sediment at the bottom of the tank, in evaporator), which could lead to criticality;
(8) Incorrect setting on process control equipment;
(9) Malfunction of instrumentation or equipment, leading to overfilling or underfilling of a container or inability to conduct monitoring;
(10) Failure of process control equipment (e.g. for heating, cooling, pressure control);
(11) Internal missiles (e.g. from explosions, ruptures, collapses, dropping, high energy rotating machinery);
(12) Failure of safety systems, alarms and early warning systems;
(13) Fire;
(14) Dust explosions;
(15) Sparks from operating equipment;
(16) Collision of transport vehicles (e.g. fork-lift trucks);
(17) Failure of critical process equipment, resulting in generation of unnecessary waste;
(18) Failure of equipment (e.g. overhead cranes) during handling of equipment;
(19) Ageing of equipment not properly monitored or managed.

Laboratories

(1) Loss of ventilation, leading to the buildup of asphyxiating or toxic gases;
(2) Loss of instrumentation, resulting in the inability to control analysis or leading to inaccurate results;
(3) Lack of effective calibration, resulting in poor quality analytical data (a postulated initiating event in a laboratory can lead to an event in a processing facility if incorrect data are provided to the facility);
(4) Internal flooding due to pipe rupture, which could lead to criticality or other failure of equipment;

(5) Loss of confinement or leaking containment;
(6) Failure of emergency equipment (e.g. malfunction of fire extinguishers).

Decommissioning facilities

(1) Incorrect characterization of waste, resulting in overexposure of workers, and incorrect use of personal protective equipment;
(2) Hidden sources of radiation or contamination not detected (e.g. from a high radiation source or sediment located at the bottom of a tank);
(3) Malfunction of monitoring equipment;
(4) Loss of ventilation, resulting in spread of contamination;
(5) Compromise of containment structures during dismantling of equipment;
(6) Internal missiles (e.g. from explosions, ruptures, collapses, dropping of loads, rotating machinery);
(7) Fire due to wrong decommissioning techniques applied (e.g. hot cutting of flammable materials);
(8) Internal flooding due to pipe rupture, which could lead to criticality or other failure of equipment;
(9) Criticality due to compromise of specific assembly matrix from equipment being decommissioned;
(10) Damaged structures (which could lead to collapse);
(11) Ageing equipment not identified;
(12) Failure or malfunction of emergency equipment (e.g. malfunction of fire extinguishers).

Facilities processing radioactive material of natural origin

(1) Loss or damage of engineering controls (e.g. damage to tailings dam liner);
(2) Loss or malfunction of instrumentation (e.g. malfunction of environmental instrumentation or monitoring instrumentation);
(3) Malfunction of systems that control ambient conditions (e.g. de-watering systems);
(4) Human activities leading to ground collapse (e.g. change in infrastructure on mining site);
(5) Biological phenomena not properly controlled (e.g. insect damage to engineering controls or spread of contamination);
(6) Effects due to natural weather conditions not properly managed (e.g. erosion after heavy rain);
(7) Failure of emergency equipment (e.g. malfunction of fire extinguishers).

REFERENCE TO ANNEX I

[I–1] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary, Terminology Used in Nuclear Safety and Radiation Protection, 2007 Edition, IAEA, Vienna (2007).

Annex II

TOPICAL ISSUES FOR REVIEW OF THE SAFETY CASE BY THE REGULATORY BODY

LEGAL AND REGULATORY FRAMEWORK

II–1. Topical issues:

(1) Is there clear and unequivocal allocation of responsibility for safety during the entire process of predisposal management of radioactive waste and does the operator, in the documentation presented, assume the prime responsibility for safety within the whole process?
(2) In those cases where the predisposal management of radioactive waste might involve the transfer of radioactive waste from one operator to another, is the responsibility for safety clearly assigned throughout the whole process?
(3) Is the relevant article of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [II–1] observed in the event of transfer of radioactive waste beyond national boundaries?
(4) Is the predisposal waste management strategy proposed by the operator aligned with the national policy and strategy for radioactive waste management, and are the preferred options for radioactive waste management defined in this policy?
(5) Are all safety requirements for the development of radioactive waste management facilities or activities met and are all procedures for meeting the requirements at the various stages of the licensing process in place?
(6) The regulatory body needs to review and assess the safety case and the environmental impacts of predisposal facilities or activities, as prepared by the operator, both prior to authorization and periodically during operation.

Regulatory process

II–2. Topical issues:

(1) Does the operator adequately take into consideration the relationship between the operator itself, the regulatory bodies involved in the licensing process of the facility and other interested parties involved in the process of

development of safety requirements and authorizations for predisposal management of radioactive waste?

(2) Is the operator acquainted with the regulatory process, especially as it relates to the specific characteristics of the operator's own facility?

(3) Is the operator acquainted with the specific requirements and criteria developed by the regulatory body for:
   (i) Handling and transport of waste?
   (ii) Acceptance of waste packages for disposal?
   (iii) Any other issues relating to the operator's own facility?

Preparation of the safety case and safety assessments

II–3. Topical issues:

(1) For each step in the licensing process of the facility or activity, are a safety case and supporting safety assessments prepared and updated?

(2) The regulatory body needs to provide the operator with guidance on the definition of the end points for analysis and other relevant output information necessary to support the request for authorization and to serve as the basis for the decision making and regulatory approval and control processes.

(3) Does the operator check and consider all provisions that have been made for the development of safety cases at previous stages of development of the facility as a basis for the regulatory decision making and approval process?

(4) As the project proceeds, are these safety cases progressively developed and refined?

(5) Does the operator hold all of the responsibility for the development of the safety case and safety assessments that will be submitted for analysis by the regulatory body?

Scope of the safety case and safety assessments

II–4. Topical issues:

(1) Does the operator, within the safety case presented, understand all of the safety aspects of the site, the facility design and the managerial controls to comply with the regulatory criteria?

(2) Within the safety case presented, does the operator demonstrate that the safety requirements will be met?

(3) Does the operator demonstrate how the results of the safety assessments are used to implement appropriate safety related improvements for the facility or activity?
(4) Does the operator indicate how the safety case addresses and justifies the facility design, operational management arrangements and system processes that are used to ensure that the safety objectives and criteria set by the regulatory body are met?
(5) Does the operator demonstrate, within the safety case presented, what considerations are included for reducing risks to workers, members of the public and the environment under normal operation, anticipated operational occurrences and design basis accidents?
(6) Does the operator demonstrate that the safety case developed is sufficiently comprehensive and detailed as to address the complexity of the operations and the magnitude of the risks associated with the facility or activity?

Documentation of the safety case and safety assessment

II–5. Topical issues:

(1) Are the safety case and the supporting safety assessments adequately documented (at a level of detail and quality) so as to demonstrate safety and support the decision making process, as well as to allow for independent review, justification, traceability and clarity?
(2) Is the documentation submitted by the operator for analysis at each step of the licensing process adequate in scope and structure to clearly set out the safety case and the supporting safety assessments in order to adequately support the regulatory approval process, with account also taken of considerations such as justification, traceability and clarity?
(3) Does the documentation submitted for analysis by the operator adequately address justification issues, i.e. does it explain why choices were made and provide the arguments in favour of and against the decision, especially those decisions that relate to the main safety arguments?
(4) Does the documentation submitted for analysis by the operator include traceability considerations, i.e. does the documentation allow for an independent reviewer to follow within the documentation what has been done?
(5) Is the documentation submitted for analysis by the operator sufficiently clear, i.e. does it allow for adequate understanding of the safety arguments and clearly present the work that has been done?

Step by step development and evaluation of the safety case

II–6. Topical issues:

(1) Does the operator describe the different phases of the development of the facility and present the different analyses carried out at each phase to support the demonstration of the overall performance and safety of the system?
(2) Does the operator demonstrate the impact of the step by step approach in the confidence building process of the safety analysis that justifies safety analysis outcomes, such as:
   (i) Collection, analysis and interpretation of relevant scientific and technical data?
   (ii) Development of engineering designs and operational plans?
   (iii) Development of the safety case itself for operational safety?

BASIC ELEMENTS ASSOCIATED WITH PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

II–7. Topical issues:

(1) Does the operator carry out safety assessments and develop the necessary supporting safety cases for siting, design, construction, commissioning, operation, shutdown and decommissioning of facilities? The safety cases are required to be carried out in compliance with legal and regulatory requirements established within the regulatory framework.
(2) Does the operator demonstrate the commitment of senior management to safety and the establishment and maintenance of a safety culture within the facility?
(3) Does the operator demonstrate the implementation of an integrated approach to safety and security at the facility?
(4) Does the operator take into account the interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option?
(5) Does the operator apply an effective management system to all steps and elements of the facility for predisposal management of radioactive waste? Features that are important for the safe operation of the facility or activity and that are considered in the management system need to be clearly identified in the safety case and supporting safety assessments.

(6) Has the operator adequately contemplated, in the safety cases and supporting safety assessments, the basic elements of sound predisposal management of radioactive waste, such as:
   (i) Identification and control of all radioactive waste streams?
   (ii) Use of measures to keep secondary waste generation to the minimum practicable?
   (iii) Reuse and recycling of materials, provided that protection objectives are met?
   (iv) Authorized discharge of effluents and the clearance of materials from regulatory control, according to the regulations in place?

TECHNICAL REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

Waste characterization and classification

II–8. Topical issues:

(1) Is radioactive waste adequately characterized and classified, in accordance with the requirements established and approved by the regulatory body, at the various steps of the predisposal management process within the facility?

Pretreatment of radioactive waste

II–9. Topical issues:

(1) Does the pretreatment of waste in the facility or activity appropriately consider the characteristics and properties of the waste and the requirements imposed by subsequent steps in the predisposal management of radioactive waste (treatment, conditioning, transport, storage and disposal)?
(2) Within the facility or activity, are the objectives of pretreatment of waste adequately achieved, i.e. (i) to reduce the amount of radioactive waste that would be subject to additional processing and disposal; and (ii) to adjust the characteristics of the remaining radioactive waste that might require treatment, conditioning and disposal to make it more amenable to additional processing and disposal?
(3) When pretreatment operations, such as waste collection, segregation, chemical adjustment and decontamination, are being carried out, does the

appropriate characterization of the waste serve to enable the appropriate allocation of treatment and conditioning processes?

Treatment and conditioning of radioactive waste

II–10. Topical issues:

(1) Are the interdependences between the basic steps in the predisposal management of radioactive waste adequately taken into account?
(2) Is appropriate conditioning for radioactive waste chosen in order to ensure a waste form that is compatible with the selected storage option and the selected or anticipated disposal option?
(3) Does the conditioning process selected produce a waste package that complies with the established waste acceptance criteria for transport and disposal?
(4) Is the packaged solid waste form compatible with the selected or anticipated disposal option and does it also meet the requirements for safe handling, transport and storage?
(5) Are the selected materials and processes chosen for the conditioning process compatible with the radioactive waste form?
(6) Are processing of waste and selection of containers carried out so as to ensure operational safety, sufficient stability between the waste, waste form and the container, and compatibility of the waste packages with the storage and disposal environment?

Storage of radioactive waste

II–11. Topical issues:

(1) Does the safety case developed for the storage facility take into consideration normal operation aspects and appropriate scenarios for accidents at the facility?
(2) Is the period of storage taken into account in the safety case and does the design of the facility consider the use of passive safety features that can cope with the natural degradation of any safety barriers to be used for confinement of the waste?
(3) Does the safety case also consider natural site characteristics (e.g. geological, hydrological, climate) that could impact on the performance of the safety features of the facility, in order to ensure that no radiological impact beyond the established limits will occur?

(4) Does the facility incorporate design characteristics in order to allow for regular inspection of the waste packaging conditions, for development of maintenance actions, for retrievability, reconditioning and transport, if necessary, and for adequate radiological surveillance?

(5) For fissile material, is special attention given to avoiding (i) the risk of criticality, even in the case of natural phenomena, and (ii) the risk of heating beyond the design safety limits?

(6) Does the operator understand the role to be accomplished by the storage facility within the waste management process, providing for features that allow for:
   (i) Proper confinement of the waste during the storage period?
   (ii Monitoring of the waste as required?
   (iii) Facilitation of the next steps to be accomplished within the waste management process, i.e. decay until clearance, authorized discharge or authorized disposal?

(7) Has the design of the facility taken into account the type of radioactive waste to be stored, its characteristics and associated hazards, its inventory and anticipated storage period, and have the appropriate technical and engineered features been provided?

(8) Has the design of the facility taken into consideration the purpose of storage of the waste, i.e. to make possible retrievability of the waste for authorized discharge, authorized use or clearance, for processing or disposal at a later time?

(9) Have provisions been made by the operator for regular monitoring, inspection and maintenance of the waste packaging and the storage facility to ensure continued integrity of the waste?

(10) Are procedures in place to deal with the adequacy of storage capacity (with account taken of the predicted waste arisings including in accident conditions), the expected lifetime of the storage facility and the availability of disposal options?

(11) In those cases in which the storage facility has been proposed to store radioactive waste for an extended period of time, have provisions (technical and managerial) been made in order to ensure the protection of present and future generations?

(12) Have provisions been made in the design of the facility to deal adequately with liquid waste and gases arising from the waste?

Radioactive waste acceptance criteria

II–12. Topical issues:

(1) Do the actual characteristics of the waste accepted for storage in the facility (waste packages or unpackaged waste) meet those characteristics taken into account in the development of the safety case?
(2) Is the operator acquainted with the classification system and acceptance criteria for disposal of radioactive waste established by the regulatory body and are these applied to the facility?
(3) Does the operator know the waste acceptance criteria in terms of radiological, mechanical, physical, chemical and biological properties or any other applicable characteristics for waste packages or unpackaged waste?
(4) Does the operator know the role of the waste acceptance criteria to ensure the safe handling and storage of waste packages and unpackaged waste, in normal and abnormal conditions, and for disposal?
(5) Is the operator acquainted with the process for approval of the waste acceptance criteria by the regulatory body? Does the operator know and apply the provisions to be made for identifying, assessing and dealing with waste or waste packages that do not meet process specifications or disposal criteria?
(6) Has the operator put in place adequate procedures and instructions to determine the need for waste processing after storage to meet the acceptance criteria and are staff properly trained to follow these procedures?
(7) Has the operator put in place adequate provisions for identifying, assessing and dealing with the waste acceptance criteria (radiological, mechanical, physical, chemical and biological) established by the regulatory body?
(8) Has the operator put in place adequate procedures and instructions to certify that the final product arising from waste processing meets the acceptance criteria (radiological, mechanical, physical, chemical and biological) established by the regulatory body?
(9) The regulatory body has to implement procedures (on-site surveillance, package testing) in order to ensure that the waste or the waste packages meet the required acceptance criteria for storage.
(10) Is the operator acquainted with the IAEA transport regulations [II–2] and other international or national standards applicable, and does it meet their provisions adequately, where applicable?

Facility siting and design

II–13. Topical issues:

(1) Does the operator demonstrate, through the analyses carried out during the siting and design stages, that safety standards will be met in both the operational and decommissioning stages? Is emphasis placed on the use of the concept of defence in depth in the design of the facility?
(2) Does the operator clearly identify those features that have been incorporated into the design of the predisposal waste management facility to deal with (and which are largely dependent upon) the properties, total inventory and hazard potential of the radioactive waste and to meet the requirements of the regulatory body?
(3) Is the need for operational maintenance, testing, examination and inspection from the concept design stage onwards adequate to meet the safety requirements?
(4) Does the operator understand the overall process for siting of storage facilities for radioactive waste and the issues that need to be considered, such as:
    (i) Investigation of the proposed region to evaluate its present and foreseeable future characteristics, population distribution and the present and future uses of land and water?
    (ii) Determination of ambient levels of radioactivity in the region as a baseline for future investigations?
    (iii) Estimation of expected and potential releases of radioactive material via direct and indirect pathways?
    (iv) Exposure of the population for operational states of the facility as well as under accident conditions?
    (v) Evaluation of potential effects of natural and human induced external events (e.g. seismic events, meteorological events, geotechnical impacts, aircraft crashes, explosions)?
    (vi) The likely period of storage, the use of passive safety features, the potential for degradation during that period and consideration of natural site characteristics that could impact on performance, such as geology, hydrology and climate?

Facility construction and commissioning

II–14. Topical issues:

(1) Does the operator have in force the technical and management systems necessary to ensure that the facility is constructed according to the design approved by the regulatory body and as described in the approved safety case and safety assessments? Does the operator also demonstrate that the construction of the facility will be carried out in such a way as to provide reasonable assurance of safety during the operational period and decommissioning?

(2) Does the operator demonstrate that the responsibility of the operator for constructing the facility and performing any verification or test that needs to be performed (welds, foundation, etc.) is clearly allocated? Does the operator also demonstrate that it is responsible for and is acquainted with the evidence required by the regulatory body to prove it complies with its responsibility during construction?

(3) Does the operator know and demonstrate to the regulatory body how the process of commissioning has been organized in the facility? Does the operator describe the stages carried out within the frame of the commissioning process for the facility, i.e. as applicable, completion and inspection of construction, equipment testing, performance demonstration, inactive commissioning (without radioactive waste) and active commissioning (with radioactive waste)?

(4) Has the operator appropriately documented in the final commissioning report the predisposal waste management facility under its responsibility?

(5) Does this documentation include:
   (i) The as-built status of the facility, which, in addition to providing information to facilitate operation, is important when considering possible future modifications, shutdown and decommissioning of the facility?
   (ii) All testing carried out and evidence of its successful completion and of any modifications made to the facility or procedures during commissioning?
   (iii) The evidence providing assurance that all the conditions of authorization have been satisfied?

(6) Does the operator also demonstrate to the regulatory body the arrangements that have been made for this report to be maintained by the operator as part of the documentation needed for the operation and the development of the decommissioning plan of the facility, and is the regulatory body regularly updated in the process?

(7) Does the documentation presented by the operator set out clear information on the codes and standards that are used to choose structural materials, fabrication and construction techniques, and testing procedures?
(8) Does the operator also clearly present the considerations given to the potential effects that the waste, any associated material and the environmental conditions may have on the capabilities of any safety related features of the facility to perform their intended functions (e.g. prevention of high temperature corrosion of material and mitigation of adverse consequences of irradiation in high radiation fields)?

Facility operation

II–15. Topical issues:

(1) Do the operational procedures proposed for the facility or activity comply with the requirements in force and the conditions approved by the regulatory body, during both the operational period and the decommissioning stage? Does the operator also provide for regular updating of these operational procedures in the light of operational experience?
(2) Does the operator:
  (i) Ensure that all operations and activities important to safety are subjected to documented limits, conditions and controls, and are carried out by trained personnel?
  (ii) Describe how and where the operational limits, conditions and controls for the operation of the facility or activity are documented?
  (iii) Ensure that positions with responsibility for safety are properly qualified and authorized?
  (iv) Describe how documented operating procedures and emergency plans are developed (by the operator) and approved by the regulatory body?
  (v) Ensure that a programme of periodic maintenance, testing and inspection of systems that are essential to safe operation is included in the documented procedures?
(3) Has the operator put in place a technical or management system to ensure active control of safety by the operator for as long as the facility or activity remains under regulatory control?
(4) Does the operator take into consideration, in the safety features proposed for the facility and the safety assessment carried out, the prevention of criticality and adequate heat removal in the management of high level waste?

Facility shutdown and decommissioning

II–16. Topical issues:

(1) Does the documentation presented by the operator for licensing already contemplate the lifetime of the facility, including all stages, from design to shutdown and decommissioning? Is the operator aware of the need to obtain approval for such steps and periodically to update the plans for shutdown and decommissioning?
(2) Is the operator aware of the need to take into consideration in the planning and design of the facility the decommissioning stage, addressing specifically:
    (i) The procedure for the development of the decommissioning plan?
    (ii) Demonstration that the decommissioning plan can be accomplished safely?
    (iii) How the need for decommissioning was taken into account during the planning and construction stages of the facility?
(3) Will the shutdown and decommissioning of the facility take place in accordance with the conditions set by the regulatory body?
(4) Is the operator aware of its responsibility within this process and are adequate procedures in place for clear allocation of responsibility in the case of transfer of ownership of the facility?
(5) Does the operator report to the regulatory body any updating of the decommissioning plan and does this updating particularly contemplate changes in the facility or regulatory requirements, advances in technology and needs of the decommissioning activities?

Accounting and control for nuclear material

II–17. Topical issues:

(1) Does the operator take into consideration requirements for accounting and control of nuclear material, when applicable, in the design and operation of the facility or activity?
(2) Does the operator demonstrate how it is ensured that requirements for accounting and control of nuclear material are implemented in such a way as not to compromise the safety of the facility or activity?
(3) Has the operator, when applicable, put in place in the facility an adequate system for accounting and control of nuclear material that takes into account, among other issues:

(i) Provisions for accountability for nuclear material through the implementation of requirements for accounting and control of nuclear material, in order to ensure the prompt detection of any diversion of nuclear material to unauthorized or unknown purposes in the short and medium term?
(ii) How active surveillance and controls on which measures for accounting and control for nuclear material depend are organized in the facilities or activities?
(iii) How surveillance measures for waste containing fissile materials are implemented in the facility for ensuring continuity of knowledge of fissile materials and the absence of any undeclared practices at the site relating to such material?

Existing facilities or activities

II–18. Topical issues:

(1) Does the operator perform all of the regulatory steps to ensure adequate safety levels for existing facilities or activities and compliance with the safety requirements established by the regulatory body?
(2) Is the facility or activity within a regulatory process that covers the review of an existing safety case or the elaboration of a new one, as well as all of the supporting safety assessments? This process needs to be started by the regulatory body, in order for the existing facility to comply with all of the safety requirements established for predisposal waste management facilities or activities.
(3) Does the operator indicate the additional operational restrictions, modifications or decisions that have been identified or implemented on the basis of the regulatory process in force?
(4) Does the operator carry out, for the facilities or activities under its responsibility, regular safety reviews and safety upgrades in accordance with the requirements specified by the regulatory body?

REFERENCES TO ANNEX II

[II–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, IAEA International Law Series No. 1, IAEA, Vienna (2006).

[II–2] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2012 Edition, IAEA Safety Standards Series No. SSR-6, IAEA, Vienna (2012).

Annex III

SAMPLE TEMPLATE FOR A REGULATORY REVIEW REPORT

1. INTRODUCTION

A brief description of the purpose and background of the review, titles and developers of reviewed documents, information on organizations involved in the review, etc.

2. SCOPE AND OBJECTIVES OF REVIEW

A description of the documents reviewed, high level objectives of the review (including reference to the applicable regulatory requirements), a general overview of the review process as it relates to the scope, etc. If the review report is either a summary (e.g. the final report before licensing) or a partial review report that has other supporting review reports that have previously been completed, they are described here with their general scope and applicability.

3. APPLICABLE REGULATORY REQUIREMENTS

A list of regulations, established procedures and/or international recommendations for review to be followed. Summaries of the key points of the regulations, procedures and/or international recommendations could be included.

4. REVIEW METHODOLOGY AND PROCESS

A description of the review procedure including the review plan and possible steps (primary review, main review, review of improved document), interactions with developer of the safety case, categorization of comments, requirements on comment format and indication, interactions within review team, etc., as well as any guidance documents used in the review.

5. MAIN RESULTS OF EVALUATION

A description of each of the areas reviewed, with reference to the particular areas (including the degree to which the response of the applicant resolved those issues).

6. KEY COMMENTS

General comments summarizing the main deficiencies of the reviewed documents.

6.1. Specific comments

More detailed comments on specific chapters of the reviewed documents or areas of investigation.

6.2. Unresolved comments

Comments that remain unresolved. Their relative safety significance should be noted and what actions will be taken to resolve the comments, if necessary. Any conditions for authorization are placed, described and justified here.

7. CONCLUSIONS AND RECOMMENDATIONS

Conclusions of the review and recommendations for authorization conditions.

Annex IV

SAFETY ASSESSMENT DRIVING RADIOACTIVE WASTE MANAGEMENT SOLUTIONS: FRAMEWORK FOR THE OVERALL PROCESS

INTRODUCTION

IV–1. In this annex, a framework for the overall process of predisposal waste management is developed. This can serve as a basis for developing guidelines for the application of existing safety assessment methodologies and the identification of what is needed with regard to safety justification. The emphasis lies on waste orientated activities, and other aspects such as political considerations and engineering aspects are not considered

IV–2. In support of this activity, flow charts have been developed covering the main steps in predisposal waste management. A description of the individual elements and their relationships within the overall scheme is provided in paras IV–4 to IV–42.

IV–3. In paras IV–43 to IV–46 and Tables IV–1 to IV–8, for each predisposal activity shown in the flow charts in Figs IV–1 to IV–6, the following aspects are addressed:

(1) Identification of necessary safety assessments;
(2) Compilation of decisions that have to be made on the basis of these safety assessments and for which, consequently, the safety assessments have to provide a basis;
(3) General aspects for the assessment context of these safety assessments (further detail will be provided as part of subsequent activities within the IAEA SADRWMS project).

FRAMEWORK

IV–4. Figures IV–1 to IV–6 provide an overview of predisposal waste management activities. Figure IV–1 describes the general process. Figures IV–2 to IV–6 provide details for the individual process steps defined in Fig. IV–1.

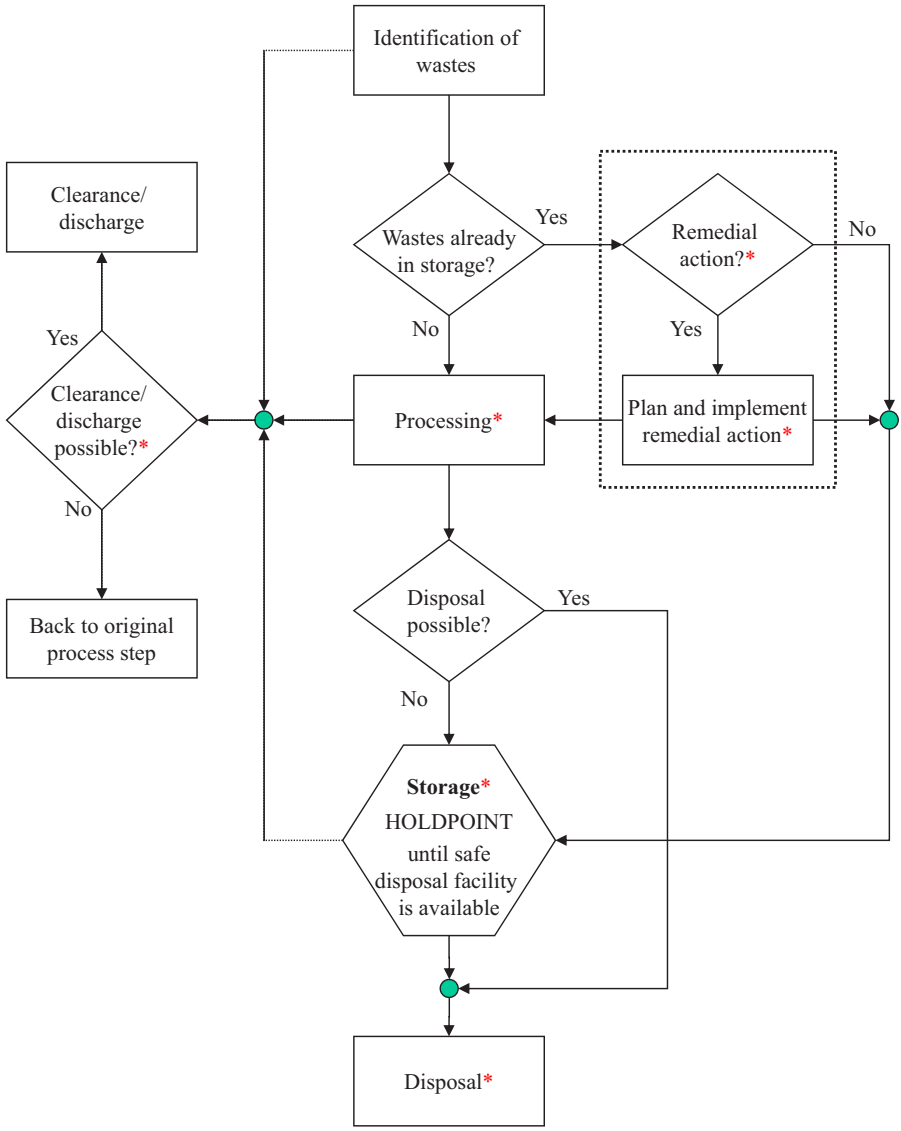

FIG. IV–1. Overall process (asterisks indicate activities that necessitate further steps which have decisions and safety assessments associated with them, as shown in Figs IV–2 to IV–6 (see also footnote 1 on p. 133)).

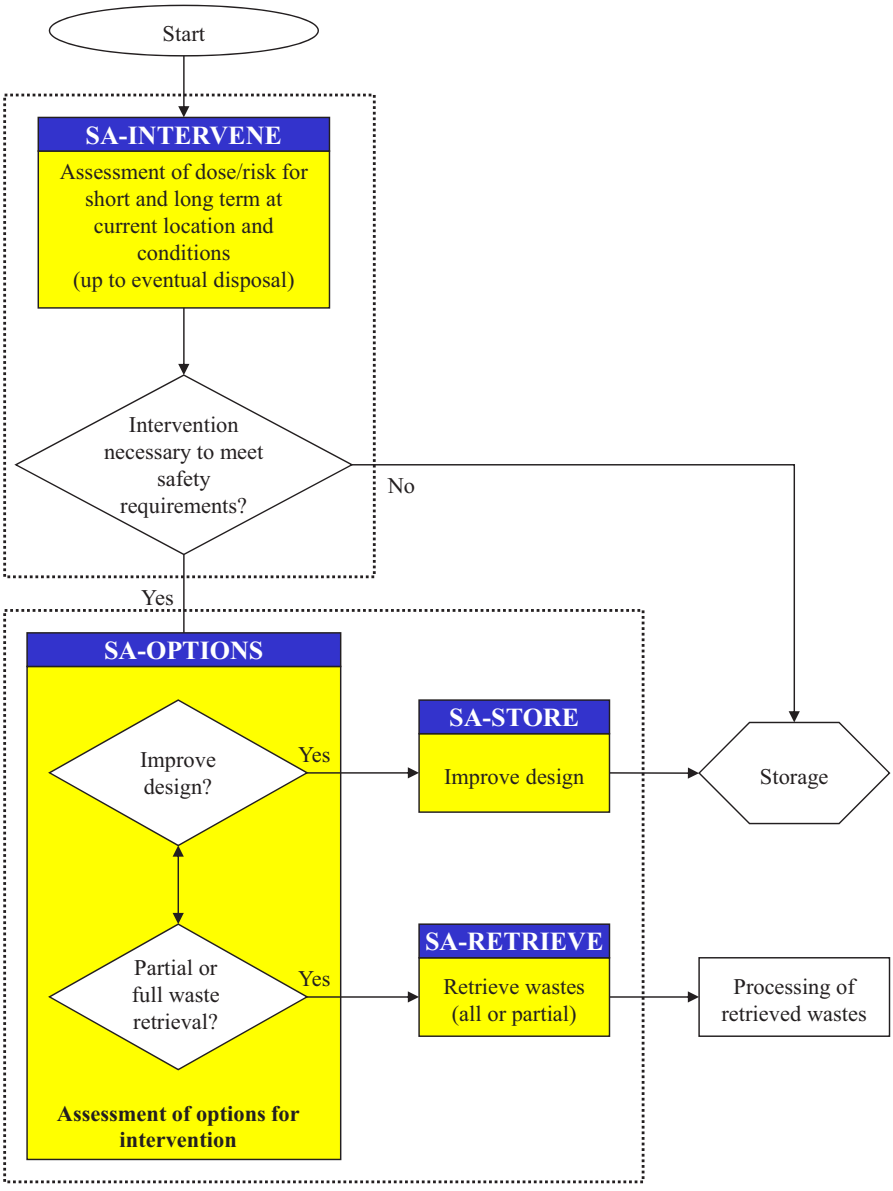

FIG. IV–2. Remedial action.

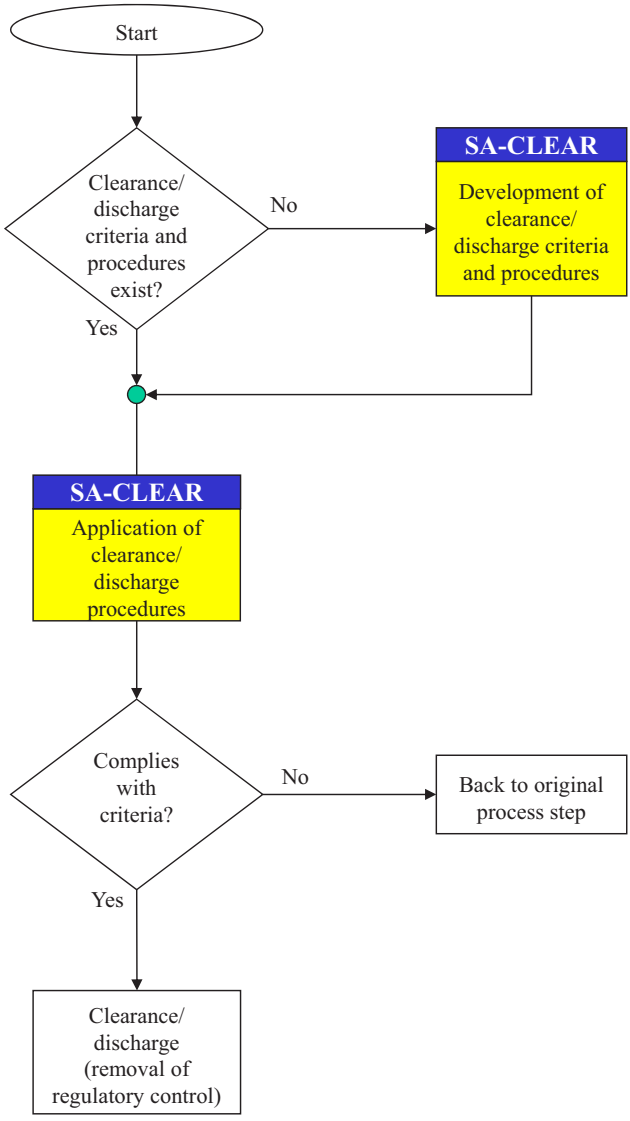

FIG. IV–3. Clearance/discharge possible.

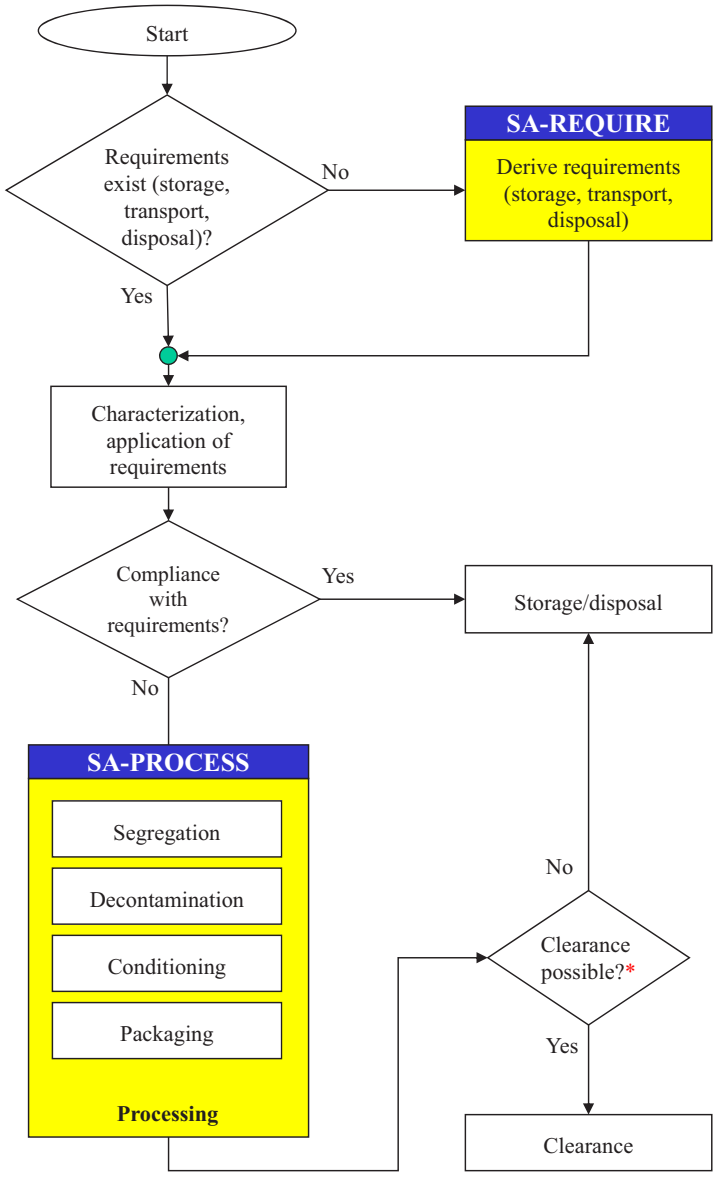

FIG. IV–4. Processing (the asterisk indicates activities that necessitate further steps which have decisions and safety assessments associated with them (see also footnote 2 on p. 145)).

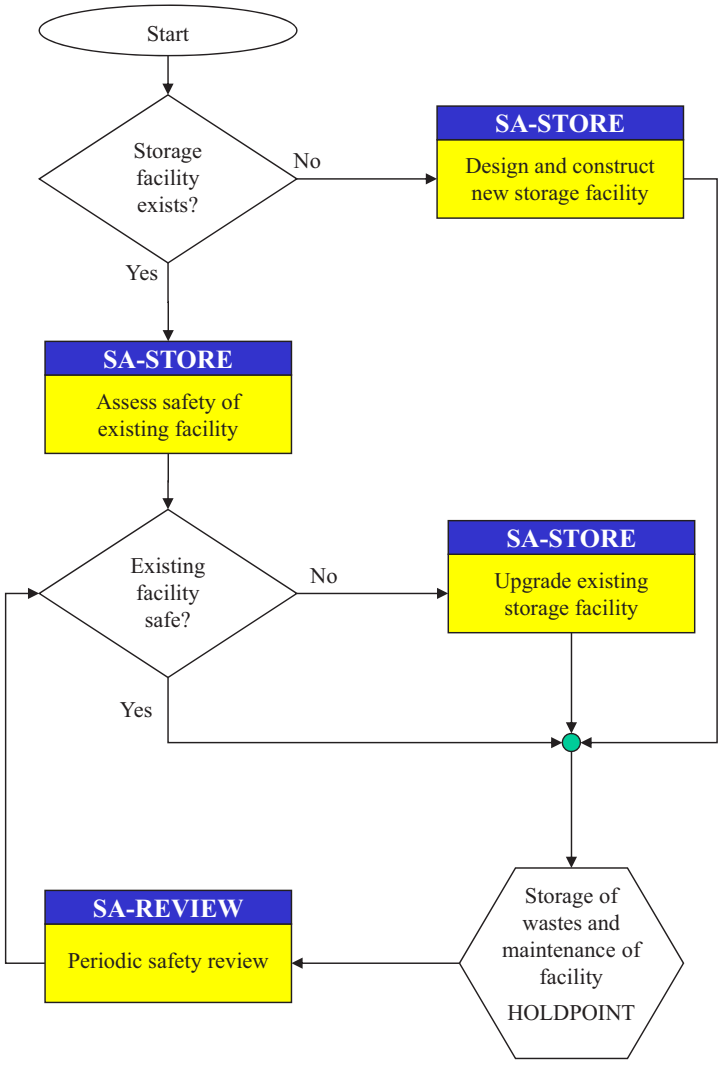

FIG. IV–5. Storage.

IV–5. Figures IV–2 to IV–6 indicate activities requiring safety assessment by boxes with a coloured background. An acronym identifying the type of safety assessment required is indicated at the top of each of these boxes.

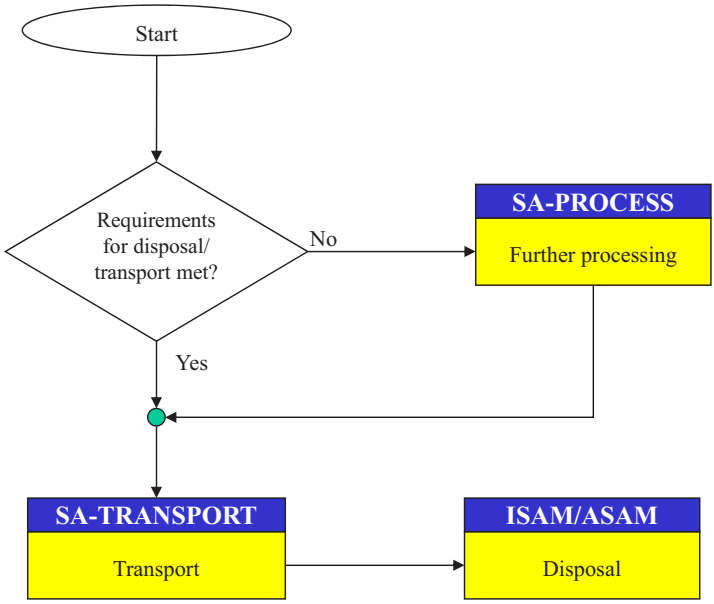

FIG. IV–6. Disposal.

IV–6. A description of the activities indicated in the flow charts is provided below. The purpose and scope of the required safety assessments is described in Tables IV–1 to IV–8.

Overall process

IV–7. The first activity in the overall flow chart shown in Fig. IV–1 is identification of the type of waste. This has to address all of the parameters for the particular type of waste that are required to decide about its classification in terms of the flow chart.

TABLE IV–1. ASSESSMENT CONTEXT FOR SA-INTERVENE

Assessment of safety of waste stored in an existing facility	**SA-INTERVENE**
Purpose of assessment	To determine whether the existing situation is acceptable from a safety and security point of view or whether corrective action to upgrade safety and/or security measures is necessary. Note: The identification of the required corrective action is not part of this assessment (see SA-OPTIONS).
Assessment end points	Assessment of impacts from the facility in current conditions and from possible changes (e.g. degradation of barriers, external or internal events). Possible end points include: — Radionuclide releases from the storage facility; — Radionuclide concentrations in the surrounding environment; — Doses and risks to workers for activities such as maintenance and surveillance; — Doses to the public (potential exposure or actual exposure of a member of a certain group); — Doses to non-human biota; — Level of security at the facility.
Assessment philosophy	— Use of cautious assumptions, but in view of the intervention situation, these need to be as realistic as possible; i.e. the existing situation has to be addressed realistically and cautious assumptions only used to the extent that impacts from events and processes potentially affecting the assessment end points need to be assessed. — Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site specific data are not available (e.g. data concerning the impact of potential events and processes or data such as the contents of waste packages that cannot be measured at this stage) or to cases in which site specific sampling and measurements are not warranted by the importance of the data for the assessment results.

TABLE IV–1. ASSESSMENT CONTEXT FOR SA-INTERVENE (cont.)

Assessment of safety of waste stored in an existing facility	**SA-INTERVENE**
Assessment time frames	Anticipated time frame for establishing a disposal facility and for commencing the retrieval of the waste. Note: Frequently existing uncertainties in this respect are accounted for by using a contingency allowance.
Remarks	The aim of this assessment is only to determine whether there is a need for intervention. If this need is shown, SA-OPTIONS will be used to compare available intervention options and to lead to the identification of the upgrading option to be implemented.

IV–8. An important distinction arises between waste types that already exist and which are kept in a storage facility, as opposed to waste that is newly generated. In cases of existing waste that has been put into a storage facility in the past, the safety and security of these storage arrangements may not be adequate based on current standards. This may require remedial action to upgrade safety and security measures by changes in the condition of the waste, improvements of the storage facility and/or retrieval of the waste and storage in another facility.[1]

IV–9. For new waste as well as for waste retrieved from an old storage facility, the next step is to determine whether processing is required and, if so, which type of processing is necessary to allow for safe and secure storage of the waste. Ideally, the processing of the waste will also be planned and conducted such that the waste is suitable for later transport and disposal.

[1] The decision to consider remedial action, i.e. an intervention, for waste already in storage, as shown in Fig. IV–1, does not apply to waste that is in interim storage pending processing within a predisposal waste management activity. Rather, it applies to waste for which the decision to store it in its current form has already been made, so that any changes would be considered an intervention. Waste in interim storage would be treated in the same way as newly arising waste within an activity and it would be decided at the processing decision point whether processing is required.

Text cont. on p. 142

TABLE IV–2. ASSESSMENT CONTEXT FOR SA-OPTIONS

Assessment of options to upgrade safety	**SA-OPTIONS**
Purpose of assessment	— To identify options to improve the existing situation of waste stored in the facility and/or the condition of the facility itself by: • Improving the design of the facility; and/or • Retrieving part or all of the waste from the facility. — To compare identified options and to determine the optimal option with regard to all attributes relevant for the specific situation (doses, risks, costs, etc.).
Assessment end points	— Assessment of the retrieval of waste and/or upgrading of the facility (to the extent that these are within the scope of options considered). Possible end points include: • Radionuclide releases caused by the retrieval and upgrading operations; • Radionuclide concentrations in the surrounding environment; • Doses and risks to workers during waste retrieval and upgrading of the facility; • Doses to the public (potential exposure of a group member); • Doses to non-human biota. — Assessment of impacts from the upgraded facility (i.e. improved design and/or partially retrieved waste). Possible end points include: • Radionuclide releases from the storage facility; • Radionuclide concentrations in the surrounding environment; • Doses and risks to workers for activities such as maintenance and surveillance; • Doses to the public (potential exposure of a group member); • Doses to non-human biota; • Level of security at the facility. — Assessment of processing, storage or disposal of the retrieved waste (to the extent that waste retrieval is within the scope of options considered). Note: The necessity and scope of this part of the assessment will be very case specific and will depend on whether capacities for waste processing, storage or disposal already exist. In any case, it is important to include the fate of the retrieved waste (in particular, doses, risks and costs incurred by their management) into the comparison of options for intervention.

TABLE IV–2. ASSESSMENT CONTEXT FOR SA-OPTIONS (cont.)

Assessment of options to upgrade safety	**SA-OPTIONS**
Assessment philosophy	— Use of cautious assumptions, but in view of the intervention situation these need to be as realistic as possible (see Table IV–1): • The comparison of options has to be based in general on realistic assumptions; • The assessment of compliance with regulatory standards within each of the options considered will require sufficiently cautious assumptions. — Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site specific data are not available (see Table IV–1).
Assessment time frames	— Assessment of the retrieval of waste and/or upgrading of the facility: duration of these activities. — Assessment of impacts from the upgraded facility: anticipated time frame for establishing a disposal facility and for starting the retrieval of waste (including contingency allowance, see Table IV–1). — Assessment of processing, storage or disposal of retrieved waste: case specific (see above).
Remarks	— This assessment will only be required if the results of SA-INTERVENE indicate the need for intervention. — The actual planning of the measures to upgrade the facility and/or to retrieve the waste is not part of this safety assessment (see SA-STORE, SA-RETRIEVE). Thus, assessments of these activities are required only to the extent and depth of allowing for a comparison of options. Detailed planning will only be necessary for the option identified as optimal (i.e. the option that is going to be implemented).

TABLE IV–3. ASSESSMENT CONTEXT FOR SA-RETRIEVE

Assessment of waste retrieval	**SA-RETRIEVE**
Purpose of assessment	— Assessment of the safety of retrieval operations, to allow for their detailed planning. — Establishment of: • Limits (qualitative or quantitative restrictions to any part of the activity, which are applied to ensure compliance with safety principles and requirements); • Controls (processes, procedures or other instruments that are put in place to ensure compliance with safety principles and requirements); • Conditions (prerequisites, requirements for functions, facilities or organizations that must exist to ensure safety) for the retrieval operations.
Assessment end points	Assessment of the retrieval operations. Possible end points include: — Radionuclide releases caused by the retrieval and upgrading operations; — Radionuclide concentrations in the surrounding environment; — Doses and risks to workers during waste retrieval and upgrading of the facility; — Doses to the public (potential exposure of a group member); — Doses to non-human biota.
Assessment philosophy	— Use of cautious assumptions, but, in view of the intervention situation, these should be as realistic as possible (see Table IV–1). — Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site specific data are not available (see Table IV–1).
Assessment time frames	Duration of retrieval activities.
Remarks	The assessment of the fate of retrieved waste is not part of this safety assessment. This will be covered by other relevant safety assessments addressing the management steps for such waste, i.e. its clearance, discharge, processing, storage, transport and disposal.

TABLE IV–4. ASSESSMENT CONTEXT FOR SA-CLEAR

Derivation of clearance and discharge levels and procedures	**SA-CLEAR**
Purpose of assessment	For clearance: — To establish generic clearance levels for waste in general or for certain waste types, possibly also including certain restrictions on clearance (e.g. clearance levels for metal scrap subject to smelting); or — To determine whether unconditional or conditional clearance of certain types of waste is possible (i.e. whether this particular waste type complies with criteria for clearance). For discharges: — To establish general or facility specific discharge limits. For clearance and discharges: — To develop clearance and discharge procedures (in particular the type and extent of required measurements and monitoring).
Assessment end points	Assessment of exposure from waste after clearance or discharge. Possible end points include: — Doses to the public (potential exposure of a group member). Note: For clearance, scenarios are to be determined on the basis of the type of material and the possible (for unconditional clearance) or the restricted (for conditional clearance) options for disposal and recycling of the material.
Assessment philosophy	— In general, cautious assumptions are used. However, in particular when applying the low dose levels that meet the criteria for clearance, overly conservative assumptions should be avoided (see Ref. [IV–1]). — For generic clearance levels and discharge limits as well as for addressing the unconditional clearance of certain waste types, necessarily generic data have to be used. The use of site specific data will only be possible for certain cases of conditional clearance (i.e. when the recycling or disposal routes are known and will be ensured by regulatory provisions) and for facility specific discharge limits.

TABLE IV–4. ASSESSMENT CONTEXT FOR SA-CLEAR (cont.)

Derivation of clearance and discharge levels and procedures	**SA-CLEAR**
Assessment time frames	— Dose assessments for clearance, in principle, have to be carried out for unlimited time frames. However, in practice, limitations of time frames to be considered arise from the half-lives of the radionuclides involved and from the fact that within the scenarios usually considered the highest exposures arise immediately or shortly after clearance (exception: water pathways). — For discharges, exposures usually occur within short time frames, with the exception of exposures resulting from the accumulation of radionuclides in the environment (e.g. through adsorption by river sediments or ground deposition of aerosols). The latter case has to be treated in analogy to clearance.
Remarks	— As shown in Fig. IV–1, clearance and discharges can be a waste management option at all stages of the overall process. The derivation of general clearance levels and discharge limits is often easier and more effective than addressing clearance at each individual process stage. — Since scenarios and dose assessments used for the derivation of clearance levels are usually very general, it appears to be adequate for most cases to use generic clearance levels derived on an international basis (e.g. Ref. [IV–1]). Specific assessments can then be limited to particular waste types or to establishing levels for conditional clearance. — The development of clearance procedures in general will have to consider waste types and radionuclides of interest in order to determine adequate sampling and measurement procedures.

TABLE IV–5. ASSESSMENT CONTEXT FOR SA-REQUIRE

Derivation of requirements (for storage, transport and disposal)	**SA-REQUIRE**
Purpose of assessment	Derivation of requirements for different waste management steps: — Storage; — Transport; — Disposal in order to define waste processing requirements.
Assessment end points	End points depend on specific activity considered (see remarks).
Assessment philosophy	— In general, cautious assumptions are used. — Data are either generic (for waste management activities not addressing a specific facility) or site specific (when deriving requirements for a particular facility).
Assessment time frames	Time frames depend on the specific activity considered (see remarks).
Remarks	— The derivation of requirements will be part of the safety assessments conducted for the different waste management activities (see SA-STORE, SA-TRANSPORT, and ISAM [IV–4] and ASAM). End points and time frames considered will be determined as part of these assessments. — The derived requirements are either of a generic nature (such as in the case of transport) or are based on safety assessments for specific storage or disposal facilities and are, therefore, only valid for certain waste management routes. — The derived requirements have to be sufficiently specific to determine the type and extent of waste processing required.

TABLE IV–6. ASSESSMENT CONTEXT FOR SA-PROCESS

Assessment of processing of wastes	**SA-PROCESS**
Purpose of assessment	— Siting guidelines and/or site selection for the waste processing facility; — Assessment of the safety of the waste processing operations, to allow for their detailed planning; — Establishment of: • Limits; • Controls; • Conditions for the waste processing operation.
Assessment end points	Assessment of the waste processing operations. Possible end points include: — Radionuclide releases caused by the waste processing operations; — Radionuclide concentrations in the surrounding environment; — Doses and risks to workers during waste processing; — Doses to the public (potential exposure of a group member); — Doses to non-human biota.
Assessment philosophy	— In general, cautious assumptions are used. — Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site specific data (e.g. data concerning the impact of potential events and processes) are not available or to cases in which the collection of data concerning the waste to be processed are not warranted by the importance of the data for the assessment results.
Assessment time frames	Duration of the waste processing activities.
Remarks	The necessary type and extent of waste processing depend on the requirements derived for subsequent waste management steps (see Table IV–5).

TABLE IV–7. ASSESSMENT CONTEXT FOR SA-STORE

Assessment of storage of wastes	**SA-STORE**
Purpose of assessment	— Siting guidelines and/or site selection for the storage facility; — Assessment of the safety of the waste storage, allowing for detailed planning; — Establishment of: • Limits; • Controls; • Conditions for the waste storage.
Assessment end points	Assessment of the storage facility. Possible end points include: — Radionuclide releases caused by the storage operation and the stored waste; — Radionuclide concentrations in the surrounding environment; — Doses and risks to workers during activities involved in storage of the waste and for activities such as maintenance and surveillance; — Doses to the public (potential exposure of a group member) during the storage operation and during the storage period; — Doses to non-human biota; — Level of security at the facility.
Assessment philosophy	— In general, cautious assumptions are used. — Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site specific data are not available (e.g. data concerning the impact of potential events and processes) or to cases in which the collection of data concerning the waste to be stored is not warranted by the importance of the data for the assessment results.
Assessment time frames	Anticipated time frame for establishing a disposal facility (including contingency allowance (see Table IV–1)).
Remarks	Controls and conditions for the safety of waste storage will require regular review. These are addressed in SA-REVIEW (Table IV–8).

TABLE IV–8. ASSESSMENT CONTEXT FOR SA-REVIEW

Assessment of regular safety reviews of a storage facility	**SA-REVIEW**
Purpose of assessment	To determine the frequency and scope of the required regular reviews of the safety of a waste storage facility.
Assessment end points	Assessment end points are identical to those addressed in SA-STORE (Table IV–7) concerning the waste storage period.
Assessment philosophy	Identical to SA-STORE.
Assessment time frames	Identical to SA-STORE.
Remarks	— This safety assessment addresses the same events and processes as already considered in SA-STORE. Therefore, it will usually be conducted in combination with or even as part of SA-STORE. — During the regular reviews, assumptions made in the underlying safety assessments (SA-STORE, SA-REVIEW) may turn out to be inadequate (e.g. neglecting certain events or processes, overly conservative assumptions). This may require updates of these safety assessments and additional measures to maintain safety.

IV–10. After processing to the extent required, the waste will be put into a storage facility unless direct disposal is possible. This storage facility serves as a holdpoint for the time required to establish a suitable disposal facility.

IV–11. During all the stages of this process, it may be possible to clear the waste, i.e. to remove it from regulatory control and dispose of it as non-radioactive waste or to recycle the waste material (e.g. in the case of metals). Clearance from regulatory control is a waste management option that may be available already at the very beginning of the process, i.e. following identification of the waste. Alternatively, clearance may be considered at later stages of the process because the option to clear waste may only be available after processing of the waste (segregation, decontamination) or after storage for radioactive decay.

IV–12. For liquid or gaseous waste, an analogous waste management option is their discharge. As described for clearance above, discharge may be an option at any stage of the overall process. Examples of discharge of waste at later stages are discharge of liquid or gaseous waste arising during waste management

activities (in particular, processing) and discharge of liquids after storage for radioactive decay.

Waste identification

IV–13. In order to determine adequate management options for the waste in question, several of its key characteristics need to be known, such as:

(1) Liquid, solid or liquid/solid mixture?
(2) High or low dose rate?
(3) Dominant radioisotopes: long lived or short lived?
(4) Flammable or non-flammable?
(5) Explosive or non-explosive?
(6) Containing alpha particles or not?
(7) Corrosive or non-corrosive?
(8) Gas emitter or non-gas-emitter?
(9) Fissile or non-fissile?
(10) Contained or not contained?
(11) Well contained or poorly contained?
(12) Records available?
(13) Waste properly labelled?

IV–14. Waste characterization at this stage is, however, only of a general nature and is performed only to the extent necessary to decide about the further course of action and about immediate measures that might be necessary (e.g. to improve security or emergency response provisions). The collection of detailed data is performed as part of the preparation of safety assessments at later stages of the process to avoid sampling and measurements that are unnecessary (e.g. detailed chemical and physical characterization of waste that is later identified as a candidate for clearance or discharge).

Remedial action

IV–15. In the case of waste in an old storage facility (not in interim storage as part of a current practice, as explained in footnote 1, para. IV–8), remedial action may be necessary to upgrade safety and security (see Fig. IV–2).

IV–16. The first question to be addressed is whether the existing situation is acceptable from a safety and security point of view or whether corrective actions to upgrade safety and security are necessary. This means that only the question of the necessity to consider corrective action is addressed, not the question of which

corrective action would be taken (in the event that this is considered necessary). The safety assessment required at this stage ('SA-INTERVENE') considers, in particular, doses and risks arising from the current location and condition of the waste. The time span to be considered reaches up to the time at which it is anticipated that a disposal facility for the waste will become available.

IV–17. If this safety assessment indicates the need for an intervention, it is necessary to identify and evaluate options to improve the situation ('SA-OPTIONS'). This may necessitate improvements in the design of the storage facility and/or the full or partial retrieval of the waste.

IV–18. In the event that an intervention is found to be necessary within SA-INTERVENE, this safety assessment will, in practice, probably be combined with the safety assessment SA-OPTIONS to determine the type and extent of intervention. Nevertheless, these two safety assessments have different scopes and will be carried out consecutively. They are treated separately from a methodological point of view.

IV–19. In the event that the waste is being retrieved from an existing storage facility, the retrieved waste will be treated analogously to newly arising waste, i.e. options for its processing and safe storage and, when available, disposal will be determined. Special safety considerations are, however, necessary for the retrieval of waste. This is the case particularly when waste was stored originally without or with only limited processing and in an unsuitable form (e.g. no packaging). The planning and execution of such retrieval activities will be based upon the safety assessment 'SA-RETRIEVE'.

IV–20. For the storage of wastes after retrieval and processing, the existing facility may be used, normally after the implementation of measures to upgrade its safety and security. Alternatively, such waste may be stored in another existing or in a new facility. The safety assessment 'SA-STORE' required at this stage is, in principle, identical to the safety assessment required for storage in the case of newly arising waste, which is discussed in paras IV–34 to IV–38.

Clearance or discharge

IV–21. Clearance (mainly for solid waste) and discharge (for liquid and gaseous waste) are important options for reducing the volume of waste to be stored and eventually to be disposed of. In some cases (e.g. stainless steel), the economic value may also provide an incentive to clear the waste.

IV–22. The first question shown in Fig. IV–3 is whether criteria and procedures for clearance or discharge, as appropriate, exist. If this is not the case, these need to be developed ('SA-CLEAR'[2]).

IV–23. With regard to clearance levels, the generic approaches recommended in Ref. [IV–1] can be applied. Alternatively, specific clearance criteria and procedures can be developed for certain waste types or for certain disposal or recycling options. In the latter case, criteria for conditional clearance may be derived, i.e. regulatory control will only be removed if the waste producer can assure the regulatory body that certain restrictions on the disposal or recycling of waste are being complied with.

IV–24. Guidance on the development of criteria and procedures for discharges is given in Ref. [IV–2].

IV–25. After the development of clearance and discharge criteria and procedures, the waste in question will be subject to these, and it will be determined whether clearance or discharge is possible. The aim of the safety assessment SA-CLEAR is to provide, as part of the developed procedures for sampling and measurements, requirements for this decision.

IV–26. If the waste complies with these criteria, it can be cleared or discharged. Otherwise, the waste remains within the overall scheme of radioactive waste management and will be subject to the appropriate processing step according to Fig. IV–1.

IV–27. In the case of unconditional clearance, the waste will be removed from regulatory control. For conditional clearance and discharge in general, some regulatory requirements will remain, such as ensuring that clearance and discharge are performed according to the specified restrictions and prescribing, in particular in the case of discharges, requirements for monitoring.

Processing

IV–28. Processing of waste consists of any operation that changes the characteristics of waste, including pretreatment, treatment and conditioning. The goal of processing is to modify the waste form, as necessary, to comply with the requirements for its storage, transport and disposal (Fig. IV–4).

[2] For the sake of brevity, the acronym for this safety assessment refers to clearance only, but criteria and procedures for discharges are also addressed as appropriate.

IV–29. If such requirements do not exist, they will need to be developed before any decision about waste processing can be made ('SA-REQUIRE'). As already stated, ideally at this stage, requirements for all further waste management steps — including transport and disposal — will be derived. This avoids the necessity of further processing of the waste at a later stage, which would be economically unfavourable and which would also, if avoidable, conflict with the overall requirement to optimize the process. In practice, however, this will not be possible in all situations, such as in the frequently occurring case in which a disposal facility or planning for such do not exist.

IV–30. After the development of requirements, or if these already exist, the waste in question will be characterized to the extent necessary in order to determine whether it complies with these requirements or not. The aim of the safety assessment SA-REQUIRE is to provide the necessary specifications for the required characterization.

IV–31. If the waste in its current form does not comply with the requirements, processing is necessary. This may involve the following main steps:

(1) Segregation of waste types that are subject to different types of treatment, clearance and/or discharge;
(2) Storage of the waste to allow radioactive decay to facilitate its treatment or allow for clearance or discharge;
(3) Conditioning and packaging of the waste.

IV–32. After processing, the waste will be sent for storage or disposal. Segregated or decontaminated portions of the waste that could potentially meet clearance or discharge levels will be subject to the application of clearance or discharge procedures (see paras IV–21 to IV–27).

IV–33. The detailed activities associated with waste processing can be quite complex. Depending on the nature of the waste and the required changes to its chemical and physical form, risks for workers as well as for the public and the environment will have to be considered. These are addressed in the safety assessment 'SA-PROCESS' carried out for the facility in which the waste processing is being performed and for all relevant activities therein.

Storage

IV–34. As already discussed in paras IV–7 to IV–12, storage of waste is considered only as a holdpoint until a disposal facility becomes available.

However, since in many States disposal facilities are not available and will not be available in the short term, safe and secure storage arrangements play an important role in the overall management of radioactive waste (Fig. IV–5).

IV–35. The first question arising is whether a storage facility already exists. In the case of an existing facility, it is necessary to assess whether this facility allows for safe and secure storage of waste. If this is not the case, upgrading of the facility will be necessary. In this case, the situation is comparable to what is set out in Fig. IV–2, for assessing the adequacy of storage arrangements for existing waste.

IV–36. If no facility exists so far, it will be necessary to design and construct a new facility, with account taken of the safety and security requirements for the particular types of waste that have to be stored.

IV–37. The safety assessment 'SA-STORE' for addressing the adequacy of a storage facility will be in principle identical in both cases. The main difference arises from the fact that assessments will be based on the current situation and on options for its improvement in the case of an existing facility, while for a new facility the intended design will form the basis for the assessment.

IV–38. After a storage facility has been commissioned, periodic safety review will be necessary in particular in the case of extended storage periods. Parameters that need to be addressed include changes in waste forms or containment structures as well as the appropriate functioning of all safety and security related systems. Details of the required review procedures will be determined by the safety assessment 'SA-REVIEW', which in most practical cases will be developed in conjunction with, or may even form a part of, SA-STORE.

Disposal

IV–39. The eventual target for radioactive waste is its safe disposal. When an adequate disposal facility exists, waste will be transported to this facility directly after processing or following a storage period.

IV–40. Further processing may be necessary in order to meet transport and disposal criteria, although this necessity should be avoided to the extent possible (see paras IV–28 to IV–33). If, however, additional processing is necessary, the type of activities and the safety assessment 'SA-PROCESS' required are identical to those described in paras IV–28 to IV–33.

IV–41. For the transport of waste, a safety assessment 'SA-TRANSPORT' will be necessary. This may be very simple for unproblematic waste, and will involve only demonstration that the criteria on activity contents, dose rates, etc., stipulated in the IAEA transport regulations [IV–3], are complied with. For more problematic waste (in particular for high level waste), more detailed assessments of the transport risks may be necessary.

IV–42. The eventual disposal of the waste will require a thorough safety assessment covering the operational phase of the repository as well as its long term safety. A methodology for this purpose was developed in the ISAM coordinated research project [IV–4] and its successor project ASAM. Consideration of this stage of radioactive waste management is outside the scope of the SADRWMS project.

PURPOSE AND SCOPE OF SAFETY ASSESSMENTS

IV–43. Based on the description of relevant waste management steps, the safety assessments identified as necessary for the individual process steps can be characterized with regard to the following aspects:

(1) Purpose of the safety assessment, i.e. questions that need to be addressed and answered;
(2) General aspects of the assessment context for each assessment.

IV–44. The different safety assessments are identified using the acronyms already defined. For each safety assessment, the following tables indicate key elements of their:

(1) Purpose;
(2) End points;
(3) Philosophy;
(4) Time frames.

IV–45. In addition, remarks concerning the contents of each safety assessment and the relationship to other safety assessments are provided.

IV–46. Some general aspects of the safety assessments are not mentioned in Tables IV–1 to IV–8, such as the regulatory framework as part of the assessment context and the use of the safety assessment to contribute to enhancing public

confidence. These will strongly depend on the specific conditions under which the assessments are undertaken.

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