IAEA Safety Standards

for protecting people and the environment

The Safety Case and Safety Assessment for the Disposal of Radioactive Waste

Specific Safety Guide

No. SSG-23

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

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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

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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 DISPOSAL 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. SSG-23

THE SAFETY CASE AND SAFETY ASSESSMENT FOR THE DISPOSAL OF RADIOACTIVE WASTE

SPECIFIC SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2012

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1400 Vienna, Austria
fax: +43 1 2600 29302
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
http://www.iaea.org/books

Printed by the IAEA in Austria
September 2012
STI/PUB/1553

IAEA Library Cataloguing in Publication Data

The safety case and safety assessment for the disposal of radioactive waste : specific safety guide. — Vienna : International Atomic Energy Agency, 2012.
p. ; 24 cm. — (IAEA safety standards series, ISSN 1020–525X ; no. SSG-23)
STI/PUB/1553
ISBN 978–92–0–128310–8
Includes bibliographical references.

1. Radioactive waste disposal — Safety regulations. 2. Radioactive substances — Transportation — Safety measures. 3. Radioactive substances — Security measures. I. International Atomic Energy Agency. II. Series.

IAEAL 12–00753

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 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

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

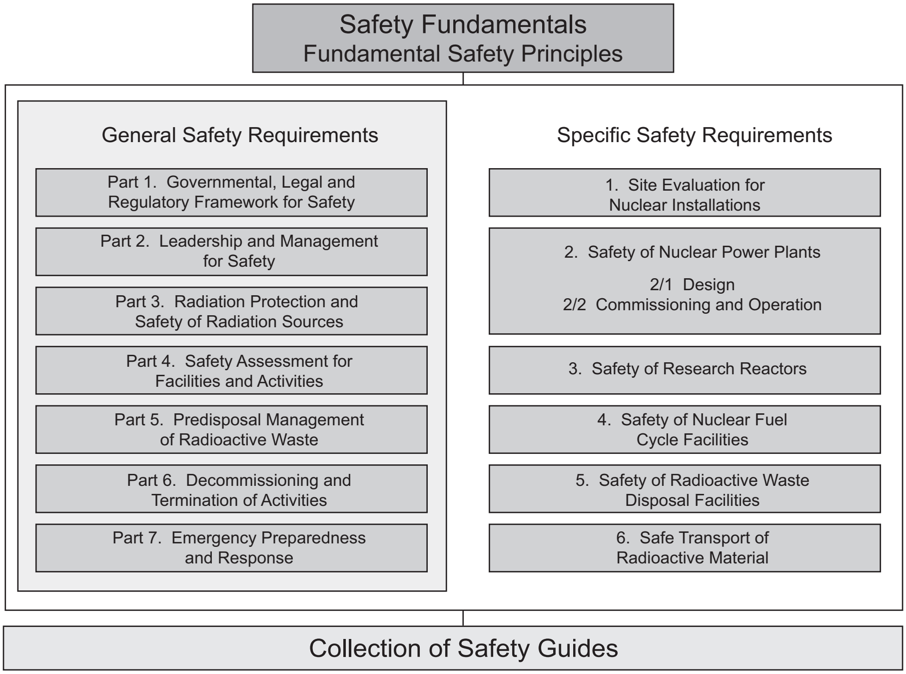

FIG. 1. The long term structure of the IAEA Safety Standards Series.

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).

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

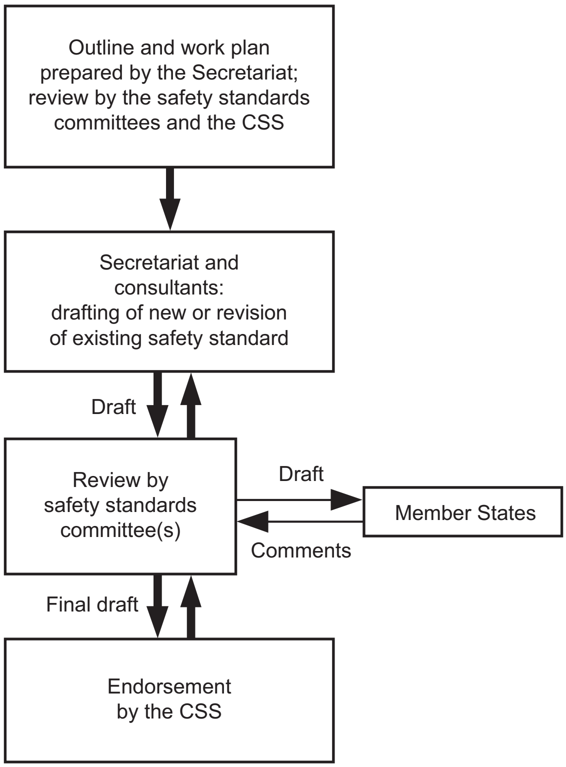

FIG. 2. The process for developing a new safety standard or revising an existing standard.

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. Disposal of radioactive waste represents the final step in its management, and disposal facilities are designed, operated and closed with a view to providing the necessary degree of containment and isolation[1] to ensure safety. The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation [1] and as a principle:

> "Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management" [1].

1.2. As for all facilities and activities involving radioactive material and radiation, the operator of a disposal facility has the prime responsibility for safety and has to assess the safety of the facility and demonstrate that the design and operation of the facility are compliant with the relevant safety requirements [1]. The safety requirements for radioactive waste disposal require, inter alia, that a safety case[2] be developed together with supporting safety assessment [2].

1.3. The safety case is the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a disposal facility, covering the suitability of the site 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 disposal facility. Safety assessment, an integral part of the safety case, is driven by a systematic

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[1] Containment denotes all methods or physical structures designed to prevent or control the release and the dispersion of radioactive substances. Isolation of the waste from the accessible biosphere substantially reduces the likelihood of inadvertent human intrusion into the waste and its consequences.

[2] The concept of developing a safety case for disposal facilities, as outlined in this publication, is used in many States. The terminology used is different, though, in some States. For example, in the United States of America the term 'total system performance analysis' is used (together with the regulations relevant to the specific disposal method), covering all aspects of the safety case as described in this Safety Guide. In France, the term 'dossier' is used to describe the safety case. In Germany and Switzerland, the term 'Sicherheitsnachweis' is used. In Spain, the term 'estudio de seguridad' is used to describe the safety case.

assessment of radiation hazards and is an important component of the safety case. The latter involves quantification of radiation dose and radiation risks that may arise from the disposal facility for comparison with dose and risk criteria, and provides an understanding of the behaviour of the disposal facility under normal conditions and disturbing events, considering the time frames over which the radioactive waste remains hazardous. 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 disposal facility, and will assist and guide decisions on siting, 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 disposal facility will be developed.

1.4. This Safety Guide provides guidance and recommendations on meeting the safety requirements in respect of the safety case and supporting safety assessment for the disposal of radioactive waste.

OBJECTIVE

1.5. The objective of this Safety Guide is to provide guidance on how to assess, demonstrate and document the safety of all types of radioactive waste disposal facility. The most important considerations when assessing the safety of radioactive waste disposal facilities after closure are identified, and guidance is provided on best practice in undertaking such assessment and presenting the safety case. This guidance is relevant for operating organizations, which bear the responsibility of preparing the safety case, as well as for the regulatory body, which is responsible for developing regulations and regulatory guidance that determine the basis and scope of the safety case. To further support regulatory processes, the Safety Guide also provides guidance on the review by the regulatory body of the safety case.

SCOPE

1.6. This Safety Guide covers the preparation of the safety case and supporting safety assessment for all types of radioactive waste that require specialized disposal facilities. The Safety Guide provides guidance and recommendations on all periods in the development of a disposal facility. The emphasis is on the performance of the disposal facility and the assessment of its impact after closure. Other relevant aspects, such as operational safety and non-radiological risks, are addressed but are not discussed in detail. Security aspects are also not discussed in detail although recommendations are provided on meeting the requirement for measures to be implemented to ensure an integrated approach to safety measures and nuclear security measures in the disposal of radioactive waste [2].

1.7. This Safety Guide also provides some recommendations on the involvement of interested parties, issues of communication of risk and approaches to decision making, as these are essential components of the decision making process in which the safety case is used. It also provides guidance and recommendations on the regulatory process.

STRUCTURE

1.8. Section 2 of this Safety Guide discusses the overall process of demonstrating the safety of a radioactive waste disposal facility. 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 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 closure of a disposal facility are described. Possibilities for building confidence in the safety case are also discussed. Section 5 addresses methodology for the assessment of radiological impact after closure, 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 radiological impact 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. Section 7 addresses documentation of the safety case, and indicates possible uses of the safety case in the development of the disposal facility. Section 8 provides guidance and recommendations on the regulatory review of the safety case.

2. DEMONSTRATING THE SAFETY OF RADIOACTIVE WASTE DISPOSAL

2.1. The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation [1]. Furthermore,

> "Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management" [1].

The preferred strategy for the management of all radioactive waste is to contain it and isolate it from the accessible biosphere [2].

2.2. In accordance with the graded approach [2, 3], the ability of a chosen disposal system to contain the waste and isolate it from humans and the accessible biosphere should be commensurate with the hazard potential of the waste. This is achieved primarily by appropriate selection of waste forms and packaging, of the site for the disposal facility and of its design. Disposal facilities are not expected to provide complete containment and isolation of the waste forever; this is neither practicable nor demanded by the hazard of the waste, which declines with time.

2.3. Disposal facilities for radioactive waste have been constructed and operated in many States for several decades. Most facilities currently operating are near surface disposal facilities, but there is one geological disposal facility currently operating[3], and progress is being made in many States towards the construction and operation of further deep geological disposal facilities suitable for high level waste [4–13].

2.4. As national programmes for radioactive waste disposal have developed, considerable effort has been put into developing systematic and internationally recognized approaches for demonstrating the safety of disposal facilities and for preparing safety cases for specific facilities. The safety case is defined as "the collection of arguments and evidence to demonstrate the safety of a facility" [2]. The demonstration of an acceptable level of safety of a disposal facility depends on the arguments in the safety case about the characteristics of the site and the facility engineering (e.g. the system of engineered barriers), the results of safety assessment and the management arrangements for ensuring quality in all aspects of safety related work.

2.5. Safety assessment entails evaluating the performance of a disposal system and quantifying its potential radiological impact on human health and the

[3] The United States Department of Energy, Waste Isolation Pilot Plant (WIPP), Carlsbad, NM, USA.

environment. Safety assessment is a major component of the safety case for a disposal facility and should take account of the potential radiological impacts of the facility, both in operation and after closure. Radiological impacts may arise from gradual processes after closure that may cause the facility and its components (e.g. natural and engineered barriers) to degrade, and from discrete disturbing events that could affect the isolation of the waste (e.g. earthquakes, faulting and inadvertent human intrusion). Safety assessment should demonstrate whether the disposal facility complies with applicable regulatory requirements.

2.6. Recommendations on meeting the safety requirements established in Ref. [2] for different types of disposal facility are provided in Refs [14–16]. Reference [3] establishes requirements for safety assessment; these requirements apply to all facilities and activities, including disposal facilities during operation and after closure. For disposal facilities, particular consideration should be given to the need for assurance of safety over long time periods commensurate with the half-lives and amounts of radionuclides contained in the waste.

2.7. A classification scheme for radioactive waste is provided in Ref. [17] and is illustrated in Fig. 1. The classes of waste defined in Ref. [17] and discussed in para. 2.8 are generic, and the linkages made in the waste classification scheme of Fig. 1 between classes of radioactive waste and types of waste disposal facility are indicative. The linkages do not remove the requirement for thorough site specific safety assessment for each disposal facility, which, among other aspects, is used to establish the waste acceptance criteria for each facility. Nevertheless, the waste classification scheme provides an international point of reference and facilitates the exchange of information between States on waste management and can assist in the establishment of national strategies for waste management.

2.8. The following waste types are considered in this Safety Guide[4]:

— Very low level waste (VLLW): VLLW arises from the operation and decommissioning of nuclear facilities, from the mining or processing of ores and minerals, and from research, medical and educational applications of radioactive substances. VLLW has activity concentrations above the levels for the clearance of material from regulatory control. Some radiation protection provisions are required for safe management of VLLW, but these

[4] Very short lived waste and exempt waste are not considered further in this Safety Guide because they do not require specialized radioactive waste disposal facilities.

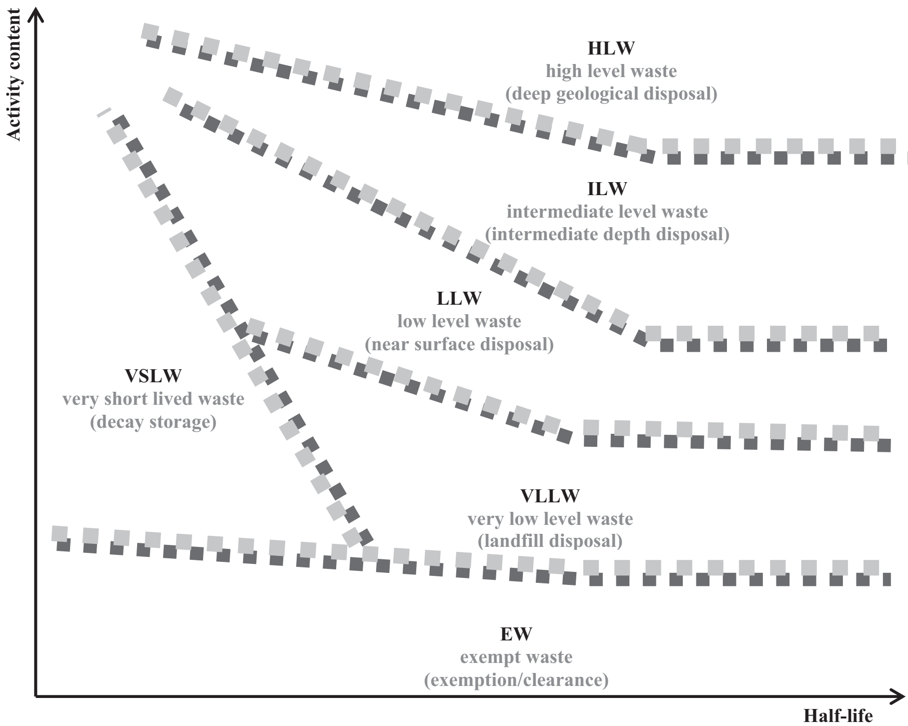

FIG. 1. Conceptual illustration of the waste classification scheme.

provisions are very limited in comparison to those required for radioactive waste with higher activity concentrations described in the classes below.

— Low level waste (LLW): LLW is suitable for near surface disposal, and includes a very wide range of radioactive waste, from radioactive waste just above levels for VLLW, to radioactive waste with levels of activity that require shielding and containment and isolation for periods of up to several hundred years. Low concentrations of long lived radionuclides may be present in LLW, but the acceptable concentrations are limited by the time period over which near surface disposal can ensure the isolation of the waste and, in particular, can sufficiently reduce the likelihood of inadvertent human intrusion into the facility through institutional control.

— Intermediate level waste (ILW): ILW contains long lived radionuclides in quantities that need greater (i.e. longer) containment and isolation from the biosphere than can be provided by near surface disposal. The boundary between LLW and ILW cannot be specified in terms of a particular level of activity concentration because allowable levels will depend on the actual waste disposal facility.

— High level waste (HLW): HLW contains higher concentrations of radionuclides than ILW and generates significant quantities of heat from radioactive decay. Owing to the high concentrations of long lived radionuclides, significant heat generation may last for several centuries. HLW may include spent nuclear fuel where this has been declared as waste, vitrified waste from the processing of spent nuclear fuel, and any other waste requiring a comparable degree of containment and isolation.

2.9. "The term 'disposal' refers to the emplacement of radioactive waste into a facility or a location with no intention of retrieving the waste…. Disposal options are designed to contain the waste by means of passive engineered and natural features and to isolate it from the accessible biosphere to the extent necessitated by the associated hazard. The term disposal implies that retrieval is not intended; it does not mean that retrieval is not possible.

"By contrast, the term 'storage' refers to the retention of radioactive waste in a facility or a location with the intention of retrieving the waste. Both options, disposal and storage, are designed to contain waste and to isolate it from the accessible biosphere to the extent necessary. The important difference is that storage is a temporary measure following which some future action is planned. This may include further conditioning or packaging of the waste, and ultimately its disposal" (paras 1.8 and 1.9 of Ref. [2]).

2.10. The development of a disposal facility usually involves an extensive programme of research, design and assessment work that may last for several years or decades. Once established, a disposal facility may be operated for several more decades. The lifetime of a radioactive waste disposal facility may be defined in three periods: the pre-operational period, the operational period and the post-closure period:

— Activities commonly undertaken during the pre-operational period include the development of the disposal concept and the safety strategy, site evaluation (selection, verification and confirmation), environmental impact assessment[5], initial design studies for the facility, the development of plans

[5] The term is used here in a broad sense. In some States, the term 'environmental impact assessment' is a specified process covering all potential impacts of the project with a view to soliciting acceptance of a project from all relevant authorities and which often involves participation of the public.

for research and development and monitoring, and the development of the detailed facility design. Licensing and construction of the facility also take place in this period.

— The operational period begins when waste is first received at the facility and continues up to the final closure of all parts of the facility. Radiation exposures may occur in this period as a result of waste management activities and these are, therefore, subject to regulatory control in accordance with requirements for radiation protection and safety of workers. Safety assessment, monitoring, and research and development programmes should be used to inform management decisions on the operation and closure of the facility. During the operational period, construction activities may take place at the same time as waste emplacement in and closure of other parts of the facility.
— The post-closure period begins after the facility is closed. After closure, a period of institutional control may contribute to the safety of certain disposal facilities (in particular, near surface disposal facilities). Institutional controls may be of an active or passive nature. Examples of active measures are the monitoring of radionuclide concentrations in environmental media or the monitoring of the performance and integrity of barriers, in particular in the case of near surface disposal facilities. Post-closure maintenance measures (e.g. the repair of covers for near surface disposal) also fall into this category. Other institutional controls may be of a passive nature. These could, for example, be ensuring that records on the disposal facility are kept and restrictions on land use are in place. States may have specific requirements for a maximum duration for which credit can be taken in the safety case for such controls. Since the functioning of such controls cannot be guaranteed, such controls cannot solely be relied on to ensure safety. They may, nevertheless, provide an important element of defence in depth.

3. SAFETY PRINCIPLES AND SAFETY REQUIREMENTS

3.1. This section lists the main principles and requirements to be taken into account when preparing the safety case and supporting safety assessment.

SAFETY PRINCIPLES

3.2. The safety principles to be applied in all radioactive waste management activities are set out 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. Many of the safety principles are reflective of some basic elements in Article 1 of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [18]. The relevant requirements for radiation protection are established in Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [19]. Many of the concepts of protection adopted in Refs [18, 19] are derived from the recommendations of the International Commission on Radiological Protection [20–24].

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/maintenance and use of the safety case. Other requirements in Refs [2, 3] are addressed in later sections of this Safety Guide.

Responsibilities for developing the safety case and safety assessment

3.5. “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]).

3.6. For disposal facilities:

"The operator shall carry out safety assessment and develop and maintain a safety case, and shall carry out all the necessary activities for site selection and evaluation, design, construction, operation, closure and, if necessary, surveillance after closure, in accordance with national strategy, in compliance with the regulatory requirements and within the legal and regulatory infrastructure" (Requirement 3, Ref. [2]).

3.7. "The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met" (Requirement 2, Ref. [2]).

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

Requirements for the safety case

3.8. The following requirements apply for the safety case governing the development, operation and closure of a disposal facility:

— "A safety case and supporting safety assessment shall be prepared and updated by the operator, as necessary, at each step in the development of a disposal facility, in operation and after closure. The safety case and supporting safety assessment shall be submitted to the regulatory body for approval. The safety case and supporting safety assessment shall be sufficiently detailed and comprehensive to provide the necessary technical input for informing the regulatory body and for informing the decisions necessary at each step" (Requirement 12, Ref. [2]).
— "The site for a disposal facility shall be characterized at a level of detail sufficient to support a general understanding of both the characteristics of the site and how the site will evolve over time. This shall include its present condition, its probable natural evolution and possible natural events, and also human plans and actions in the vicinity that may affect the safety of the facility over the period of interest. It shall also include a specific understanding of the impact on safety of features, events and processes associated with the site and the facility" (Requirement 15, Ref. [2]).

— “The disposal facility shall be constructed in accordance with the design as described in the approved safety case and supporting safety assessment. It shall be constructed in such a way as to preserve the safety functions of the host environment that have been shown by the safety case to be important for safety after closure” (Requirement 17, Ref. [2]).
— “The disposal facility shall be operated in accordance with the conditions of the licence and the relevant regulatory requirements so as to maintain safety during the operational period and in such a manner as to preserve the safety functions assumed in the safety case that are important to safety after closure” (Requirement 18, Ref. [2]).
— “Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system” (Requirement 11, Ref. [2]).
— “A disposal facility shall be closed in a way that provides for those safety functions that have been shown by the safety case to be important after closure. Plans for closure, including the transition from active management of the facility, shall be well defined and practicable, so that closure can be carried out safely at an appropriate time” (Requirement 19, Ref. [2]).
— “The safety case for a disposal facility shall describe all safety relevant aspects of the site, the design of the facility, and the managerial control measures and regulatory controls. The safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met” (Requirement 13, Ref. [2]).

3.9. The following requirement applies for all facilities and activities, including disposal facilities: “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 explained by 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]).

Requirements for safety assessment

3.10. The following requirements apply for safety assessment:

— "A safety assessment has to be carried out at the design stage for a new facility or activity, or as early as possible in the lifetime of an existing facility or activity. For facilities and activities that continue over long periods of time, the safety assessment needs to be updated as necessary through the stages of the lifetime of the facility or activity, so as to take into account possible changes in circumstances (such as the application of new standards or new scientific and technological developments), changes in site characteristics, and modifications to the design or operation, and also the effects of ageing" (para. 4.6 of Ref. [3]).
— "The primary purposes of the safety assessment shall be to determine whether an adequate level of safety has been achieved for a facility or activity and whether the basic safety objectives and safety criteria established by the designer, the operating organization and the regulatory body, in compliance with the requirements for protection and safety as established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources…, have been fulfilled" (Requirement 4, Ref. [3])[6, 7].
— "The safety assessment has to address all radiation risks that arise from normal operation (that is, when the facility is operating normally or the activity is being carried out normally) and from anticipated operational occurrences and accident conditions (in which failures or internal or external events have occurred that challenge the safety of the facility or activity). The safety assessment for anticipated operational occurrences and accident conditions also has to address failures that might occur and the consequences of any failures" (para. 4.5 of Ref. [3]).

[6] The current edition of the International Basic Safety Standards is Ref. [19].

[7] It is recognized that radiation doses to individuals in the future, including those that may occur after institutional management of a waste disposal facility has ceased, can only be estimated. "Nevertheless, estimates of possible doses and risks for long time periods can be made and used as indicators for comparison with the safety criteria" (para. A.4 of Ref. [2]).

— “It is determined in the safety assessment whether adequate measures have been taken to control radiation risks to an acceptable level. It is determined whether the structures, systems, components and barriers incorporated into the design fulfil the safety functions required of them. It is also determined whether adequate measures have been taken to prevent anticipated operational occurrences and accident conditions, and whether any radiological consequence can be mitigated if accidents do occur” (para. 4.9 of Ref. [3]).
— “The safety assessment has to address all the radiation risks to individuals and population groups that arise from operation of the facility or conduct of the activity. This includes the local population and also population groups that are geographically remote from the facility or activity giving rise to the radiation risks, including population groups in other States, as appropriate” (para. 4.10 of Ref. [3]).
— “The safety assessment has to address radiation risks in the present and in the long term. This is particularly important for activities such as the management of radioactive waste, the effects of which could span many generations” (para. 4.11 of Ref. [3]).
— “The safety assessment has to include a safety analysis, which consists of a set of different quantitative analyses for evaluating and assessing challenges to safety in various operational states, anticipated operational occurrences and accident conditions, by means of deterministic and also probabilistic methods. The scope and level of detail of the safety analysis are determined by use of a graded approach, as described in Section 3. Determination of the scope and level of detail of the safety analysis is an integral part of the safety assessment” (para. 4.13 of Ref. [3]).

Maintenance of the safety assessment

3.11. With regard to the maintenance of the safety assessment,

> “The frequency at which the safety assessment is to be updated is related to the radiation risks associated with the facility or activity, and the extent to which changes are made to the facility or activity. As a minimum, the safety assessment is to be updated in the periodic safety review carried out at predefined intervals in accordance with regulatory requirements. Continuation of operation of such facilities or conduct of such activities is subject to being able to demonstrate in the reassessment, to the satisfaction of the operating organization and the regulatory body, that the safety measures in place remain adequate” (para. 4.8 of Ref. [3]).

3.12. Furthermore:

> "In the updating of the safety assessment, account also has to be taken of operating experience, including data on anticipated operational occurrences and accident conditions and accident precursors, both for the facility or the activity itself and for similar facilities or activities" (para. 4.7 of Ref. [3]).

3.13. The following requirements for the updating of the safety assessment apply specifically for waste disposal facilities:

— "Safety assessment in support of the safety case has to be performed and updated throughout the development and operation of the disposal facility and as more refined site data become available. Safety assessment has to provide input to ongoing decision making by the operator. Such decision making may relate to subjects for research, development of a capability for assessment, allocation of resources and development of waste acceptance criteria" (para. 4.13 of Ref. [2]).
— "The operator has to decide on the timing and the level of detail of the safety assessment, in consultation with, and subject to the approval of, the regulatory body" (para. 4.14 of Ref. [2]).

Documentation of the safety case

3.14. With regard to the documentation of the safety case:

> "The safety case and supporting safety assessment for a disposal facility shall be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review of the safety case and supporting safety assessment" (Requirement 14 of Ref. [2]).

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 this Safety Requirements publication, and any other safety requirements as established in national laws and regulations" (para. 4.62 of Ref. [3]).

Uses of the safety case

3.16. The following additional requirements concerning the use of the results of the safety assessment apply specifically for disposal facilities:

- "Waste packages and unpackaged waste accepted for emplacement in a disposal facility shall conform to criteria that are fully consistent with, and are derived from, the safety case for the disposal facility in operation and after closure" (Requirement 20, Ref. [2]).
- "Plans shall be prepared for the period after closure to address institutional control and the arrangements for maintaining the availability of information on the disposal facility. These plans shall be consistent with passive safety features and shall form part of the safety case on which authorization to close the facility is granted" (Requirement 22, Ref. [2]).

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 DISPOSAL OF RADIOACTIVE WASTE

4.1. This section identifies and provides guidance on the components of the safety case, its development and its role during the development, operation and closure of a disposal facility.

4.2. The components of the safety case are indicated in Fig. 2 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 closure and licence

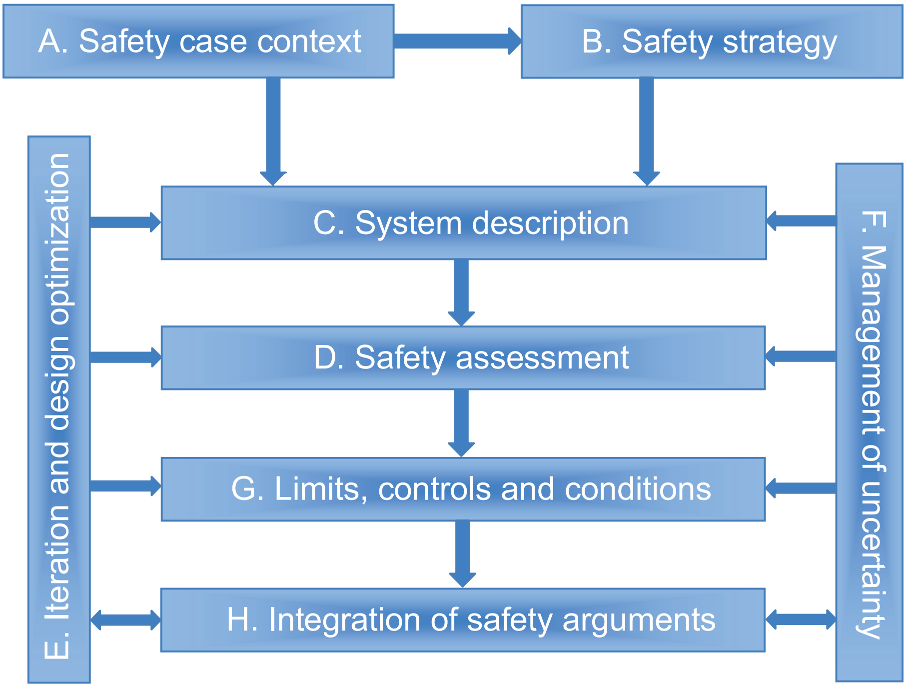

FIG. 2. Components of the safety case.

termination. Management systems for ensuring the quality of all safety related work are required to be applied throughout, and the regulatory process is required to be applied, as illustrated in Fig. 3. Arrangements to facilitate the involvement of all interested parties in the development and use of the safety case should be put in place.

4.4. Safety assessment is the main component of the safety case and involves assessment of a number of aspects, as illustrated in Fig 4. 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 4.20–4.100 provide guidance on the various components of the safety case.

4.5. Individual components of the safety case have been or are already being developed for most new disposal facilities. The benefit of introducing the concept of a safety case is to provide a structured framework for documenting and

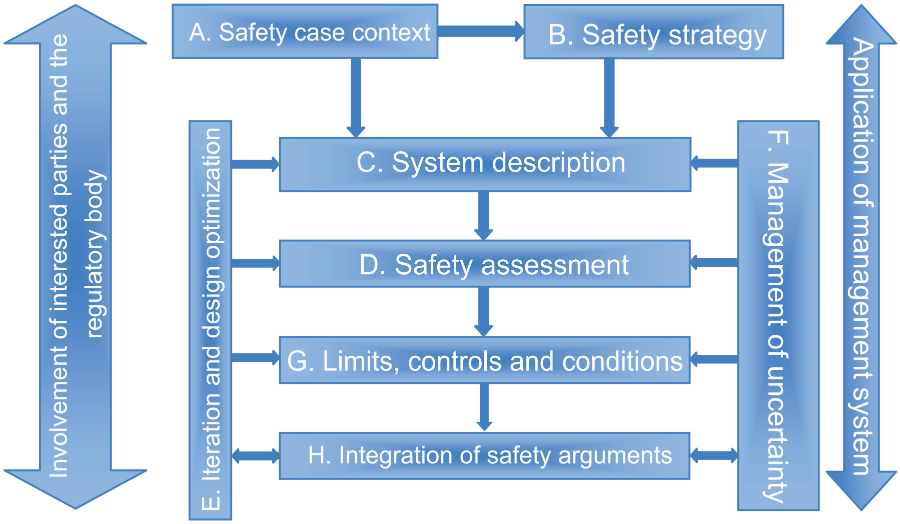

FIG. 3. Application of the management system and the process for interaction with the regulatory body and interested parties.

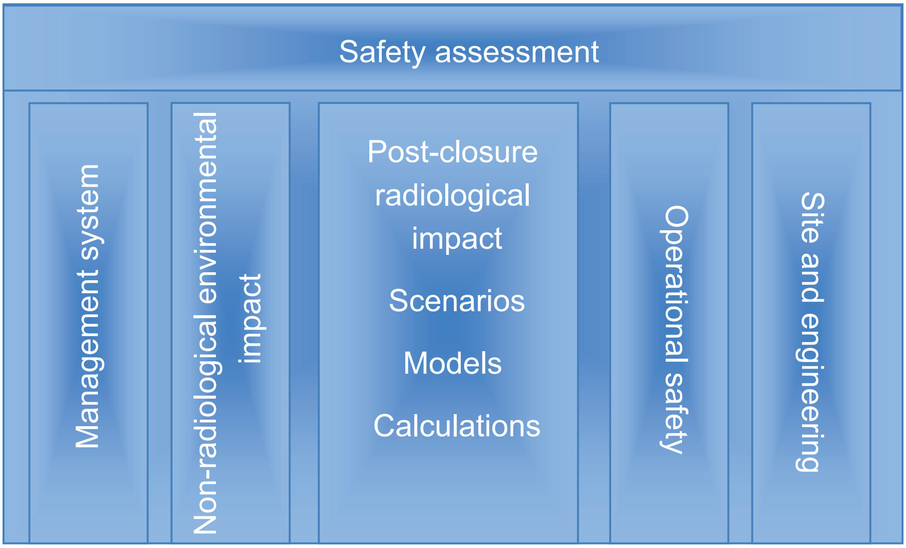

FIG. 4. Aspects included in safety assessment.

presenting all of the safety related information for the disposal facility in a consolidated manner.

ROLE AND DEVELOPMENT OF THE SAFETY CASE

4.6. In accordance with the requirements of Ref. [2] (see para. 3.8), a safety case is required to be developed to address safety during the operation of a disposal facility and after its closure. This Safety Guide focuses on safety in the post-closure period and provides guidance on the role and components of the safety case necessary to present all of the arguments and supporting assessment, analysis and evidence demonstrating the safety of a disposal facility. In this regard, the role of the safety case should be to provide:

- Integration of relevant information in a structured, traceable and transparent way that demonstrates an understanding of the behaviour and performance of the disposal system in the period after closure;
- Identification of uncertainties in the behaviour and performance of the disposal system, analysis of the significance of the uncertainties, and identification of approaches for the management of significant uncertainties;
- Demonstration of long term safety by providing reasonable assurance that the disposal facility will perform in a manner that protects human health and the environment;
- Support to decision making in the step by step approach to development of a disposal facility;
- Facilitation of communication between interested parties on issues relating to a disposal facility.

4.7. As outlined in para. 2.10, a disposal facility is developed in a step by step manner. The step by step approach adopted should enable:

- Systematic collection and assessment of the necessary scientific and technical data;
- Evaluation of possible sites;
- Development of disposal concepts;
- Iterative studies for design and safety assessment with progressively improving data;
- Incorporation of comments from technical and regulatory reviews;
- Consultation with the public for specific decision points;
- Political involvement.

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

4.8. Development of the safety case should commence at the inception of the project and should be continued through all steps in the development and operation of the facility through to its closure and licence termination. The safety case should also be used throughout all steps to guide the site selection process, the facility design, excavation and construction activities, operation of the facility and its closure. It should be used to identify research and development needs, to identify and establish limits, controls and conditions at the various steps, and primarily to provide the basis for the licensing process. It will also be the main vehicle of communication with interested parties, in terms of explaining the safety features and how a reasonable level of safety will be ensured.

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 in Ref. [2], the development of the safety case should be an iterative process that evolves with the development of the disposal facility. According to Ref. [2], 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. The step by step approach adopted for development of disposal facilities provides a basis for decision making relating to the siting, design, excavation and construction, operation and closure of facilities, and should allow the identification of issues that require further attention in order to improve the understanding of aspects influencing the safety of the disposal system and/or to reduce remaining uncertainties by appropriate design choices.

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 safety case, including 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. 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 step by step approach, together with the consideration of a range of options for the design and operation of a disposal 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. The approach may also include options for reversal of a particular step in the development of a disposal facility and for retrieval of waste after its emplacement, if this is considered appropriate.

4.13. Within the step by step approach, the scientific understanding of the disposal system and the design of the disposal facility should be progressively advanced, and the safety case should become more focused on key areas of concern. It should not only be scientific understanding that is advanced, but also an understanding of the important contributors to risk. At each step (i.e. at each major decision point), safety assessment should be performed in a manner that will enable the current level of understanding of the disposal system to be evaluated and the associated uncertainties to be assessed before decisions are made to proceed to the next step. The safety case and supporting safety assessment should be reviewed and updated prior to each major decision point and periodically as necessary to reflect actual experience and increasing knowledge (e.g. knowledge gained from scientific research), with account taken of operational aspects that are relevant for long term safety. Following commencement of facility operation, revisions or updates to the safety case and supporting assessment should be conducted if significant changes are identified in operational practices, waste forms, design, etc.

4.14. The evolution of the safety case and supporting assessment from one iteration to the next should be documented so that it is transparent to interested parties (e.g. explanation of new data or reasons for changing aspects of conceptual or mathematical models). Of importance in this respect is to avoid an impression that the assessment is being manipulated to give more favourable results.

4.15. The regulatory body should specify the types and/or magnitude of changes and the time frames for which an update is 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, turnover and training of personnel, improvements in knowledge and advances in computational capabilities.

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 disposal facility and, therefore, the safety assessment will provide only preliminary estimates of how the disposal 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 disposal facility. At later stages, more site specific data will be necessary and details of the proposed design will have been developed, which will allow operational and long term performance issues to be addressed in more detail in the safety case.

4.17. Revisions to the safety case at each step should be based on up to date knowledge about the facility and its evolution, including events that have occurred, the waste received, etc. It is also important that the safety case prepared for each step of the facility lifetime should provide sufficient depth of information and assessment to support the decisions required.

4.18. At the end of the facility lifetime, the safety case should contain all of the information that needs to be passed on to future generations (e.g. the basis for institutional controls).

4.19. It should be recognized that different facilities will accommodate different types of radioactive waste with different levels of hazard potential. Principle 3 (in para. 3.15) in Ref. [1] states that "Safety has to be assessed for all facilities and activities, consistent with a graded approach." This is further detailed by the following recognition in Principle 5: "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 of Ref. [1]). Consequentially, "The extent and complexity of [safety] assessment will vary with the type of facility and will be related to the hazard potential of the waste" (para. 1.24 of Ref. [2]). Furthermore, the level of detail of the safety assessment performed for each step of the development and operation of a disposal facility will vary depending on the magnitude of the risks. 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 to which they are subjected by the regulatory body and other interested parties (which may change over time), should be commensurate with the potential hazard. Further guidance on the application of the graded approach to the development of the safety case is provided in paras 6.23–6.28.

COMPONENTS OF THE SAFETY CASE

Safety case context

Purpose of the safety case

4.20. As stated in para. 4.13, 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.

4.21. The purpose of each revision of the safety case will depend on a number of factors, such as the stage of development of the disposal facility, and whether the safety case is to be 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 selection;
- Demonstration of the safety of the disposal facility;
- Optimization of the facility design;
- Identification of safety related issues to be addressed by research and development programmes;
- Definition or revision of limits, controls and conditions such as waste acceptance criteria;
- Assessment of the maximum inventory that can be disposed of (the ‘radiological capacity’ of the facility);
- Rationale for the duration of institutional control;
- Input to monitoring and data acquisition programmes;
- Periodic re-assessment as required by law or regulation;
- Application to extend or upgrade the facility or to co-locate new plant or waste management facilities;
- Closure of the facility, either at the planned end of the lifetime of the facility or as a consequence of non-compliance with the regulations;
- Application to re-open the facility after closure for non-compliance or for other reasons;
- Determination of whether remedial action is necessary.

Demonstration of safety

4.22. 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 and should reflect the safety objective specified in para 2.15 of Ref. [2]:

> "The safety objective is to site, design, construct, operate and close a disposal facility so that protection after its closure is optimized, social and economic factors being taken into account. A reasonable assurance also has to be provided that doses and risks to members of the public in the long term will not exceed the dose constraints or risk constraints that were used as design criteria."

The safety principles adopted should reflect those established in Ref. [1], with particular reference to Principle 7 on protection of present and future generations: "People and the environment, present and future, must be protected against radiation risks." The regulatory criteria will be established by the regulatory body and, as a minimum, need to address radiation dose and risk constraints for workers and the public (both present and future generations), and protection of the environment. They need to cover the normal evolution of the facility and disturbing events — both events of natural origin and human induced events such as human intrusion into the facility. Internationally agreed criteria covering these aspects are set out in Ref. [2].

4.23. In addition to quantitative criteria, the regulatory body should set out qualitative criteria to be met and should provide guidance on how compliance with these criteria should be demonstrated. These criteria should cover all of the requirements in Ref. [2], with a view to ensuring that the disposal facility will be in compliance with the requirements.

4.24. 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

4.25. A graded approach is required to be taken in determining the scope, extent and level of detail of the safety case and supporting assessment [2, 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 assessment are commensurate with the level of risks posed by a facility or activity and the stage of facility development, e.g. generic disposal concepts being considered prior to site selection might be considered in less detail than for a specific site and disposal facility. Three aspects to be considered in a graded approach are given in Ref. [3]: the magnitude of the possible radiation risks and the maturity and complexity of the facility. Further guidance on the application of these criteria to waste disposal facilities is provided in paras 6.23–6.28.

Safety strategy

4.26. The early development and adoption of a strategy for safety is a key point in the development of the safety case. The safety strategy is explained in Refs [22, 25] as a high level integrated approach adopted for achieving safe disposal of radioactive waste. According to Ref. [25], the safety strategy should comprise an overall management strategy for the various activities required in planning, operation and closure of a disposal facility, including siting and design, development of the safety case, safety assessment, site characterization, waste form characterization, and research and development.

4.27. The safety strategy refers to the approach that will be taken in site selection and facility design 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 disposal facility. In the early stages, the strategy may develop and mature, but it should be defined at as early a stage as possible. By the time the site is selected, the design concept to implement the strategy should be sufficiently well developed to provide assurance that the overall disposal system will provide and preserve the safety functions envisaged for the disposal facility. As the project develops, the safety strategy should be continually validated and any changes to it should be justified in the safety case. Any evolution of the safety strategy should be carefully recorded and the records should be preserved for use in the future when staff may have changed.

4.28. The safety strategy should address a number of key elements, namely: the provision of multiple safety functions and defence in depth, containment and isolation of the waste, the adoption of passive safety features, robustness of the disposal system, demonstrability of safety related features and aspects[8], and interdependences with the predisposal management of the waste. It should also address the approach that will be taken to management of uncertainties, with a view to ensuring that the approach to safety described in para. 4.17 will be respected.

4.29. Reference [2] requires that multiple safety functions be provided, such that safety does not depend unduly on any single safety function and to ensure that if one safety function does not perform as intended, there are further safety functions to compensate. For example, if waste packaging is assigned a containment function and degrades more quickly than anticipated, the surrounding backfill material can provide a further element of physical containment to retard the migration of radionuclides by adsorption; or the host geological environment can provide for dispersion of radionuclides. The safety strategy should identify the intended safety functions, the time frames over which they will be available and how degraded performance of one barrier will be compensated by another mechanism or by components of the disposal system. The safety strategy should also address how the adequacy of the various safety functions will be demonstrated, e.g. by assessment, analogy, testing, etc. The strategy should indicate how an adequate degree of defence in depth will be ensured by the various safety functions. The adequacy of the defence in depth may be expressed in quantitative and in qualitative terms.

4.30. The manner in which containment of the radioactive waste will be provided should be set out in the strategy for safety, together with the manner in which the adequacy of the containment will be demonstrated consistent with the regulatory approach. The time frames over which the containment functions will be available should be specified and a justification for the time frames should be provided.

4.31. The concept of isolation involves essentially two aspects: physical separation of the waste from the accessible environment and ensuring that the safety functions are isolated from disturbing effects. An explanation and justification of how these two aspects will be provided for should be given in the

[8] Such demonstrability may be ensured by means of assessment, testing or other physical demonstration of functionality.

safety strategy, together with the manner in which their adequacy will be demonstrated, consistent with the regulatory approach.

4.32. The various safety functions are required to be provided, to the extent possible, by passive features of the disposal facility [2] and the strategy for safety should explain and justify how this will be achieved. It should also indicate and justify where active controls or features are to be used and how it will be demonstrated that reliance can be placed on such active controls, for example, monitoring or institutional control in the period after closure.

4.33. The safety strategy should set out how robustness[9] of the safety functions will be provided for and how the adequacy of such robustness will be demonstrated.

4.34. The safety strategy should explain how it will be demonstrated that the intended design of the facility can be realized in practice. This may be undertaken by physical demonstration in mock-up facilities or on the site of the disposal facility, either on the surface or underground.

4.35. The safety strategy should set out how it will be demonstrated that interdependences with predisposal management of waste will be taken into account to ensure compatibility of the waste to be disposed of with the design and operation of the disposal facility.

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

- The degree of caution that will be exercised when making decisions and the use of multiple lines of reasoning;
- The rationale for selecting the assessment methodology and the 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;

[9] A component of the disposal system may be considered robust if it will continue to fulfil its expected safety function(s) no matter what kind of perturbations may reasonably be expected to occur. The disposal system may be considered robust if it continues to provide adequate protection and safety under a wide range of conditions and scenarios that may reasonably be expected to occur.

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

Description of the disposal system

4.37. The description of the disposal system should record all of the information and knowledge about the disposal system and should provide the basis on which all safety assessment is carried out. Information will be obtained and knowledge about the disposal system will 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 system characterization and facility design. The system description should contain, depending on the type of disposal facility, information on the following:

- The near field, including: (i) the types of waste (e.g. the origin, nature, quantities and properties of the waste and the radionuclide inventory); (ii) system engineering, e.g. waste conditioning and packaging, disposal units, engineered barriers, cap or cover of the disposal facility, drainage features); and (iii) the extent and properties of the zone disturbed by any excavation or construction work;
- The far field, e.g. geology, hydrogeology, hydrology, geochemistry, tectonic and seismic conditions, erosion rates;
- The biosphere, e.g. climate and atmosphere, water bodies, the local population, human activities, biota, soils, topography and the geographical extent and location of the disposal facility.

4.38. Depending on the type of disposal facility, the description of the disposal system should include the following:

- A clear specification and description of the components of the system and their interfaces and associated uncertainties;
- A description of the overall safety concept and the safety functions;
- A description of how the components of the system will continue to be able to fulfil their assigned safety functions, both for the expected evolution of the system and for less likely events;
- A discussion of how regulatory or other requirements on system components have been addressed in the facility design;
- A description of the radiological, thermal, hydraulic, mechanical, chemical and biological processes that may affect the disposal system;

— A description of the interactions that may occur between system components;
— A description of how spatial heterogeneity of the waste has been taken into account, including associated uncertainties;
— A description of possible time dependent changes in the properties and behaviour of the system components and their interfaces, including how components may degrade or fail, and associated uncertainties;
— A description of possible environmental changes and their impacts on the components of the disposal system;
— A description of possible radionuclide migration pathways both for the expected evolution of the system and for less likely events.

4.39. The description of the disposal system should provide information on the data supporting the safety assessments, including the following:

— An outline of how the management system will ensure the quality of all safety related data that have been used;
— The sources of all data used (e.g. by reference to measurements and reports);
— The rationale behind the site characterization programme (e.g. sample selection, sample location) — data acquisition programmes should reflect the conclusions from any previous safety assessment on the need for information for the subsequent iteration of the assessment;
— A description of the techniques that have been used to characterize the site and collect monitoring data, and the uncertainties associated with these techniques and data;
— A description of how the radionuclide inventory has been estimated, and the uncertainties associated with the inventory;
— Any information used to support an understanding of possible future human behaviour in the region of the disposal facility (e.g. current human practices in the area, records of mineral exploration).

4.40. The depth and extent of information provided in the description will be influenced by the disposal facility type and will be more extensive and complex for facilities designed for the disposal of larger quantities and more long lived or higher activity waste. The description for a facility designed for the disposal of very low level waste will be less extensive and complex than one for high level waste. The actual extent and complexity for any particular facility will depend on a number of factors, including the amount of waste, its particular radioactive characteristics, the nature and complexity of the host site and the associated meteorological and hydrological characteristics. A justification for the extent and complexity of the description should be provided as part of the safety case and this should be agreed with the regulatory body as part of the discussions that should take place at the conceptualization of the disposal facility and throughout its development and operation.

Safety assessment

4.41. The term ‘safety assessment’ is used in this Safety Guide to refer to all assessments performed as part of the safety case (see Fig. 4). This encompasses all aspects that are relevant for the safety of the development, operation and closure of the disposal facility. Thus, the safety assessment also addresses qualitative aspects, non-radiological issues, and organizational and managerial aspects.

4.42. In earlier publications (e.g. Ref. [26]), the term ‘safety assessment’ was used to describe assessment focused on the radiological impacts of the facility:

— Safety assessment was defined as the overall process of performing quantitative assessments of the radiological impact of the facility for the period after closure. This included development of the context for the assessment and description of the disposal system and its environment, as well as interpretation of the results. However, in terms of the broader context for the safety case, as illustrated in Fig. 2, these elements are considered part of the overall safety case and are not only part of the quantitative safety assessment. Addressing these elements in the broader context of the safety case does not represent any change of the actual methodology for the performance of quantitative assessments as discussed in Ref. [26]; the approaches developed in those publications are now integrated into the broader context of the safety case.
— Safety assessment in this Safety Guide also relates to aspects relevant for safety beyond the quantitative assessment of radiation risks, such as operational safety and the management system. 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.

4.43. The following sections provide an overview of the key elements of the safety assessment as shown in Fig. 4.

Radiological impact assessment for the period after closure

4.44. Assessment of the post-closure radiological impact forms the core of the safety case for a disposal facility. In addition to qualitative assessments, this involves a comprehensive quantitative analysis of the evolution of the disposal system and its environment, possible challenges to the safety functions and the resulting potential radiological impacts. A systematic approach to radiological impact assessment for the period after closure has been developed and described in Ref. [26]. In this approach, scenarios are used to describe possible evolutions of the disposal system and its environment. The potential migration of radioactive substances from the disposal facility, their movement in the environment and resulting radiation risks are quantitatively analysed by means of conceptual and mathematical models. Detailed guidance on this approach is provided in Section 5.

Site and engineering aspects

4.45. Quantitative assessment of the evolution of the disposal system as part of the radiological impact assessment for the period after closure should result in conclusions on the adequacy of the chosen or proposed site as well as of the intended design of the disposal facilities. The conclusions drawn from the quantitative assessment should be supplemented by qualitative arguments and assessments. The integrated set of results of the qualitative and quantitative assessments should provide:

- — Sufficient demonstration of the adequacy of the site and engineering;
- — Reasonable assurance of compliance with the relevant safety requirements, as summarized in Section 3;
- — Assurance that the safety strategy set out for the facility is fulfilled.

4.46. The safety of any disposal facility depends primarily on the favourable characteristics or properties of natural barriers and the engineered barriers. Important characteristics of the natural and engineered barriers include their robustness and reliability over prolonged periods. Aspects that favour the robustness and reliability of a disposal facility and its environment are described in the following, and arguments for the quality of a specific site and facility design should be made on the basis of the provisions made in respect of these aspects.

Passive safety

4.47. The operator should demonstrate that, to the extent possible, the safety of the disposal system is ensured by passive means. This means that no active components or actions (e.g. monitoring) are necessary for the long term safety of the facility, although these may contribute to safety, in particular for near surface disposal facilities. Thus, it is primarily a combination of natural and engineered barriers that provides for safety after closure of the facility (see Ref. [2]).

4.48. In the design of the facility, passive safety measures are required to be taken into account to minimize the dependence of safety on active systems during operation and after closure.

Multiple safety functions

4.49. According to Ref. [3], an assessment of 'defence in depth' is required for waste disposal facilities, which will entail a demonstration that multiple safety functions are provided at the disposal facility. The term 'defence in depth' means a hierarchical deployment of diverse equipment and procedures in order to maintain the effectiveness of physical barriers placed between radioactive material and workers, members of the public or the environment, in normal operation, anticipated operational occurrences and, for some barriers, under accident conditions at the facility.

4.50. Application of the concept of defence in depth to a disposal facility will ensure that safety is not unduly dependent on a single component or control procedure, or on the fulfilment of a single safety function. The role and relative weight of the safety functions may vary over time. Application of the defence in depth concept to radioactive waste disposal facilities is discussed further in Section 6.

Robustness

4.51. Robustness (see para. 4.33) is a concept that is related to the defence in depth concept and may be applied to individual components of the disposal system, or to the disposal system as a whole. Guidance on the concept of robustness and demonstration of the robustness of a disposal system is provided in Section 6.

Scientific and engineering principles

4.52. 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 developing an understanding of groundwater flow at a particular site. Such work might involve taking surface and borehole measurements, putting forward hypotheses on influences on groundwater flow, 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 their reproducibility, and subjecting the work to independent peer review (see paras 4.92–4.94).

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

Quality of the site characterization

4.54. 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 safety strategy and any criteria that have been established. The safety case should integrate knowledge of the site and its surroundings (e.g. geology, hydrogeology, surface characteristics, climate, local population), and modelling should be employed to help understand the possible behaviour of the system; the site information should be sufficiently comprehensive to enable this to be carried out.

4.55. Confidence in the assessment results will be enhanced if the site characterization and safety assessment programmes are of high quality; if site data collected by the operator are consistent with other existing data in terms of parameter values and the measurement methodology applied; if 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 if 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

4.56. In the assessment of safety in the operational stage, similar approaches are applied to those applied for predisposal management of radioactive waste as described in Ref. [27]. Also relevant for the operation of disposal facilities are Safety Requirements and Safety Guides for the operation of nuclear power plants, such as Refs [28, 29]. In addition, other issues, such as mining safety, may need to be considered in the assessment of safety in the operational stage of a disposal facility (e.g. in the case of deep geological disposal). Applicable requirements for non-radiological aspects (e.g. those for occupational health and safety) should be applied in an integrated manner with those for radiological aspects; how this is achieved will depend on the type of facility, the legal and regulatory framework, and the stage of facility development.

Non-radiological environmental impact

4.57. Radioactive waste may contain potentially hazardous non-radioactive components (e.g. heavy metals, pathogens). In particular, waste from uranium mining usually contains many non-radioactive toxic and/or carcinogenic substances in significant concentrations. The site selection and design development for the disposal system should provide adequate protection of people and the environment against such non-radiological hazards.

4.58. The assessment of non-radiological impacts arising from the disposal facility will be required and governed by environmental protection legislation. 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 and in optimization of protection and safety against all potential hazards.

4.59. Environmental protection legislation and its associated regulations will result in several requirements on the construction, operation and closure of the disposal facility. 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 water management at the facility in construction and operation, as well as provisions made for post-closure control of water discharges. Such requirements arising from environmental protection legislation should be properly considered in the facility design. Thus, the integration of safety arguments (see Fig. 2) should also take into account non-radiological impacts and should demonstrate the overall safety of the disposal facility and its overall compliance with all relevant legislative and regulatory requirements.

Management system

4.60. Requirement 25 of Ref. [2] states that:

> "Management systems… to provide for the assurance of quality shall be applied to all safety related activities, systems and components throughout all the steps of the development and operation of a disposal facility."

General requirements for the management system are established in Ref. [30], and recommendations on how to meet these requirements are provided in Ref. [31]. 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, including provision of the necessary financial and human resources.

4.61. The requirements on the management system influence the development of the safety case in two ways. First, the description of the management system applying 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, closure and post-closure 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 para. 4.39.

Management of uncertainties

4.62. The importance of addressing uncertainties in safety assessment is reflected in para. 4.59 of 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."

4.63. Guidance on approaches to managing uncertainties in connection with the quantitative assessment of post-closure radiological impacts is provided in Section 5.

Iteration and design optimization

4.64. The process of making decisions on design options is multi-faceted 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 the availability of data and models.

4.65. Early iteration in the decision making process should be undertaken with the available data and capacity for conducting assessment. The iteration needs to proceed only until the assessment is judged to be adequate for its purpose. Furthermore, additional information needs to be acquired only to the extent necessary to improve the basis on which the decisions will be made. Some decisions may necessitate iteration in respect of only one specific aspect of the safety case (e.g. the improvement of the data requirements for a specific model). Other decisions may necessitate more iterations, which may involve revisions of several 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 considered.
— The strategy for safety may be revised.
— 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 assessment may need to be revised and developed further.

4.66. The optimization of protection for a disposal facility 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 good management principles should be applied to ensure the quality of all safety related work throughout the development, construction, operation and closure of the disposal facility.

4.67. For some decisions on the optimization of protection and safety, a qualitative approach based on expert judgement and on 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 disposal facility, the greater the need to demonstrate optimization. In order to demonstrate that safety can be considered optimized, the following important arguments should be shown to be valid:

- Due attention has been paid to the long term safety implications of various design options at each stage in the development, construction and operation of the disposal facility.
- There is reasonable assurance that the doses and/or risks resulting from the expected evolution of the disposal system will not exceed the constraints, over time frames for which the uncertainties are not so large as to prevent meaningful interpretation of the results.
- The likelihood of events that might disturb the performance of the disposal facility so as to give rise to higher doses or risks has been reduced as far as is reasonably possible by siting or design.

4.68. It should be demonstrated that the selected design option has been chosen by means of 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. [32]).

4.69. Substantially different options to a project are generally considered at the project design stage. The safety case should describe the process used to select the most appropriate option 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).

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

- What are the alternatives?
- What are the impacts, in particular the advantages and disadvantages, associated with each alternative?
- What is the rationale for selecting the preferred alternative?

4.71. Alternatives should be identified and described in sufficient detail to provide clear answers to these questions. For example, if alternative design options, such as different barrier types, 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 paras 6.79–6.89. 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 lifetime of the facility.

Limits, controls and conditions

4.72. The safety case should be used to assist in the establishment of limits, controls and conditions to be applied to all work and activities that have an influence on the safety of the facility and to be applied to the waste that will be disposed of in the facility. Examples include controls on construction processes, emplacement operations and backfilling materials and techniques, site specific limits on the types, activities and quantities of waste that may be disposed of in order to ensure operational and long term safety, and requirements on monitoring and on staff training.

4.73. Limits and conditions of particular importance for disposal facilities are the total waste inventory acceptable and/or the acceptable concentration levels for specific radionuclides in the waste. These should be defined and/or justified on the basis of the safety assessment. Waste acceptance criteria should be established both for individual packages and for the entire facility by considering the analysis of various scenarios (e.g. for the release of radionuclides to the environment and for transfer of radionuclides along environmental pathways). Consideration of human intrusion scenarios is also important and is often used to determine the acceptable levels of long lived radionuclides in the case of near surface disposal facilities. It should be noted, however, that large quantities of short lived radionuclides can also present potential problems, particularly for operational safety, and such radionuclides should also be considered in the safety assessment and in specifying limits on the inventory and on concentration levels. In addition, the safety case should also be used to assess the levels of (e.g. chemical) substances in the waste or the engineered barriers that may cause degradation of the natural and engineered barriers. Further details on the derivation of waste acceptance criteria for near surface disposal facilities are provided in Ref. [33].

4.74. The safety case and supporting assessment should also be used to establish a monitoring and surveillance programme for the site and the surrounding area that is appropriate for the specific disposal facility and for subsequent review of the programme. Surveillance and monitoring programmes should be developed and implemented to provide evidence for a certain period of time that the disposal facility is performing as predicted and that the components are able to fulfil their safety functions.

4.75. The safety of a disposal facility will depend on a combination of site features and administrative arrangements, which in turn may depend on the availability of suitably qualified staff. Training needs for staff who may be involved in development and operation of the facility should be determined on the basis of the potential hazards identified in the safety assessment and the measures that need to be taken to prevent anticipated operational occurrences and accident conditions.

Integration of safety arguments

4.76. The safety case should provide a synthesis of the available evidence, arguments and analyses. These 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 disposal system 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, the facility design or even the disposal concept may need to be revised.

4.77. In general, the safety case for each stage of planning and development of the disposal facility will include all of the different evidence, arguments and analyses that are available to support the assessment of the quality and performance of the disposal 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 uncertainty 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 each scenario, 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.

4.78. The emphasis placed on different arguments when presenting the safety case can vary, however, depending on:

— The concerns and requirements of the intended audience;
— The timescale for which safety of the disposal system is to be demonstrated, and the variation of the hazard with time;
— The stage of project development;
— The possible evolution of the disposal system;
— The associated uncertainties and their implications for the performance of the disposal system.

4.79. 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

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

4.81. 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 lower than the relevant dose or risk constraint is not in itself sufficient for the acceptability of the safety case for a disposal facility, since other requirements have to be fulfilled, such as the provision of multiple safety functions. Furthermore, safety is required to be optimized. Conversely, an indication that doses could, in some unlikely circumstances, exceed the dose constraint need not necessarily result in the rejection of the safety case.

Complementary safety indicators and performance indicators

4.82. Indicators other than dose and risk can be used in the safety case, and these may provide additional confidence and be used to set the radiological impact assessment results in an appropriate context. The concept of complementary safety indicators (i.e. the calculation of other values at the end point of the assessment that complement the calculated values for dose or risk) has mainly been used in the context of geological disposal facilities, but can also be used for other types of disposal facility.

4.83. Commonly used complementary safety indicators include radionuclide concentrations and fluxes. Other such indicators may be based on properties that are not related to the radionuclide inventory but, for example, allow conclusions to be drawn about the performance of the engineered barriers. Other complementary safety indicators could include targets of a monitoring plan to verify the performance of the facility.

4.84. Complementary safety indicators may be compared with guidelines, criteria and reference values in order to judge the effectiveness of the performance of the disposal facility or of individual components. Reference values may be derived from a number of sources, such as legislation or regulations and other considerations, which may include:

— Regulatory criteria concerning maximum permissible radionuclide concentrations in environmental media;
— The results of sensitivity analyses conducted in the safety assessment (which may indicate that, for example, a particular minimum lifetime for a certain container is critical for the safety of the disposal system as a whole);
— Independent consideration of the processes by which the safety functions of the disposal system are provided;
— Societal values or expectations.

Multiple lines of reasoning

4.85. Confidence in the safety case may also be enhanced by the use of multiple lines of reasoning. The use of multiple lines of reasoning may add value to the safety case by providing a range of different arguments that together build confidence in certain data, assumptions and results. Furthermore, certain arguments may be more meaningful to specific audiences.

4.86. Alternative lines of reasoning to complement the results of safety assessment are, for example, natural and anthropogenic analogues; aspects of the safety case in which such lines of reasoning might be established include those parts dealing with palaeohydrogeology, palaeoclimatology and neotectonics. In addition, confidence in the results of modelling in the safety assessment may be enhanced by the presentation of simplified calculations (‘scoping calculations’) of radionuclide migration or radiological impact.

Plans for addressing unresolved issues

4.87. The safety case for a radioactive waste disposal facility is required to be developed and progressively updated throughout the lifetime of the disposal facility [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 significant unresolved issues, in particular to reduce significant remaining uncertainties or to reduce their relevance or avoid them entirely by, for example, changes in the design of system components.

4.88. At the earliest stages of the programme to develop a disposal 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 an approach by which these plans will be achieved. At later stages of the programme, and certainly by the time the safety case is to be presented as part of a licence application, uncertainties and open questions on 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. Some uncertainties will inevitably remain (a geological barrier, for example, can never be fully characterized without, in the process, perturbing its favourable characteristics to some extent), but the safety case should indicate the reasons why these uncertainties do not undermine the arguments for the safety of the facility.

INTERACTING PROCESSES

4.89. As indicated in Fig. 2, 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 are 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.

4.90. 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 within a comprehensive management system that ensures the quality of the safety case and its documentation (see paras 4.95–4.100).

Involvement of interested parties

4.91. Early involvement of interested parties should be ensured as part of the process of building confidence in the safety of the disposal facility. A range of different models for interested party involvement 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

4.92. Independent peer review should play an important role in building confidence in the safety case for a radioactive waste disposal facility. 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 interest) in the outcome of the work.

4.93. 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 [34, 35]. 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.

4.94. 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

4.95. The regulatory body and the operator are required to put in place an appropriate management system to ensure the quality of all safety related work and activities [30]. 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 those conducting and reviewing the safety case and supporting assessment, for example, through the provision of training programmes and through their 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 recommendations, safety objectives, safety assessment methodologies, time frames, disposal concepts, etc. in the development of the safety case;
- The need to develop and maintain the competence and knowledge of the operator and the regulatory body over the whole project time frame.

4.96. The management system should include 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 in the development of a disposal facility.

4.97. 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 (Section 8). Other interested parties may also wish to verify that issues important to them have been addressed. It is advisable, therefore, 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 disposal facility and may derive from several sources, including legislation, regulations and concerns of interested parties. Methods for demonstrating completeness may, therefore, include well structured cross references or mappings that provide a link from these sources to the safety case.

4.98. 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 the 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 modelling tools were used, and what the ultimate sources are for the data.

4.99. 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 disposal system 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, in order to inform decision makers. To increase transparency, it may also be appropriate to make the safety case documentation available to the public and to ensure that it is prepared in a manner and at a level of detail that is suitable for the intended audience.

4.100. Further recommendations on traceability and transparency in the documentation of the safety case are provided in paras 7.12–7.17.

5. RADIOLOGICAL IMPACT ASSESSMENT FOR THE PERIOD AFTER CLOSURE

5.1. As indicated in para. 4.44, assessment of the post-closure radiological impact forms the core of the safety case for a disposal facility. Radiological impact assessment for the period after closure is a process of evaluating the performance of a disposal system and quantifying its potential impact on human health and the environment. The assessment includes both quantification of the overall level of performance of the disposal system and analysis of the associated uncertainties. The methodology used for radiological impact assessment should be systematic and the assessment should adequately address all safety relevant aspects in a graded manner (see para. 5.6).

5.2. The general methodology for assessing the impact of near surface disposal facilities after closure was developed within the Improvement of Safety Assessment Methodologies for Near Surface Disposal Facilities (ISAM) project [26]. The methodology has been adapted and tested, and has been found to be equally useful in assessing the impact of other types of disposal facility.

5.3. With regard to terminology, it has to be noted that in Ref. [26] the term 'safety assessment' is used primarily to indicate the radiological impact assessment for the period after closure. However, as already explained in para. 4.42, in this Safety Guide the term 'safety assessment' is used to reflect all elements of assessment (see Fig. 4) integrated into the broader concept of the safety case. This does not entail any changes to the assessment methodology, which is still based on that set out in Ref. [26].

5.4. The key components of the methodology for the radiological impact assessment for the period after closure, as discussed in this section, are:

- — Specification of the context for the assessment;
- — Description of the waste disposal system;
- — Development and justification of scenarios;
- — Formulation and implementation of models;
- — Performance of simulations and analysis of results, including sensitivity and uncertainty analyses;
- — Comparison with safety criteria;
- — Review and modification of the assessment, if necessary (i.e. iteration).

5.5. Some of these components (context for the assessment, description of the waste disposal system, evaluation of results) overlap with the respective components of the safety case described in Section 4. This is a natural consequence of considering the radiological impact assessment for the period after closure as one element of the broader safety case. The discussions in this section relate specifically to the quantitative assessment and supplement the more general presentation in Section 4.

CONTEXT FOR THE ASSESSMENT

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 applies for quantitative assessment of the radiological impact of the facility for the period after closure.

Philosophy underlying the assessment

5.7. The philosophy underlying the assessment, i.e. the choice of approach taken in conducting the assessment, has 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. For demonstrating compliance with regulations, it is usually required to show that the radiation dose or risk from the possible migration of radionuclides from the disposal facility will remain below a prescribed dose or risk constraint. It then suffices to demonstrate that an upper estimate for the possible release of radionuclides satisfies the constraint. This type of approach to assessment is usually referred to as a deterministic approach and is generally carried out in a conservative manner.

5.9. Uncertainty in a parameter value can, in principle, be described by a probability density distribution, either derived from observed statistics or more generally introduced as an expression of the degree of confidence in the accuracy of the value on the basis of expert judgement. Many uncertainties associated with a parameter that is not a numerical parameter can nevertheless be quantified and expressed as a probability distribution. An approach using probabilistic calculations derives the probability distribution for the outcome of the assessment from the probability density distributions for the parameters used in the assessment.

5.10. Radiological impact assessment for the period after closure should be performed using an appropriate selection of approaches that, when used in a complementary manner, can increase confidence in the safety of a disposal facility. The different approaches that can be considered include: probabilistic and deterministic approaches, the use of simple conservative models and the use of complex, more realistic models. If a conservative approach is to be used, it should be realistic, making use of empirical data, as practicable, as well as expert judgement in selection of exposure scenarios, conceptual models, parameters and simplified calculation models.

Probabilistic and deterministic approaches

5.11. A combination of probabilistic and deterministic approaches 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.

5.12. A deterministic approach is easier to implement and might be more easily explained to a range of interested parties. This approach can also be useful for illustrating the impact of specific individual uncertainties or alternative model assumptions. Limitations of the deterministic approach include the inability to take probabilities and variability into account, and difficulty in justifying the choice of best estimate or conservative values for the parameters.

5.13. A strength of the probabilistic approach lies in its ability to provide a more comprehensive and explicit representation of uncertainty by considering the whole range of variation of the uncertain parameters. Such approaches also provide for more thorough and systematic sensitivity analyses, and can be used to derive risk estimates. Another strength of the probabilistic approach is that it allows examination of the projected performance of the disposal system under a range of conditions and assumptions, and therefore contributes to the robustness of the safety case and the regulatory decisions.

5.14. Challenges associated with a probabilistic approach include difficulties in obtaining or specifying appropriate probability distributions for the parameters, difficulties in assigning probabilities that can be justified to alternative model assumptions, the difficulty in communicating probabilistic assumptions and results, and the additional resources necessary.

Conservative assessments and realistic assessments

5.15. A realistic assessment is aimed at providing an indication of the most likely behaviour of the disposal system. In a conservative assessment, the ability of the disposal system to provide protection is deliberately underestimated. If a conservative approach is taken, the assessment should describe the justification for labelling certain parameter values or assumptions as conservative and quantitative estimates of the degree of conservatism should be provided, if possible. Further recommendations on the use of conservative assumptions and on assigning conservative values to parameters are provided in para. 5.67.

5.16. Both conservative and realistic calculations might be necessary in radiological impact assessment for the period after closure, and both approaches can be used to increase confidence in the safety of the disposal facility. For example, conservative models can be used, especially in early phases of assessment, to assess quickly the performance of part of or the entire disposal system. Simple conservative models may also be used to increase confidence in results obtained with more complex models. Conservative models are also necessary to deal with uncertainties that are not amenable to quantification. Conservative estimates may be used in the assessment for some parameters, while realistic values based on detailed characterization and/or more realistic models may be used for others.

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

5.18. For optimization of the design of the facility or in order to demonstrate a detailed understanding of the behaviour of the disposal system, the assessment should be as realistic as is possible, depending on the availability of data with which to parameterize the models. A realistic assessment may, however, necessitate complex calculations involving a large number of parameters, and significant resources may be required to demonstrate that the data and models used do in fact lead to a realistic representation of the performance of the disposal system.

5.19. In order to demonstrate 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 disposal system may lead to poor decision making that is based on assessment results that bear little resemblance to the actual performance of the facility. In addition, the use of an overly conservative approach can raise concerns of interested parties about manipulation of results, if later assessments adopt a more realistic (or less conservative) approach to demonstrate compliance with regulatory requirements. In order to avoid such situations, the choice of a conservative approach or a realistic approach, and the reasons for modifying the approach if this is done, should be clearly documented and communicated.

Regulatory framework

5.20. The regulatory framework governing the conduct of a safety assessment should be documented as part of the context for the assessment, and the safety assessment should be conducted in a manner consistent with that framework. Thus, the safety criteria to be used in the assessment will typically be specified by the regulatory framework.

5.21. With regard to quantitative regulatory criteria, para. 2.15 of Ref. [2] states that:

> "the calculated dose or risk to the representative person who might be exposed in the future as a result of possible natural processes… affecting the disposal facility does not exceed a dose constraint of 0.3 mSv in a year or a risk constraint of the order of 10^{-5} per year".

5.22. Furthermore, if inadvertent human intrusion:

> "is expected to lead to an annual dose of less than 1 mSv to those living around the site, then efforts to reduce the probability of intrusion or to limit its consequences are not warranted.
>
> "(d) If human intrusion were expected to lead to a possible annual dose of more than 20 mSv…to those living around the site, then alternative options for waste disposal are to be considered, for example, disposal of the waste below the surface, or separation of the radionuclide content giving rise to the higher dose.
>
> "(e) If annual doses in the range 1–20 mSv…are indicated, then reasonable efforts are warranted at the stage of development of the facility to reduce the probability of intrusion or to limit its consequences by means of optimization of the facility design"[10] (para. 2.15 of Ref. [2]).

[10] The term 'site' refers to the area of the former site and its environs, as in the future the boundary of the site will have little meaning.

5.23. The quantitative criteria and the time frames for which compliance with the criteria has to be demonstrated may differ in different States and need to be specified in the context for the safety case and assessment.

5.24. If several facilities exist or are planned for the same site, the impact of all facilities should be taken into account in establishing which criteria to consider and when comparing the results of the assessment with these criteria. This may not be straightforward if a mixture of old and new facilities exists at a site, or if the periods over which risks in principle could exist are different for each facility at the site. In such situations, consultation between the operator and the regulatory body will usually be necessary in order to specify the criteria that are to be used in the assessment.

End points for the assessment

5.25. A clear description of the end points for the assessment should be provided, together with a justification for their selection, including:

— The assessment end points for radiological impact such as levels of dose or risk. These will usually relate to the regulations applicable to the facility, 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 concentrations and fluxes of radionuclides, concentrations and fluxes 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 and environmental standards, or to make comparisons with natural background levels of radioactivity.

5.26. Different end points may be used for different periods (time windows) within the assessment time frame (see paras 5.34 and 5.35, and Section 6).

Receptors

5.27. A fundamental principle of radioactive waste disposal is that individuals and populations in the future have to be adequately protected without any need for them to take significant protective actions [1]. The protection of non-human species has been under discussion for several years (e.g. Ref. [24]). However, an international consensus on approaches and criteria for addressing this issue is still evolving. Therefore, this issue is not considered further in this Safety Guide.

5.28. In Ref. [23], the concept of a ‘representative person’ is used for the assessment of radiological impact on members of the public. Either the dose or the risk to the representative person of a potentially exposed group can be used as an end point for the assessment, depending on regulatory requirements. The receptors associated with each of the various end points should be clearly specified and described. The use of a range of possible receptors should be considered.

5.29. Normally, it is assumed that the representative person is located within the region of potential radionuclide contamination in the accessible biosphere giving rise to the highest radiological impact. It may also be assumed that radioactive contamination of the biosphere due to releases of radioactive material from the disposal facility is likely to remain relatively constant over periods that are considerably longer than the human lifespan. It is then reasonable to calculate the annual dose or risk by averaging over the lifetime of the individuals.

5.30. In Ref. [23], it is recommended that three age categories be used for estimating the annual dose to the representative person for prospective assessments. These categories are 0–5 years (infant), 6–15 years (child) and 16–70 years (adult). For practical implementation of this recommendation, dose coefficients and data on habits for a 1 year old infant, a 10 year old child and an adult should be used to represent the three age categories.

5.31. For long term dose assessments, it can be assumed that radioactive contamination of the biosphere due to releases of radioactive material from the disposal facility is likely to remain relatively constant over periods that are considerably longer than the human lifespan. It is then reasonable to calculate the annual dose or risk by averaging over the lifetime of the individuals, which means that it is not necessary to calculate doses to different age groups; the average annual dose can be adequately represented by the annual dose or risk to an adult [23, 24].

5.32. It should be ensured that the characteristics assumed for the individuals in the group are consistent with the capability of the biosphere to support such a group. For example, depending on the assumed environmental conditions (location, climate, etc.), the agricultural capacity or other productivity of a particular setting may limit the size of the group that can reasonably be expected to be present.

Time frame for the assessment

5.33. The time frame for the assessment is the longest period considered in the calculations for the radiological impact assessment for the period after closure. The rationale for selecting the assessment time frame should be explained and justified. More detailed recommendations concerning the time frame for safety assessment are provided in paras 6.43–6.51.

5.34. Depending on the purposes of the assessment, it might be convenient to divide the overall time frame into several shorter time windows for modelling or presentational reasons. It is also possible that different end points are used for different time windows [36].

DESCRIPTION OF THE DISPOSAL SYSTEM

5.35. Guidance on the description of the waste, the disposal system and its surroundings has already been provided in paras 4.37–4.40 because this is necessary, to a certain extent, for all elements of the safety case. The quantitative assessment of radiological impact over long time periods needs specific data to be provided that are determined by the scenarios defined and models used. The collection of the data needed for the quantitative assessment should proceed within an iterative process in parallel with the development and refinement of the scenarios and models.

DEVELOPMENT AND JUSTIFICATION OF SCENARIOS

5.36. When assessing the safety of a waste disposal facility, it is important to consider the performance of the disposal system under both present and future conditions. This means that many different factors (e.g. future human actions, climate and other environmental changes as well as events or processes that could affect the performance of the disposal facility) need to be taken into account. This may be achieved through the formulation and analysis of a set of scenarios. In this respect, development of scenarios constitutes the fundamental basis for the quantitative assessment.

5.37. Scenarios are descriptions of alternative possible evolutions of the disposal system. The development of scenarios is used to identify and define ‘assessment cases’ that are consistent with the assessment context. Each assessment case may represent or bound a range of similar possible evolutions of the disposal system.

The choice and the rationale for the choice of an appropriate range of scenarios and associated assessment cases are vital, and the scenarios selected strongly influence the subsequent assessment of the performance of the waste disposal system.

5.38. Scenarios represent structured combinations of features, events and processes relevant to the performance of the disposal system. Different types of scenario are usually considered, including a ‘base case scenario’ and ‘alternate evolution scenarios’ (which will include disturbing processes and events). The various alternate scenarios considered in an assessment will have most features, events and processes in common with the base case scenario (also called the ‘reference scenario’, ‘expected evolution’, ‘normal evolution’ or ‘undisturbed performance’). However, some particular features, events and processes will differ between the scenarios, and these will characterize each particular scenario.

5.39. Scenarios are often not designed with the aim of illustrating the possible evolution of the disposal system and its surroundings, but rather in order to illustrate the properties of one or more of the natural or engineered barriers. For that purpose, it can be instructive to assign parameter values or other properties to the remaining parts of the barrier system such that the barrier under consideration is influenced in an exaggerated way. The aim is then to show conclusively that such exaggerated conditions do not hold true or that they can be avoided by design. By assuming such extreme conditions, the robustness of the various natural and engineered barriers can be more clearly exhibited. Scenarios of this sort are often called ‘what if’ scenarios to distinguish them from realistic scenarios.

5.40. Two main methods have been used for constructing scenarios. The method described, for example, in the ISAM project [26] may be described as a ‘bottom-up’ method and is based on screening of features, events and processes. When using this method, a comprehensive list of features, events and processes should be developed as a starting point. This may involve the use of generic lists of features, events and processes (internationally agreed lists, regulations, etc.) and the determining of site specific and system specific features, events and processes. This is followed by a screening process to exclude features, events and processes from further consideration that would have either a very small impact on the disposal system or a very low probability of occurrence. For the relevant features, events and processes, a thorough examination of interactions between them and their combination in suitable scenarios is performed. The process used for development of scenarios should be fully documented and justified. Criteria for screening features, events and processes may include rules relating to regulations and/or to the probability of occurrence or consequences of events and processes.

5.41. An alternative ('top-down') method for developing scenarios is based on analyses of how the safety functions of the disposal system may be affected by possible events and processes (see, for example, Refs [4, 7, 11, 13]). This may be followed by a process of auditing the scenarios developed against an appropriate list of features, events and processes.

5.42. Regardless of the method used for developing the scenarios, all features, events and processes that could significantly influence the performance of the disposal system should be addressed in the assessment. This includes features, events and processes relating to events that could occur repetitively during the time frame of the assessment (e.g. floods, earthquakes). Hence, it should be shown that all potentially significant migration pathways from the facility have been considered and that possible evolutions of the system have been taken into account.

5.43. It should be explained and justified which scenarios are regarded as representing the normal or expected evolution of the system, and which scenarios address events and processes having a low or particularly uncertain probability of occurrence. To the extent possible, an indication of the likelihood of each scenario considered should be provided to help with assessing risk.

5.44. Depending on the time frames for the assessment, the range of environmental conditions that may occur at the site in the future should be considered and the range of potentially exposed groups of individuals should be identified. It is usually assumed that humans will be present and that they will make use of local resources. As it is not possible to predict future human behaviour with any certainty, it is generally assumed that humans in the future will have similar habits to present humans, except where such an assumption is clearly inconsistent with assumed variations in climatic conditions at a site.

5.45. When estimating risk, it is necessary to describe the approach taken to determining risk and to identify clearly whether the probabilities of occurrence of events and processes and/or scenarios were assessed, how the uncertainty associated with each scenario was dealt with, and which scenarios were included in the risk evaluations. If probabilities of occurrence of events and processes are used in risk calculations, the results can be compared to risk criteria. If the probability of occurrence of each scenario is not used — so that only doses or risks conditional on the occurrence of the scenario are calculated — it should be explained how the assessment results from various scenarios are compared to any regulatory criteria on risk.

5.46. In Ref. [22], two approaches are set out for showing whether constraints are satisfied: (i) aggregation of risk by combining doses and their probabilities of occurrence; or (ii) separate presentation of the dose and its corresponding probability of occurrence. In an aggregated approach, the total risk from all credible processes that may give rise to doses to future individuals is compared with the risk constraint. In a disaggregated approach to doses and their probabilities, the radiological significance can be evaluated from separate consideration of the resultant doses and their probability of occurrence. It should be noted that this second approach does not necessitate precise quantification of the probability of occurrence of particular scenarios, but rather an appreciation of their radiological consequences in reference to their estimated probability of occurrence. Other considerations, such as the duration or the spatial extent of the calculated doses or risks, may also be taken into account in evaluating the significance of each scenario. Although a similar level of safety can be demonstrated by either of these approaches, more information may be obtained for decision making purposes from separate consideration of the probability of occurrence of a particular situation giving rise to a dose, and the resulting dose.

FORMULATION AND IMPLEMENTATION OF ASSESSMENT MODELS

5.47. 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 behaviour of the system that is suitable for the particular purpose of the assessment as defined in the context for the assessment: The conceptual model provides a description of the components of the system and the interactions between these components. It also includes a set of assumptions concerning the geometry of the system and the chemical, physical, hydrogeological, biological and mechanical behaviour of the system, consistent with the information and knowledge available.
- A mathematical model, which is a representation of the features and processes included in the conceptual model using mathematical equations: The representation can vary in scope and complexity depending on the level of understanding of the phenomena or processes being modelled and the

information and data available. 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.

5.48. Specific models often have to be developed for particular processes and/or system components. For the purposes of radiological impact assessment for the period after closure, information provided by these detailed models will need to be integrated in such a way that it is possible to assess the overall performance capabilities of the disposal system. This integration process may necessitate simplifications, which should be properly justified and managed.

5.49. 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 programme for development of a disposal facility, the context for the assessment and existing knowledge of the disposal system;
— The conceptual model provides a reasonable representation of the disposal system, 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 evaluation are conducted and documented to build confidence in the suitability of the model for its intended purpose;
— Adequate quality assurance and quality control measures are applied to the software used.

5.50. In developing the models, it is necessary to identify and select the parameters that will be quantified, a process that is called model parameterization. Parameter values also have to be selected. In this process, the following should be ensured:

— Parameter values used in the models and codes for assessment calculations should be documented, together with the justification for their use. 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 deterministic approach has been applied, a justification for the conservatism or realism of selected parameter values used in the calculations should be provided.
— Where a probabilistic approach has been used in the assessments, a justification of the selected probability distributions should be provided.

PERFORMANCE OF CALCULATIONS AND ANALYSIS OF RESULTS

5.51. 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.

5.52. The assessment cases should adequately address the appropriate scenarios using the conceptual models and site and design information, and using a sufficient range of sensitivity and uncertainty analyses. The latter will contribute to an understanding of the system. It is important that uncertainties and parameter correlations are recognized and treated in an appropriate way.

5.53. When presenting the output from the calculations, sufficient results should be provided, both those necessary for comparison with the ultimate assessment end points and those necessary for comparison with alternative safety or performance indicators. In addition to fully aggregated results (e.g. annual dose or risk evolution over time), disaggregated entities (such as fluxes through different components of the system) should be presented in order to improve understanding of the assessment and to make the assessment traceable. The approach to be used to treat the assessment results should be set out in the safety case. For example, it should be explained whether the 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

5.54. In view of the complexity of radioactive waste disposal systems, efforts should be undertaken in the assessment to understand the significance of uncertainties and to reduce or bound uncertainties.

5.55. The analysis of uncertainties should be an integral part of the 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

5.56. In a post-closure radiological impact assessment for a disposal facility, there are several sources of uncertainty, which can be broadly categorized as: (i) scenario uncertainty; (ii) modelling uncertainty; and (iii) data and/or parameter uncertainty.

5.57. Scenario uncertainty refers to uncertainty in the future states of the disposal system. It includes uncertainty in the evolution of the disposal system, human use of the environment, and geological and other long term processes, as well as human intrusion.

5.58. Modelling uncertainty arises from a necessarily imperfect knowledge of the processes, which leads to an imperfect conceptual model. The mathematical representation of the conceptual model will have involved some simplification, also contributing to modelling uncertainty. An example is the use of one dimensional models to describe transport processes. Imprecision in the numerical solution of mathematical models is another source of uncertainty falling into this category.

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

— Waste characteristics: radionuclide inventory, physical and chemical form, content of chemical substances such as complexing agents, hazardous substances, etc.;
— Waste package characteristics: mechanical and chemical performance of the container and the matrix, composition of the waste form, etc.;
— Disposal facility characteristics: dimensions, backfill material, characteristics of concrete, etc.;
— Geosphere characteristics: hydrogeology, geochemical properties, etc.;
— Biosphere characteristics: soil properties, crop characteristics, etc.

Uncertainty and sensitivity analyses

5.60. A distinction should be made between uncertainties in the value of a variable due to its random variability, called aleatory uncertainties, and uncertainties due to lack of knowledge, called epistemic uncertainties. The main reason for distinguishing between these two types of uncertainty is that, although they are usually treated analogously in modelling, the possibilities and approaches to quantify and reduce these uncertainties are different. Aleatory uncertainties can, in principle, be quantified objectively on the basis of measurements and can be described with probability distributions. Quantification of epistemic uncertainties is always subjective and may be difficult or, in some cases, even impossible. Unlike aleatory uncertainties, epistemic uncertainties are sometimes (although not always) amenable to reduction by further research. In some situations, it may be useful to assign probabilities also to epistemic uncertainties, so that their effects can be studied. However, these probabilities have to be distinguished from those associated with aleatory uncertainties because of different approaches for their quantification and because of different possibilities for the reduction of epistemic uncertainties.

5.61. 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. Uncertainty analysis and sensitivity analysis are described in detail in Ref. [37].

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

Treatment of scenario uncertainties

5.63. Scenario uncertainties are usually dealt with by performing the assessment for a range of scenarios, usually comprising a base case scenario and several alternate evolution scenarios. These scenarios should be derived using appropriate, well defined procedures in which choices and decisions are structured, guided and documented. This comparison of assessments for various scenarios will provide an indication of the significance of the uncertainty in respect of the evolution of the site and disposal system. It may be determined that the scenario uncertainty is acceptable in the overall context of the safety case, or the comparison may indicate that changes to the design should be considered.

Treatment of modelling uncertainties and data and parameter uncertainties

5.64. For each scenario, it is necessary to deal with uncertainties in the models and parameter values used. Correlations between parameters also have to be taken into account in the treatment of uncertainties. 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 to make decisions.

5.65. 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. It is, of course, not possible to make direct comparisons between long term predictions and observations.

5.66. Sometimes, it is possible to demonstrate by sensitivity and/or uncertainty analyses that a given uncertainty is not significant to the safety of the disposal facility. 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.

5.67. Another commonly used approach to treat uncertainties is to use conservative (cautious) assumptions. For example, 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 demonstration of compliance with regulatory criteria. However, 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 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; for example, an assumption that overestimates migration of radionuclides from a facility may underestimate the long term risk from intrusion. The conservatism of the assumptions should be justified in relation to their impact on the assessment end points.

5.68. Probabilistic assessments can be used to quantify the risks associated with the scenarios in a manner that takes account of a range of parameter values arising from associated uncertainties. Probabilistic assessments should avoid realizations with combinations of the parameters corresponding to states of the system that would be impossible or very unlikely in practice. Impossible combinations of parameters may be generated, in Monte Carlo simulations, when sampling from the probability distributions of the different variables, for example, if correlations are not taken into account. Probabilistic 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 [38].

5.69. An important issue lies in the communication of the results of the probabilistic assessments to decision makers and other interested parties. For such purposes, it may be useful to perform deterministic calculations and to analyse 'what if' scenarios for illustrating how the uncertainties affect the performance of the disposal system. When addressing uncertainties, a judgement should be provided about their relevance for safety, and a strategy should be proposed for addressing them in the future.

REFINEMENT OF THE ASSESSMENT MODEL

5.70. The level of detail to which the model is developed and the associated amount and quality of data necessary will depend on the context for the assessment (see Section 4). For example, in early versions of the safety case (such as site selection or 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 improve certain models and collect further data, and to implement them using more sophisticated computer codes. Models and data for later revisions of the safety case, especially for the final revision, may need to be even more comprehensive.

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

COMPARISON WITH ASSESSMENT CRITERIA

5.72. Radiation doses to people in the future can only be estimated and the uncertainties associated with these estimates will increase for times further into the future. Estimates of doses and risks for very long time periods can be made and compared with appropriate criteria to provide an indication of whether the disposal facility is acceptable given the current understanding of the disposal system. Such estimates should not be regarded as predictions of future health detriments.

5.73. Comparison of calculated doses with estimates of the doses that may arise from naturally occurring radionuclides may also be a useful indicator of the significance of the very long term impacts of the disposal system. Other indicators should also be considered, such as activity concentrations in the environment or the retention capacity of the disposal system.

5.74. Results from analysis of human intrusion scenarios for near surface disposal facilities should be compared with the criteria provided in para. 5.22. However, for facilities other than near surface facilities, such as geological disposal facilities, where the likelihood of human intrusion has essentially been eliminated, assessment of human intrusion scenarios may be performed to test the robustness of the system. Consideration of possibilities for human intrusion should also be one of the aspects of site selection.

6. SPECIFIC ISSUES

6.1. This section provides guidance on several issues that may need particular consideration when developing the safety case for a radioactive waste disposal facility. The issues considered are:

— The role and content of the safety case at different stages of facility development;
— The graded approach;
— Defence in depth;
— Robustness of the disposal system and of the safety assessment;
— Time frames for assessment;
— Human intrusion;

— Institutional control;
— Retrievability of waste;
— Appraisal of options.

EVOLUTION OF THE SAFETY CASE

6.2. The safety case will evolve in several stages:

— Concept development;
— Site investigation and site selection;
— Development of the design and construction;
— Operation and closure;
— The period after closure.

Especially early in the development of a disposal facility, these stages may overlap and some iteration may be necessary. This section provides an overview of the role and content of the safety case at each of these stages.

6.3. The level of detail in the safety case at each stage will depend on the type of facility, the technology to be used and other factors, and should be determined in accordance with a graded approach.

Concept development

6.4. The first step in the development of a disposal facility addresses concept definition. 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. Nevertheless, some initial information, for example, on the type of host rock, may be available. Key aspects relating to the strategy for safety and to the conceptual design of the facility should be addressed. In the absence of any quantitative demonstration, qualitative justification for the strategy for safety adopted will have to be provided in the safety case. In addition, the approach to safety 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.

6.5. In accordance with the application of the strategy for safety to the disposal facility and its components, the safety case should address specifically how, individually and in combination, the components of the disposal system will ensure that all safety requirements will be met. In general, the safety case should include a description of the safety functions assigned to each component of the disposal system (both in operation and in the period after closure) and should provide an assessment of the ability of these components (including natural barriers) to fulfil their given role. The safety case should also address the feasibility of construction. In all these respects, statements about the performance of the disposal system should be justified and uncertainties remaining at the particular step of the project should be identified.

6.6. The safety case should explain how it is intended that the characteristics and properties of each component of the disposal system 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 about the ability of each component of the disposal system to fulfil its expected role under anticipated conditions and disturbing events that have been identified as possible perturbations;
— An assessment of how the components of the disposal system 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.

These factors should be supplemented by an overview of the planned site characterization programme and the research and development programme to show how missing information will be obtained in the future.

6.7. At the stage of concept definition, the safety assessment can only be very preliminary. Nevertheless, it is desirable to carry out such a preliminary assessment in order to provide a broad estimate of the order of magnitude of possible impacts, on the basis of generic considerations of the evolution of the site, and to begin to identify the features of the facility and environment that are likely to be important to safety.

6.8. The safety case should also contain information about the management system, with particular emphasis on the timescales associated with the project and the iterative nature of the project over these timescales. Among the topics relating to the management system, at this early step, the safety case should address the organizational structure and resources necessary for the project, the programme for 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.

Site investigation and site selection

6.9. At the stage of site investigation and site selection, the safety case should support the process leading to the identification of one or more potential disposal sites and should assist in the progression to the next step of development. The safety case and its content will evolve as the project develops in terms of engineering and in terms of characterization of the different natural and engineered components of the disposal system. At this stage, the safety assessment is initially generic in nature, but will evolve as the design develops and the level of detail of the site characterization increases. Criteria for rejecting a site and desirable characteristics for a site should be determined at this stage; the site characterization should be such that it is possible to verify whether the desirable characteristics are present or to determine whether the site should be rejected when compared to the criteria.

6.10. At the stage of site investigation and selection, the basic site characteristics should be described in such a way that they show how the safety function of each natural and engineered component within the proposed design options will be achieved for the site(s) under consideration. This description should be supported by the following:

— An overview of the level of knowledge about the ability of each component of the disposal system to fulfil its expected role, including under disturbing events identified as possible perturbations;
— A research and development programme to verify the expected properties of the site determined at the stage of concept development; for programmes to develop a disposal facility for high level waste, this may include the development and operation of an underground research laboratory;
— An assessment of the capacity of the site and its ability to accommodate existing waste streams and those expected in the future;
— A preliminary assessment that, inter alia, identifies the perturbations that each component and the whole facility may undergo, both of internal origin (e.g. thermal, chemical, mechanical, radiological or reactivity changes) and of external origin (e.g. intrusion, climate change, seismicity);
— An investigation of the favourable behaviour of component materials (generally metal, clay and concrete) necessary for the safety of the disposal facility;

- Proposals on how the technical feasibility of the disposal system will be demonstrated through appropriate qualification and performance confirmation programmes;
- A demonstration that at least one design option presents good prospects of feasibility, in the sense that it relies on proven and/or easily demonstrable features and is able to accommodate uncertainties relating to the expected performances of the various components of the disposal system;
- Consideration, again, of how the components of the disposal system will function together in a complementary manner to ensure that there is adequate defence in depth, including an extensive confirmation of the overall compatibility of the system components;
- An identification of areas where uncertainties important to safety could exist, which will have to be managed as part of the demonstration of safety.

6.11. The development of scenarios and assessment modelling capabilities should be sufficiently advanced so as to allow estimates with reasonable confidence of at least the order of magnitude of impacts. In this respect, even if the selection and treatment of scenarios is not exhaustive, they should cover the expected normal evolution of the facility and should take into account the main potential disturbing events identified.

6.12. Justification should be provided for the main assumptions used and simplifications adopted. Sensitivity analyses should be carried out in order to assess the robustness of the system and its components, and to assist in directing and updating the research programme and in developing the facility design.

6.13. The safety case should contain updated information about the management system with emphasis on the following:

- The organizational structures and procedures that are in place to ensure good management of the safety assessment work and good quality control for data acquisition, especially site data;
- The overall planning of activities, in particular plans for involvement of the regulatory body and other interested parties;
- Implementation of the record keeping system, which should cover both site data and the safety case and supporting safety assessment;
- Appropriate allocation of resources to continue with the subsequent steps of the project.

Design development and construction

6.14. At the stage of design development and construction, the safety case should be further developed, so that it can be demonstrated that the adopted design will meet the safety requirements for disposal and that it is a feasible approach. The safety case should also facilitate refinement of the design within the selected waste management option and disposal concept.

6.15. It should be demonstrated in the safety assessment that the loss of a safety function of one component will not jeopardize the safety of the whole system. Thus, the safety assessment should provide a mature assessment of the engineering aspects and of the impact of the disposal facility.

6.16. Both operational safety and long term safety should be assessed. An appropriate monitoring and surveillance programme should be developed and implemented before excavation and/or construction and commissioning of the facility is commenced.

6.17. The impact of any modifications to the design that have been implemented during the excavation and/or construction period should be considered in the safety case and associated safety assessment. This process should be supported by the following:

— An update of the level of knowledge on the ability of each component of the disposal system to fulfil its expected role under the normal evolution of the facility and under disturbing events, both anticipated events and less likely events. This should include a full scale characterization of the site, the maximum waste inventory for the facility, including radiological characteristics and other properties of the waste, presentation and explanation of design features, where appropriate supported by tests, and demonstrations of prototypes of critical components identified.
— The choice of construction techniques and their validation, i.e. demonstration that these technique(s) preserve the containment and isolation properties of the natural barriers to the extent necessary.
— An identification of areas where uncertainties important to safety still exist, which will have to be managed as part of the demonstration of safety.

6.18. At this stage, information that demonstrates the quality of the assessment should be included in the safety case, in particular information on the adequacy of the range of scenarios and assessment cases considered and of the models and codes used, including justification of the models selected and substantiation of their adequacy. In addition, the methods used to verify and, to the extent possible, validate the models and codes should be presented.

6.19. As part of the safety assessment, sensitivity and uncertainty analyses should be performed. This includes identification of the main sources of uncertainties, assessment of the impact of uncertainties on the results, and development of a programme for reducing uncertainties, e.g. by additional research and development work. Alternatively, uncertainties may be avoided (e.g. by the use of better understood materials) or their effects may be mitigated (e.g. by over-dimensioning of some barriers).

6.20. The safety case should update information about the management system with particular emphasis on the following:

— The organization and procedures that are in place to ensure the quality of the design work performed, its linkage to the outcome of research and development work, site characterization and safety assessment work.
— The overall planning of activities, in particular plans for involvement of the regulatory authority and other interested parties, as well as the periodic and systematic assessment of the implementation of plans.
— Implementation of the record keeping and tracking system, which should cover data, information and records of decisions taken. Information on the design basis and design modifications, and on their validation should be captured.

6.21. All appropriate information should be made available in order to support decision making, including references to outputs from other disposal projects and sources of information.

Operation and closure, and the period after closure

6.22. After construction has been completed, the safety case should continue to be developed through a continuous process of review and refinement; detailed recommendations on the safety case at the stage of operation and closure and for the period after closure are provided in Sections 4 and 5.

GRADED APPROACH

6.23. It should be ensured that the safety case and supporting assessment are based on an appropriate level of understanding of the disposal system and its potential behaviour, and that all safety relevant issues are considered and addressed. However, under Principle 5 of Ref. [1], it is stated that the resources devoted to ensuring safety have to be commensurate with the magnitude of the possible radiation risks and their amenability to control. In accordance with this principle, the safety case should be developed and assessment should be conducted only to a level of detail that is appropriate both to the magnitude of the risks and to the stage of development of the disposal facility.

6.24. This Safety Guide applies to a wide range of types of waste and disposal facilities and, depending on site specific and facility specific characteristics, these may pose different levels of hazard and risk. A graded approach to the safety case and supporting safety assessment is, therefore, required to be used 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 disposal facilities for high level waste than for disposal facilities for low level waste and for landfill type disposal facilities. While this may be generally correct, a safety case and thorough safety assessment are still necessary for disposal facilities for low level waste, the detail of which will depend on site factors, facility design, the characteristics of the waste to be disposed of and other factors. Some parts of the safety case and assessment for a near surface disposal facility may even need more effort than for geological disposal facilities. An example is assessment of human intrusion, which may be considered an event of low significance for a well sited geological disposal facility but may be considered almost inevitable for a near surface disposal facility. The level of detail necessary in the safety case and assessment should be determined by first undertaking a relatively simple assessment that provides an indication of the levels of possible risk associated with the facility.

6.25. Various criteria may be used to help in determining the amount of effort that should be expended on the safety case and assessment or review of a particular disposal facility, component of the disposal system (e.g. on characterization of a particular barrier) or process influencing the performance of the disposal system. Reference [3] identifies the following criteria to be taken into consideration in the application of a graded approach: the possible radiation risks and the maturity and complexity of the type of facility. The use of these criteria in safety assessment for waste disposal facilities is discussed in paras 6.26–6.28.

6.26. According to Ref. [3], safety significance will usually be the most important criterion to be taken into consideration. The performance of the facility should be considered in terms of releases of radioactive material in normal operation, from anticipated operational occurrences and from reasonably foreseeable disturbing events, and the potential significance of low probability events with potentially high consequences. This criterion can be applied directly at the operational stage of a disposal facility and should also be applied in the post-closure stage. It should be based upon assessed releases of radioactive material during the normal evolution and alternate evolution scenarios, including consideration of the effects of disturbing processes and events. Relatively less effort should be expended on issues that appear to be significant to safety only on the basis of results from assessment calculations (doses and probabilities) for 'what if' scenarios (see para. 5.39).

6.27. It is also possible to use maturity as a guide to determine the amount of effort that should be expended on the assessment or review of a particular disposal facility, component of the disposal system, or process influencing the performance of the disposal system. 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 practices (and the associated uncertainties); and (iii) the availability of experienced manufacturers, constructors and those conducting safety assessment. In general, the necessary depth of assessment and review efforts will be reduced with increasing levels of maturity. While the maturity criterion can be applied to disposal facilities for radioactive waste, it has to be recognized that data on the actual long term performance of disposal facilities are not available. The limited number of facilities and the uniqueness of each disposal system also have to be recognized.

6.28. Complexity may also be used as a guide to inform decisions regarding the level of effort to be applied in assessing or reviewing a particular disposal facility, component of the disposal system, and process or assessment model. Complex active systems or complex components are generally not necessary for disposal facilities. A complex design for a disposal facility might suggest a need for a correspondingly complex representation of the design in safety assessment. Therefore, for many disposal systems, design simplicity is viewed as a virtue (e.g. because it may be easier to develop a convincing safety case for a simple system). Rather than developing a complex safety assessment, the operator should first consider whether complexities in the safety assessment can be eliminated by adopting a simpler facility design.

DEFENCE IN DEPTH

6.29. The application of the concept of defence in depth to disposal facilities is explained in Ref. [2], which states in Requirement 7:

> "The host environment shall be selected, the engineered barriers of the disposal facility shall be designed…to ensure that safety is provided by means of multiple safety functions. Containment and isolation of the waste shall be provided by means of a number of physical barriers of the disposal system. The performance of these physical barriers shall be achieved by means of diverse physical and chemical processes.... The capability of the individual barriers...shall be demonstrated. The overall performance of the disposal system shall not be unduly dependent on a single safety function."

Reference [2] (in para. 1.16) also states: "In accordance with the graded approach…the ability of the chosen disposal system to provide containment [and isolation] of the waste…will be commensurate with the hazard potential of the waste." As a consequence, the number and extent of barriers necessary to meet the requirements will depend on the type of waste to be disposed of. The required assessment of defence in depth should comprise an evaluation of the levels of defence provided by barriers of the disposal facility (see para. 3.9 and Section 4) [3].

6.30. The possibilities for performing corrective actions to influence the evolution of a disposal facility are limited. Following closure, actions can only be taken during the period of institutional control. In general, the period for which waste containment and isolation will be necessary is much longer than the period of institutional control. Consequently, the focus of implementation of the concept of defence in depth for a disposal facility lies in ensuring that the design and construction of the facility will fulfil multiple complementary safety functions.

6.31. Assessing the defence in depth is becoming normal practice in preparing the safety case for waste disposal facilities. It involves identifying the various requirements and safety functions of the disposal system, designing the disposal facility and, in particular, the engineered barriers, to fulfil these safety functions, and assessing the performance of the disposal system and the barriers in terms of their ability to fulfil the safety functions.

6.32. Safety functions are fulfilled by elements of a disposal facility, such as a physical or chemical property of part of the disposal system, or a process or combination of processes, that contribute to containment and isolation of the waste (e.g. low hydraulic conductivity, slow corrosion rates, slow dissolution of the waste matrix, low radionuclide leaching rates, low radionuclide solubility, high sorption). Active controls, such as the prevention of human intrusion or monitoring, can also provide safety functions or contribute to confidence in natural and engineered barriers and safety functions, although limitations in the timescales over which credit can be taken for such controls should be observed (see paras 6.66–6.73 on institutional control).

6.33. In the safety case, it should be assessed whether the design of the disposal system is such that safety functions are complementary in preventing the migration of radionuclides. This means that it should be determined whether a defect in one safety related characteristic is compensated for by the designed performance of other safety functions. As time passes, prevention of the migration of radionuclides will be performed successively by different elements of the disposal facility. It should be demonstrated that in the event that one element of the disposal facility does not fully perform or no longer fully performs its safety function, safety is provided by other elements.

6.34. The complementary fulfilment of the different safety functions should be evaluated over different time periods. Each safety function should be independent of the others, to the extent possible, to ensure that they are complementary and that barriers are unlikely to fail through a single failure mode. In the safety case, the functions provided by each barrier should be explained and justified and the time periods over which they are expected to perform their various safety functions should be identified, together with alternative or additional safety functions that operate if a barrier does not fully perform (e.g. Fig. 5). Figure 5 illustrates the periods during which the various safety functions are fulfilled for one concept for the disposal of spent fuel and high level waste in ‘Boom clay’[11]. In this example, the engineered barriers are expected to provide complete containment of the waste throughout the period that the disposal facility experiences elevated temperatures, a period of some thousands of years. Thereafter, the Boom clay is expected to retard the migration of radionuclides. More details on this particular example are provided in Ref. [11].

6.35. A detailed analysis of how the various safety functions are fulfilled by the elements of the disposal facility may be performed by relating the safety functions of the disposal system to measurable or calculable quantities. For

[11] A moderately swelling clay found in the region of the town of Boom, Belgium.

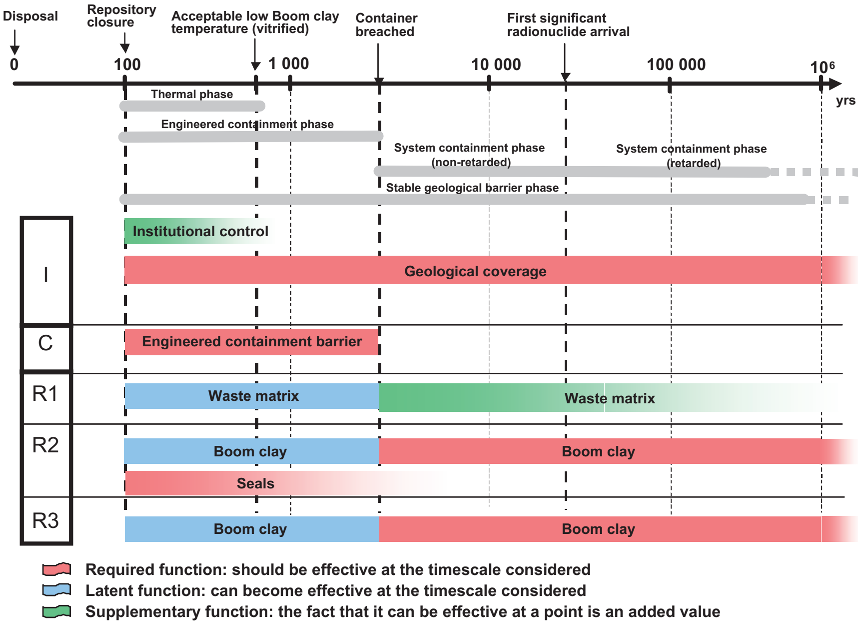

FIG. 5. Illustration of the relationship between safety functions and time for one concept for the disposal of spent fuel and high level waste [11]. I = isolation, C = containment, R = retardation.

example, if a particular barrier performs a safety function relating to limiting water flow, then the hydraulic conductivity of the barrier may be a suitable quantity to use in order to evaluate the extent to which the safety function is fulfilled. In such a case, the hydraulic conductivity of the barrier is said to be the 'safety function indicator' for that safety function. A safety function indicator is, thus, a measurable or calculable quantity through which a safety function can be quantitatively evaluated. In order to determine whether a safety function will continue to be fulfilled, quantitative criteria should be determined against which the safety function indicator can be evaluated over the time period covered by safety assessment. The definition of an a priori quantitative value for the safety function indicator may help to initiate the optimization process, but this should not be considered a target in itself (at least at the first stages of development of the safety case), since the satisfactory fulfilment of a safety function may rely on a combination of several processes and components whose characteristics may be fixed or can be changed by subsequent design or operational changes.

6.36. Criteria for determining whether safety function indicators are met will be an aid in determining whether safety will be achieved. As there will be a range of safety functions, safety function indicators and criteria, a failure to meet a criterion for a particular safety function indicator does not necessarily mean that the disposal system fails to comply with regulatory limits or targets (e.g. on dose or risk) but, rather, that more elaborate analyses and data are needed in order to evaluate safety (see Ref. [13]). Other ways of demonstrating defence in depth include evaluation of other measures of performance of the disposal facility (e.g. the containment of different radionuclides within different barriers) and presentation of the results.

6.37. In addition, in the development of some waste disposal facilities, hypothetical 'what if' scenarios have been used (see para. 5.39). These assume, for example, the absence of a particular barrier or safety function or, for near surface disposal facilities, the loss of institutional control during the assumed period of institutional control. Such scenarios allow investigation of the response of the disposal system to perturbations even if such perturbations are considered hypothetical. However, despite the assumptions made in the 'what if' scenario concerning the absence of a certain safety function, efforts still need to be expended to ensure this safety function will continue to be fulfilled, as it is an element of the defence in depth for the facility.

ROBUSTNESS

6.38. The concept of robustness may be applied to individual components of the disposal system, to the disposal system as a whole and to safety assessment.

6.39. Robustness of a component of the disposal system means that it will continue to fulfil its expected safety function(s) irrespective of disturbances that may reasonably be expected to occur (see paras 4.33 and 4.51). Sites can be selected, for example, by choosing those that are little affected by natural processes such as flooding and earthquakes. Similarly, the engineered barriers can be designed for robustness, for example, by expanding the dimensioning of certain components beyond the necessary values to ensure their resilience to disturbances and uncertainties.

6.40. A related term is the robustness of a disposal system, which addresses the robustness of individual components as well as their interactions. This is conceptually broader than the robustness of a system component only. The assessment of the robustness of a disposal system relies on several elements:

- Demonstration of the robustness of individual barriers and their safety functions;
- Evaluation of the concept of defence in depth, i.e. the presence of multiple diverse safety functions, to ensure that the overall performance of the disposal system does not rely on a single safety function, the failure or unexpected poor performance of which would lead to unacceptable radiological consequences (see paras 6.29–6.37);
- Verification that good engineering practices (demonstrability and feasibility) have been applied;
- Demonstration that safety is achieved through passive means.

6.41. Robustness of the disposal system is evaluated through comparison of the results of analyses of the base case with those of a range of scenarios illustrating specific perturbations or uncertainties. Among the different types of perturbation, the most generally considered are those where one component or one of its characteristics is considered to have failed (‘what if’ scenarios). Scenarios involving such strong perturbations applied to the disposal system are distinguished from scenarios describing degraded behaviour of the disposal system.

6.42. A related concept is the robustness and reliability of safety assessment as required in Ref. [3], i.e. the insensitivity of the results of safety assessment to uncertainties in scenarios, models and data. The robustness of safety assessment will depend on the facility design because the degree of uncertainty associated with an assessment is, to some extent, determined by the physical and chemical properties of the system components and their interaction with the environment.

TIME FRAME FOR THE ASSESSMENT

6.43. The time frame for the assessment is the period covered by safety assessment calculations. Within the time frame for each assessment, it may be necessary to consider more than one assessment time window. A complete scientific basis will not always exist for the selection of a time frame for safety assessment calculations. In such cases, decisions about the time frame should be made within the regulatory process.

6.44. The assessment time frame should be defined by taking account of national regulations and regulatory guidance, as well as the characteristics of the particular disposal facility, the site and the waste to be disposed of. Other factors that should be considered when deciding on the time frame and time windows for the assessment include the following:

— Safety assessment calculations should cover a time period that is long enough to determine the maximum, or peak, dose or risk. However, this may not always be possible. For example, in the case of disposal of long lived waste (e.g. from uranium mining) on or near the surface where there is uncertainty in the durability of engineered barriers (e.g. dams and covers), doses and risks may remain constant or may even increase long into the future, through time frames in which uncertainties in the assessment increase significantly and limit the meaningfulness of the assessment. This may limit the timescale for the assessment in general, or at least the timescale for quantitative assessments.
— Several factors that can significantly affect safety assessment results may change with time. As an example, the landscape and hydrological regime at and around a facility may change in response to climate change, and with these changes receptors and their habits may change. Assessments for long lived waste should consider such possible changes. As a means to assess the possible evolution of a disposal system, some assessments consider one or more climate scenarios involving future glacial periods or cycles. Assessment time frames should be defined as appropriate for the possible changes at the site.
— The decision about the time frame for the assessment has implications for the type and severity of disturbing events that are considered in the safety assessment. For example, a flood or earthquake that is expected to occur once in a thousand years can be more disruptive than a flood or earthquake that is expected to occur once in a hundred years.

6.45. In view of the complexity and variability of these factors, it is not possible to establish a universal timescale over which meaningful quantitative results from modelling can be obtained. For above surface disposal facilities (e.g. for waste from mining), the uncertainties in modelling results will already be substantial when considering periods of several hundred years, and quantitative estimates may become meaningless already beyond a period of a thousand years. For engineered near surface disposal facilities, which are subject to processes that may affect their integrity (e.g. erosion, human intrusion) to a lesser degree or with a smaller probability, modelling periods of a few thousand years may still be reasonable. For deeper facilities, such as geological disposal facilities for high level waste, modelling for periods of tens of thousands of years and beyond may still result in meaningful estimates of upper bounds of possible radiation doses.

6.46. It may be necessary to define several different time windows within one safety case in order to deal with different scenarios. For example, some scenarios may include events that will disrupt and/or destroy certain types of disposal facility. At some sites, erosion or glaciation may destroy a near surface disposal facility. While the time frame over which glaciation is to be expected is not relevant for waste containing mainly short lived radionuclides, disposal facilities for uranium mill tailings may be affected by glaciation, which will limit the time frame for meaningful assessment of above surface impoundments for such waste. As another example, the need to prevent criticality will need to be considered for certain waste types, and the time frame over which criticality might conceivably occur should be defined largely by consideration of radionuclide decay and in-growth. It may also be desirable to define several different time windows within one safety assessment for presentational reasons. For example, definition of more than one assessment time window may enable assessment calculations to be undertaken and presented at different levels of detail and/or for different degrees of conservatism or realism.

6.47. On the basis of such considerations, the lifetime of the disposal facility may be covered by using one or more sets of assessment calculations. In such cases, it should be shown, to the extent possible, that the calculations together cover the entire period and that consistent assumptions have been made throughout the assessment period or that inconsistencies are well justified. In some cases, differing or even inconsistent assumptions may be made to demonstrate safety for different assessment periods, because assumptions may be made that are conservative for a specific period, but which do not necessarily also have to be conservative for another period. For example, an assumption made concerning the release of radioactive material during the operational period may be conservative, while for the post-closure period the assumption that the full inventory still remains in the facility may be conservative. In such cases, deliberately introduced differences and contradictions in assumptions should be carefully documented and justified in order not to discredit the overall safety case as being based on inconsistent assumptions.

6.48. The assessment time frame is often kept fixed throughout the various iterations of safety assessment. In other cases, however, it may be necessary to revise the assessment time frame between different iterations of safety assessment to reflect new information gathered. For example, it might be considered necessary to extend the time frame to ensure that the maximum or peak dose is covered within the assessment calculations. This could be necessary if new information indicates that the waste would contain greater amounts of long lived radionuclides than previously assumed. Alternatively, it might be considered appropriate to restrict the time frame for quantitative assessments to periods over which the results of safety assessment are meaningful, given the uncertainties. As an alternative to limiting the time frame of the assessment, the emphasis put on quantitative results for the later part of the time frame could be reduced. However, in all such cases, the impacts beyond the period of quantitative assessments should be addressed in an appropriate manner in the safety case.

6.49. The safety case should also address the evolution of the disposal facility and its potential impacts for times beyond the end of the safety assessment calculations, if at that point in time non-negligible hazards are still expected to exist. This should be done by means of simplified estimates and qualitative arguments rather than through the application of quantitative safety criteria. For example, for deep geological disposal facilities, this may be done by using arguments about the geological stability of the site.

6.50. For any given time in the evolution of the disposal facility and its environment, emphasis in the safety case should be placed on those safety functions that are expected to be most effective, and on those arguments that are considered to be the most convincing. For example, initially it may be confidently expected that canisters provide complete containment of the waste, and safety arguments may emphasize evidence supporting the integrity of the canisters for a certain period of time. At later times, complete containment cannot be relied upon, and arguments based on, for example, the stability of the waste forms, geochemical immobilization, the slow rate of groundwater movement and the stability of the geological environment should be used to show that any releases of radionuclides to the environment will nevertheless be small [36].

6.51. The considerations in paras 6.43–6.50 show that the establishment of appropriate time frames and time windows for safety assessment necessitates judgement and the balancing of competing factors. The rationale for the time frame and time windows adopted for safety assessment should be described clearly. In particular, if one of the factors set out in para. 6.44 limits the assessment to a period shorter than the period over which the disposal facility could, in principle, give rise to non-negligible hazards, a clear justification should be provided for not extending the assessment time frame. For example, an assessment of radiation exposures from waste from uranium mill tailings disposed of at the surface would not be meaningful if it were to be extended beyond time periods over which glaciation is to be expected (see para. 6.46), although the hazard potential of the waste extends substantially beyond this timescale.

HUMAN INTRUSION

6.52. Future human actions may disrupt a waste disposal system. Human action affecting the integrity of a disposal facility and potentially giving rise to radiological consequences is known as human intrusion. Human intrusion is particularly relevant for disposal facilities at or near the surface. Most human activities (e.g. construction operations, farming, etc.) that could lead to inadvertent human intrusion into a waste disposal facility take place at limited depths of tens of metres (typically down to 30 to 50 m below the surface). Over long time frames, human intrusion into such a facility may be quite likely. Human activities that reach depths greater than 30 m are much less likely, but include drilling (e.g. for water, oil or gas), exploration and mining activities, geothermal heat extraction or the storage of oil, gas or carbon dioxide. In this respect, the following guidance addresses mainly disposal facilities at or near the surface. A discussion of the relevance of human intrusion scenarios for deep geological disposal facilities is presented in para. 6.65.

6.53. Only those human actions that result in direct disturbance of the disposal facility (i.e. the waste, the contaminated near field or the engineered barriers) are considered human intrusion in this Safety Guide. Human actions resulting in the disturbance of the host environment beyond the disposal facility and its immediate proximity are not categorized as human intrusion, since they do not result in direct intrusion into the disposal facility. Such actions should be considered within the scenarios used for the assessment of long term risks (see Section 5). Paragraphs 6.54–6.64 provide further guidance on the assumptions and approaches appropriate for addressing human intrusion in safety assessment. These are relevant for all disposal facilities located close to the surface where human intrusion becomes a safety concern.

6.54. During operation of the facility and for any subsequent period of institutional control, it is assumed that a variety of measures will be in place to ensure that human actions do not adversely impact the safety of the disposal system. These measures will not only be based on safety considerations, but also will satisfy security related requirements and, if relevant, requirements relating to accounting and control of nuclear material. Nevertheless, deliberate (intentional) human intrusion could occur during this period; deliberate human intrusion can be defined as entry to, or disruption of, a facility in which the person or persons carrying out the intrusion are aware of the existence of the facility and have some knowledge of its contents. Therefore, it is likely that the intruders would take measures to limit the potential impact of their intrusion, for example by minimizing their contact time with the waste. Even if this is not the case, the intruders will have to bear their responsibility and the consequences because their actions were intentional.

6.55. Although it is recognized that third parties might unknowingly be exposed to radiation as a result of deliberate intrusion by others, it is stated in Ref. [39] that “Intentional disruptive actions should not be considered in safety assessments”. In support of this position, it is noted in Ref. [39] that, while it is widely accepted that a society that generates radioactive waste bears the responsibility for developing a safe disposal system that takes into account future societies, even if future societies are forewarned of the consequences of their actions, the present society still cannot protect future societies from their own actions.

6.56. In conclusion, in the safety assessment for a waste disposal facility, inadvertent (unintentional) human intrusion should be considered but quantification of the potential risks associated with deliberate intrusion need not be carried out. Consequently, inadvertent human intrusion should be assumed to occur at some time following the loss of knowledge about the site and its hazardous contents. This implies that an individual or group of individuals intruding into the disposal facility (the intruders) will, at least for a short period, be directly exposed to radiation while being unaware of the associated potential hazard. Intrusion may also lead to increased release of radioactive material and increased long term exposure of individuals or groups around the disposal facility.

6.57. If human intrusion cannot be excluded for a certain disposal facility, the consequences of one or more plausible intrusion scenarios should be assessed. However, estimates of the probability of intrusion are uncertain and it is recommended in Ref. [20] that safety assessment should seek to evaluate the doses associated with human intrusion that may occur, but should not attempt to use a risk based concept that uses as a basis for assessment the product of the probability of intrusion and the dose arising from the intrusion.

6.58. Although details of the approach taken to assess human intrusion may be specific to the types of waste and the disposal facility in question, the approach should be consistent with the general methodology described in Section 5. Criteria for this assessment are provided in para. 5.22.

6.59. In accordance with Ref. [22], “those living around the site” should be considered receptors in human intrusion scenarios. This does not mean, however, that the intruder should be automatically excluded from consideration. A distinction should not be made between the intruder and the residents. Indeed, these could be the same persons in the case of people living on top of a former site about which knowledge has been lost. Instead, a distinction should be made between the normal behaviour of people living near or even on the site, and events with a short duration and/or low probability of affecting a small number of people (such as road construction activities). Regarding the latter as 'industrial accidents' would not require application of the same dose criteria to the intruders in these cases as those applied to the residents near or on the site. In accordance with this distinction, the actual contact of the receptor with the waste may be considered in scenarios, and the dose criteria for intrusion, as set out in Ref. [2], may be applied to the resulting exposure if this event is deemed to be possible in a normal residential situation.

6.60. In developing scenarios for human intrusion, two contrasting approaches can be adopted. One is that a few generic scenarios are developed for all or most situations. An alternative approach is that scenarios are developed on a site specific basis. There are advantages and disadvantages to both approaches and the choice of approach (generic or site specific) should be made in accordance with the purpose of the particular assessment. Even if it is decided that generic scenarios are to be developed, certain site specific features (such as the depth and design of the facility, its geological environment and the characteristics of the waste) should be taken into account.

6.61. Human intrusion scenarios should be developed on the basis of stylized representations of the nature of the intrusion and the actions of the intruder, and it should be recognized that there is an unavoidable uncertainty associated with human intrusion. Human intrusion scenarios are not meant to convey any authoritative statement about the evolution of the site and future societal activities, but are designed to provide illustrations of potential impacts of human intrusion. If stylized scenarios are being used, they should be based on the assumption of present day technologies and procedures.

6.62. For near surface disposal facilities, calculations should be performed to assess the doses to the relevant potentially exposed persons (see para. 6.57). Assessments should be based on the assumption that intrusion can occur immediately after knowledge about the site is lost. If a period of institutional control is taken account of in the safety case, the loss of knowledge should be assumed to occur immediately after the withdrawal of institutional control. The period over which credit can be taken for institutional control is limited to a maximum of a few hundred years in the regulations of many States. Although the provision of passive controls (e.g. records, facility markers) should be encouraged, in safety assessment it should be assumed conservatively that such controls will not be effective in preventing or reducing the probability of human intrusion [39].

6.63. When assessing the impact of human intrusion, consideration should be given to the volumes of waste that might be affected by the different types of intrusion and to the heterogeneity of the waste. Potentially significant heterogeneities (‘hot spots’) may occur and their impacts need to be assessed. On a large scale, such differences in activity concentrations of the waste may result from a number of factors, including changing waste acceptance criteria with time or different waste emplacement campaigns being dominated by specific waste streams. On a smaller scale, some waste packages may contain particular items that have significantly greater activity concentration (e.g. disused sealed sources) than the average for all waste packages. Heterogeneities in the waste should be assessed by performing a range of calculations that take due account of the possible range of activities and compositions of waste. The volumes of waste that might be affected in the event of intrusion should also be assessed.

6.64. A number of measures can be used to reduce the likelihood and mitigate the consequences of human intrusion into radioactive waste disposal facilities. These measures include active institutional controls and/or a system of durable physical barriers. Furthermore, compartmentalization of the waste may reduce the consequences of an intrusion event. Probably the most substantial reduction of estimated doses may be achieved by emplacing the waste at greater depth. In certain situations, an alternative site may also be considered, in particular if the risk of human intrusion is greater owing to the presence of water or mineral resources at a site that may be exploited at some time in the future. Such measures should be seen as part of the optimization of protection. Although such measures are unlikely to completely eliminate doses from human intrusion, they may reduce the likelihood of human intrusion and/or its consequences.

6.65. As discussed above, the relevance of human intrusion scenarios for geological disposal facilities is limited, as the depth and location of such facilities makes it unlikely. The time frames of concern are also far too large to enable meaningful estimates of possible impacts from intrusion events to be made. Nevertheless, it may be decided to make an assessment of the consequences to demonstrate the robustness of the disposal system. The scenarios considered are speculative and somewhat arbitrary owing to uncertainties in the boundary conditions and other parameters, such as when it is assumed that the event will take place and what the state of the facility and its host environment will be at the time of intrusion. As a consequence, for geological disposal facilities, care should be taken when making quantitative use of the results obtained for human intrusion scenarios, in particular when comparing these to other scenarios (e.g. for purposes of optimization of protection and design). The most effective measures against inadvertent intrusion involve establishing the disposal facility in deep geological formations and providing knowledge maintenance in the long term.

INSTITUTIONAL CONTROL

6.66. The unavoidable tension between the expected duration of active institutional control and the period of time over which long lived waste will remain hazardous has led to disposal strategies in which institutional control plays different roles:

- — In geological disposal and disposal at intermediate depths, institutional control may provide another layer of defence in depth, as long as it lasts, and may contribute to building confidence in the safety of the disposal facility. However, the safety objective should be achieved even in the absence of institutional control.
- — In the disposal of radioactive waste at or near the surface, institutional control is usually required for achieving the safety objective and should remain in place as long as the waste remains potentially hazardous (e.g. a few hundred years). Waste containing appreciable amounts of long lived radionuclides should be disposed of at greater depths. Assumptions concerning the duration of institutional control play a major role in defining waste acceptance criteria, particularly for near surface disposal facilities.

6.67. Institutional control should be seen as a component of the overall system of protection against the hazards of radioactive waste. This is consistent with the general defence in depth concept, as it adds a layer of protection to the natural and engineered barriers of the facility. However, the presence of institutional control should not be used to justify a reduction in the level of design performance of the containment and isolation system.

6.68. Any facility whose safety case is based on the assumption of effective long term institutional control should be subject to regular review. Such reviews may result in confirmation that existing arrangements are satisfactory and that the measures for institutional control are sustainable for the period to the next scheduled review; if a review does not provide such confirmation, the measures for control will need to be updated or other strategic decisions will need to be taken.

6.69. For near surface disposal facilities containing predominantly short lived waste, it is often the case that the greatest potential for exposures and the greatest risks are associated with inadvertent human intrusion after the cessation of the period of institutional control. In such cases, results from assessments of inadvertent human intrusion may limit the permissible inventory of long lived radionuclides that can be safely disposed of in the facility. Thus, this assessment determines, in particular, the limit for long lived radionuclides in the waste acceptance criteria for near surface disposal facilities.

6.70. In many cases involving large volumes of waste containing radionuclides of natural origin, at least given current technical and economical possibilities, all existing alternatives for disposal necessitate at least some level of ongoing institutional control. The required function of institutional controls in such cases may range from preventing human intrusion, to ensuring through surveillance and maintenance programmes that the barriers (e.g. covers) remain intact, to addressing detrimental impacts on the integrity of barriers. Such impacts may have occurred, for example, through natural processes such as erosion or degradation of covers by roots or burrowing animals.

6.71. Acceptance of the necessity for ongoing institutional control in such cases could be seen as a violation of Principle 7 of Ref. [1] by imposing a burden on future generations. However, in assessing this burden, it needs to be considered what is practically and economically achievable for large volumes of waste containing naturally occurring radionuclides. In this sense, a decision to accept disposal options involving ongoing institutional control may be the result of a generic optimization of protection that recognizes technical and economic limitations. However, each case should be considered on its merits and specific optimization studies should be carried out with the aim of ensuring that the level of protection is optimized in the long term. This should include consideration of the implementation of measures to promote passive safety. Such optimization studies should be conducted as part of the development of the safety case for the facility.

6.72. The need for ongoing institutional control at sites at which large volumes of waste containing naturally occurring radionuclides are disposed of should not be used as an argument to accept the need for such ongoing institutional control at those disposal facilities for low level waste for which practicable options exist to avoid this by definition of suitable waste acceptance criteria. Reference [2] also stipulates the requirement that safety is not to rely on ongoing institutional control. Therefore, at least for new facilities, disposal options are limited to those that do not require ongoing institutional control.

6.73. In summary:

- — The long term safety of a radioactive waste disposal facility is not to be dependent on institutional control (para 5.6 of Ref. [2]).
- — Institutional control is an important safety component for surface disposal facilities or near surface disposal facilities for preventing human intrusion for a certain period of time. Any reliance placed on institutional controls in the safety case should be justified.
- — The provision of passive institutional control should be encouraged. Some credit can be taken for this in the safety case but it should not be assumed that it will remain effective in preventing human intrusion in the long term.

RETRIEVABILITY OF WASTE

6.74. The aim of this section is to address the implications arising for the preparation of the safety case and safety assessment if the disposal concept is intended to provide for retrievability of waste. The more general concept of reversibility denotes the possibility of reversing one or a series of steps in the planning or development of the disposal facility. This implies the review and, if necessary, re-evaluation of earlier decisions, as well as availability of the means (technical, financial, etc.) to reverse a step. Retrievability denotes the possibility of reversing the action of waste emplacement. It is, thus, a special case of reversibility. Retrieval is the action of recovery of waste or waste packages [40].

6.75. Although the term 'disposal' refers to the emplacement of radioactive waste into a facility or a location with no intention of retrieving the waste (see para. 2.9), there may be situations in which there is an intention to provide the possibility of retrieving the waste. The possibility that options for reversing a given step in the development of the disposal facility or for retrieving waste after its emplacement are included in the design is recognized in Ref. [2]. Although such provisions can provide for flexibility in decision making in the development of a disposal facility, they should not be allowed to undermine the long term safety of the facility. Flexibility in the decision making process should not be seen as an objective in itself, but rather as good practice.

6.76. The introduction of measures to facilitate retrievability does not lessen the need for a thorough safety assessment and may introduce the need for additional assurances regarding certain operational aspects (e.g. the long term durability of waste packages under operational conditions before closure of the facility; provisions for facility closure). In particular, retrievability should not be made an excuse for an indefinite delay in making decisions concerning the development of the disposal facility and is not a substitute for a well designed and well sited disposal facility for which the basis for closure of the facility at the end of its lifetime can be justified. Clear plans for development of the disposal facility, including its closure, should be prepared even if flexibility is allowed to future decision makers in their implementation of the plans. Safety assessment calculations should be made to determine the consequences of failure to close the disposal facility as originally intended.

6.77. If retrievability of waste is a design option, the safety case should address administrative and technical arrangements that ensure that: an appropriate level of technical ability to retrieve waste is maintained at each stage following emplacement of the waste; the methods for retrieval are specified; and periodic evaluations are made of the appropriateness and necessity of proceeding with the next step towards closure of the facility, maintaining the facility at the current step, or reversing a step, including retrieval of the waste if necessary. The safety case should further address monitoring provisions to verify that the conditions under which retrieval could be performed safely prevail.

6.78. In most States, regulatory guidelines have not yet been issued on when retrieval is necessary and how requirements for retrievability, if any, should be implemented. Where retrievability is mentioned in national regulatory guidelines, there is usually an overriding requirement that any measures to enhance retrievability should not compromise the passive long term safety of a disposal facility. If retrievability is required as part of the national waste management policy, the regulatory requirements for retrievability should be reviewed to check that they are consistent with requirements for maintaining nuclear security and safety — including requirements for radiation protection and measures required under the system of accounting for and control of nuclear material — both in possibly prolonged periods before closure of the facility and in the long term.

APPRAISAL OF OPTIONS

Framework for the decision making process

6.79. The planning and development of disposal facilities involves making decisions of various kinds. Examples are decisions about the site of the facility or decisions about the facility design. In the case of existing facilities, new information (e.g. information obtained through a monitoring programme) may raise concern regarding the ability of the facility to continue to perform safely. In such situations, decisions may be necessary as to whether to retrieve some or all of the waste or to upgrade the facility. Decision making in such cases necessitates comparison of different management options and identification of the option that complies with all of the applicable regulatory requirements and provides an optimal level of protection, with factors such as costs and other detrimental factors taken into account.

6.80. The actual decision making process depends on the legislative and regulatory framework, and will often involve interested parties such as the local population. The safety case represents a key input to this process and should, therefore, be used to assist in reaching decisions on how to ensure the safety of a new facility or to upgrade the safety of an existing facility. Consequently, the whole range of activities necessary to develop the safety case, including all steps in the conduct of the supporting safety assessment, should satisfy the following:

- All safety aspects relevant for later decision making should be addressed in the safety case. This includes the assessment of radiation risks as well as of other factors of influence for decision making about the practicability and acceptability of intended activities.
- Relevant factors of influence for decision making should be investigated to a sufficient level of detail, using adequate methodologies. The main considerations are that relevant impacts should not be underestimated but also, in particular in existing situations, that an overestimation of risks and other important detrimental factors should be avoided, to the extent practicable, in order not to trigger the implementation of unnecessary measures.
- Efforts (e.g. for data collection and modelling) should be focused on factors of relevance for later decision making, so that time and financial resources are not wasted.
- The assessment results as well as additional arguments and considerations presented in the safety case should be sufficient to derive and justify decisions on the actions to be taken. A sufficient basis should be provided

for the assessment of compliance with regulatory requirements, for decisions on the inclusion of other relevant factors, for the balancing of benefits and detriments of available options as a basis for selecting options to be implemented (this is relevant in particular for decision making for existing facilities), and for the building of confidence in the reliability of the assessments performed and in the adequacy and safety of the actions proposed in the safety case.

Methodology

6.81. In view of the overall goals of the decision making process, it is evident that it influences all parts of the development of the safety case. In particular, all key components of the methodology for post-closure radiological impact assessment presented in Section 5 will be affected by considerations derived from the goals and requirements of the decision making process. The following are important considerations:

— As the basis for definition of the context for the assessment, the necessary decisions and potential factors of influence that have to be addressed in the safety case should be identified.
— A decisive part of establishing the context for the assessment consists of definition of the assessment philosophy. This encompasses, inter alia, the approach to the assessment of relevant end points, the nature of the assumptions to be adopted (e.g. realistic or conservative), the type of data to be used (site specific or generic) and the approach to the treatment of uncertainties. It is evident that inappropriate specification of these boundary conditions of the assessment with regard to decision making requirements would preclude the ability to make adequate and justifiable decisions.
— Apart from the range of decisions to be made, the context for assessment will also be determined by the decision making methodology adopted. If quantitative decision aiding methodologies are to be applied to compare options, requirements for addressing specific end points arise (such as requirements on collective doses[12] if a cost–benefit analysis is to be used).

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[12] With regard to the use of collective doses in such assessments, the following statement from Ref. [21] should be taken into account: “Both the individual doses and the size of the exposed population become increasingly uncertain as the time increases. Furthermore, the current judgements about the relationship between dose and detriment may not be valid for future populations. ...[F]orecasts of collective dose over periods longer than several thousand years and forecasts of health detriment over periods longer than several hundred years should be examined critically.”

Other components of the assessment philosophy, such as the treatment of uncertainties, may also depend on the decision making methodology eventually selected.
- Scenarios should be set up by considering all features, events and processes that could directly or indirectly influence the system and the radioactive inventory. To the extent that non-radiological factors are relevant, these will also need to be considered in the development of scenarios. Examples for such non-radiological factors are risks from chemically toxic or carcinogenic substances, or physical risks associated with mining activities. If such aspects are relevant for the decisions to be made, it has to be ensured that the conditions that could possibly lead to such risks are adequately covered by the scenarios.
- The models to be used and their calibration and validation should be carefully planned in the light of the actual requirements of the decision making process. In application of the graded approach, efforts invested should be in accordance with the importance of the results for making and justifying decisions.
- The results need to be analysed and interpreted in view of their relevance with regard to the decision making requirements. If the results are not considered to be sufficient for this purpose, refinement of scenario definitions and/or models and possibly the collection of additional data will be necessary.

6.82. Different approaches exist for the actual methodology employed for the selection of options. Assessment results and their implication for the decisions to be made can be evaluated by means of a qualitative process, involving deliberation of all relevant factors. Quantitative methods such as cost–benefit analysis or multi-attribute utility analysis can be applied to address and balance the various factors relevant for the decisions to be made. Examples of the application of such decision aiding methods can be found in Refs [32, 33, 41, 42].

6.83. If quantitative assessment methods are applied, these methods should be seen as tools to aid the decision making process, not as a substitute for the process. The assessment results should be used as input to discussions with the involved parties, such as the regulatory body and other interested parties. The main role of these decision aiding methodologies lies in the analysis and presentation of assessment results in a conceivable and comprehensive way that enables judgements to be made of their respective importance and implications for the decisions required.

6.84. All relevant factors should be considered in the decision making process. In the event that several facilities are present or planned at a site, including disposal facilities, the cumulative radiological impacts from these facilities should be considered in the decision making process (see para. 5.24).

6.85. The decision making process in general includes, in addition to technical aspects, other relevant factors and considerations. Although the assessment of factors other than radiological factors is not part of the methodology outlined in Section 5, the activities necessary to estimate non-radiological risks are analogous to those necessary for the estimation of radiation risks. Therefore, it might be possible to integrate the assessment of all relevant factors into this methodology, thereby providing a consistent and transparent description of all assessment activities necessary, in order to be able to compare options and select a preferred option for achieving safety (or justify doing nothing in the case of an existing facility). It is possible to refer to quantitative decision aiding methodologies such as multi-attribute utility analysis to such additional factors of influence, even if they are qualitative in nature (such as public acceptance of different options).

Application to existing facilities

6.86. The approach to support the decision making process outlined in paras 6.81–6.85 is also directly applicable to existing facilities. However, there are some specific requirements arising in such situations from the fact that the facility already exists and there may already be radiation risks, and that, therefore, decisions are limited to determining whether corrective action is necessary and, if this is the case, which type of corrective action to choose.

6.87. As a decisive part of establishing the context for the assessment consists of defining the assessment philosophy, assessments performed with the intention of comparing doses to regulatory limits, constraints and other criteria should be performed with a sufficient level of conservatism. Assessments performed with the intention of comparing options for the purposes of optimization, however, should be based on more realistic assumptions. Owing to the importance of applying the principle of optimization in existing situations, the distinction between these two types of assessment is particularly relevant for existing facilities.

6.88. For an existing situation, assessments should usually be conducted in two distinct steps. In the first assessment step, it should be determined whether corrective action needs to be considered at all or whether the current condition of the facility is considered acceptable. In the second assessment step, performed only if necessary on the basis of the results of the first step, options to improve the situation should be identified and evaluated. Which criteria (current criteria, criteria that were valid at the time of licensing of the facility or intervention criteria) to apply in this process will depend on national regulations.

6.89. In particular for existing facilities, for which several feasible options for corrective actions are available, the comparison of corrective actions should usually be performed iteratively:

— It may be possible to disregard some options for corrective actions very early on, e.g. because of prohibitive costs or because it soon becomes evident that basic regulatory requirements cannot be met. For such options, a detailed analysis of impacts would not make sense and would be a waste of effort.
— The assessment of the implications of the remaining options for corrective actions with regard to the factors to be considered in the decision making can be very time consuming and resource consuming. The decision making may even face fundamental difficulties if a basis for determining precise estimates does not exist (e.g. with respect to the durability of structures). Instead of investing great efforts in trying to improve estimates for such factors, their relevance for the decisions to be made should first be examined. It may turn out that prevailing uncertainties in some factors will not influence a particular decision because it is dominated by other factors. If this is the case, the uncertainties can be accepted and further assessment efforts are not necessary in this respect. As a justification for the decision can be provided on the basis of assessment results, the uncertainties in these factors will not interfere with the overall requirement to build confidence in the assessment.
— In accordance with the graded approach, the level of effort invested in improving data and the modelling should be commensurate with the importance of the various factors for the decisions to be taken. Within an iterative process, the implications of the results and their uncertainties for the decision making can be ‘tested’ to identify those aspects that warrant further refinement on the basis of their relevance for decision making.

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 — a process of integration (see Ref. [25]). The section elaborates on how to document the safety case and discusses its possible uses.

DOCUMENTATION OF THE SAFETY CASE

7.2. The safety case provides a basis for decision making and is presented to the relevant decision makers for their review and consideration. The parties interested in the safety case may include regulators, the general public and other interested parties. These parties will decide for themselves the extent to which they are convinced by the reasoning that is presented, and whether they share the confidence of the operator developing the safety case. The confidence of the interested parties in the findings of the safety case should, however, be enhanced if the arguments and evidence are presented in a manner that is open and transparent, and all relevant results are fully disclosed and subject to quality control and independent review.

7.3. Compliance with the requirements on the documentation of the 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 in which 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 the disposal facility (e.g. environmental impact assessments). Given these challenges, there is no universal structure for the documentation of the safety case. 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, the national legislative and regulatory requirements as well as international guidelines on the development of the safety case.

7.4. There are many possible ways of structuring and documenting the safety case and important components of the safety case are briefly discussed 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 public concerns.

7.6. For most interested parties, the summary will provide the first and most lasting impression of the project. This is often 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 of presenting 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 distributed more widely than the rest of the documentation. It may also be presented in different languages to meet the needs of local communities.

Introduction and the context for the safety case

7.7. The documentation of the safety case should be introduced by a 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 and background, the 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;
- A discussion of the status and maturity 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 adequately the challenges associated with the project.

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, develop and manage the disposal facility 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 (e.g. siting, construction, operation, closure);
— How the adopted strategies apply good engineering principles and practices;
— Management and reduction of uncertainties;
— The degree of caution to be used when making decisions and the use of multiple lines of reasoning;
— Safety features embedded in the design of the facility and the multiple safety functions used;
— The expected robustness of the disposal system to natural events and processes as well as to human induced processes;
— 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 safety assessment work undertaken, which forms the scientific and technical basis for the safety case. Documenting the safety assessment work involves a detailed description of each step of the assessment, the assessment findings and the conclusions. Owing to the large amount of detail involved, it could be more practicable 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.

Synthesis and conclusions

7.10. Following the details of all of the supporting evidence for the safety case, a section should be developed to set out evidence in support of conclusions and recommendations. The section on synthesis and conclusions should, in accordance with paras 7.2–7.9:

- Draw together the key findings from safety assessment;
- Highlight the main evidence, analysis and arguments that quantify and support the claim that the disposal facility is safe;
- Present an evaluation of uncertainties and unresolved issues and discuss planned steps to resolve them;
- Describe complementary evidence for safety, e.g. evidence for safety beyond the time frame for which quantitative assessment has been performed;
- 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

7.11. 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 improvements in modelling. If certain activities can proceed only after decision points or milestones have been reached (e.g. decisions on the site for the facility), these should be identified.

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

7.12. 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 should not be changed to suit the expectations of a particular audience. The messages contained in annexed documents and promotional material should be consistent with the main documentation of the safety case[13].
- 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 freely accessible 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 made 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 disposal system and 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

[13] 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.

be addressed. It should also be shown how key decisions have been documented and recorded by including a clear referencing system.

- The documentation should also clearly indicate the need to pass information on to future generations regarding the measures for institutional control.
- 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.

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

7.14. 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 the 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 among 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. explanations 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 and its safety case, including safety assessment, should be established and maintained.
— Accurate and direct references to the appropriate literature should be provided.

7.15. 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, while members of the general public may be more interested in 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.

7.16. 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. Traceability, therefore, 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.

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

— All of the information comprising the safety case 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 the 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 a 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.
- If the safety assessment is undertaken iteratively, there may be a tendency for references simply to refer to decisions made in a prior iteration of the safety assessment (‘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 by the reviewer. As such, 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. 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

7.18. The primary objective of the safety case is to support decision making relevant to the stage of the development, operation and closure of a disposal facility. For example, at an early stage, the safety case should be used to compare and assess the feasibility of different disposal options. As the programme to develop the disposal facility progresses, the safety case should be used to help focus and direct work on site characterization, research and development, and facility design. The safety case should be used to inform the licensing process and to provide for the establishment of suitable limits, controls and conditions on the development and operation of the disposal facility, which should at all times be consistent with the safety case. The following paragraphs discuss uses of the safety case in more detail.

Comparison of options

7.19. The safety case may be used to provide a basis for the comparison of disposal options, for example:

- — Comparison between different sites for new disposal facilities and prioritization of site characterization, and related research and development;
- — Comparison of different types, designs and depths for the disposal facility (see, for example, Ref. [33]);
- — Comparison of different risk management and remediation options for existing facilities (see, for example, Ref. [32]).

Prioritization of data acquisition and research and development

7.20. The safety case should integrate existing knowledge on a wide range of topics and should provide a means of judging their relative importance. Initially, the safety case may be based largely on generic data but, as the programme to develop the disposal facility progresses, the safety case will include more site specific information. The safety case should be used as appropriate to guide and prioritize the supporting acquisition of data and research and development programmes so that they address important areas of uncertainty as identified in the safety case.

Facility design and operation

7.21. Throughout the development of the disposal facility, the safety case should be used to assist in the design of the facility. The OECD Nuclear Energy Agency Engineered Barrier System project (see Ref. [43]) provides several examples of the use of the safety case in engineering design and optimization.

7.22. The operation of the disposal facility should, at all times, be consistent with the safety case, so that operational decisions do not cause unintentional effects on long term performance of the disposal system. Operational decisions relevant to safety should be investigated in an update of the safety case prior to their implementation.

Licensing

7.23. 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 close the disposal facility, and whenever there are significant changes in the state of the disposal facility. The safety case should also be updated periodically to reflect new information acquired according to regulatory requirements.

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 (see para. 3.8). The review should be undertaken in accordance with plans defined for the regulatory review process and in accordance with the requirements established in Ref. [44] and the recommendations provided in Ref. [45]. Some important elements of the process of regulatory review of the safety case and safety assessment for disposal facilities are discussed in the following sections. The guidance provided on review of the safety case is also relevant for other review processes, such as internal review within the operator organization or independent external peer review.

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, account should be taken of the status of the facility (e.g. whether the facility is proposed, under development, operational, undergoing re-assessment, closed or under long term surveillance) and the associated context for the safety assessment.

8.3. The overall goal of regulatory review is to verify that the disposal facility 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 the safety case 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 adequate and appropriate basis to demonstrate that the proposed facility will be operated safely and provides reasonable assurance of an adequate level of safety in the period after closure;
— To verify that relevant measures for mitigating unlikely potential effects have been identified and addressed, and that adequate follow-up plans for their implementation 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 stage of development of the disposal facility;
— Is sufficiently transparent in its presentation of data and information;
— Has been prepared by competent personnel applying an approved management system;
— Has been subjected to independent peer review;
— Is based on appropriate assumptions and makes use of adequate assessment techniques and models, and contains satisfactory supporting arguments;
— Demonstrates an adequate understanding of the disposal system that includes identification and screening of hazards and related scenarios, such that all relevant safety functions and all potential safety concerns are addressed;
— Clearly describes how the identification, establishment, justification and optimization of limits, controls and conditions were performed;
— Clearly identifies the uncertainties associated with the understanding of the disposal system (as well as input data and models used) and the performance of the disposal facility;

- Provides an adequate assessment and supporting justification that any radiation exposure has been optimized and demonstrates that safety has been optimized;
- Includes adequate consideration of the justification and optimization of remedial measures for existing facilities, if applicable;
- Addresses all relevant factors of the management system to be applied for the siting, construction, commissioning, operation and closure of the disposal facility (e.g. internal and external audits, verification and validation, use of suitably qualified and experienced personnel, training, control of processes outsourced to subcontractors, action on conclusions and recommendations);
- Demonstrates that good engineering practices with adequate defence in depth have been used in developing the design of the facility;
- Defines a programme for future development of the safety case, understanding the disposal system and institutional control of the site.

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 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, on workers and on non-human species in addition to the overall impact of the facility 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 at 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.

- 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.
- 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 facilities and should have either in-house expertise or should have access to specialists in all of the necessary disciplines involved in such assessment (see Ref. [44]).
- 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 disposal facility under consideration.
- Communication between the operator and the regulatory body should be maintained throughout the regulatory review process.
- 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 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 principles of good project management apply (see Ref. [30]).

8.8. 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.

8.9. The regulatory body should have well established and documented procedures in place for the review process as part of the overall management system for the organization.

8.10. 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 requirements, 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 disposal 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.

8.11. The review procedures applied should allow the regulatory body to verify that the review of the safety case has been performed by competent people, 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.

8.12. 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, therefore, serve as a template from which a project specific review plan can be developed. Examples of project specific review plans include those developed for the low level waste disposal site in the United Kingdom [46] and for the Yucca Mountain project in the USA [47].

8.13. To the extent practicable, the regulatory review team should possess the following characteristics:

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

THE USE OF A GRADED APPROACH BY THE REGULATORY BODY

8.14. The level of scrutiny and the 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 stage of development and operation of the disposal facility or component of the disposal system;

- The magnitude of the hazards and risks (consequences and probabilities) in the period after closure, with consideration given to relevant site factors, facility design aspects, the waste to be disposed of, the likelihood of human intrusions, etc.;
- The complexity, safety significance and maturity of the proposed disposal facility or component of the disposal system;
- The use by the operator of well established practices, procedures and designs;
- Available knowledge of the operational performance of similar facilities or practices;
- Operator aspects (e.g. the operator's record of performance and their relevant experience in the design and construction of a disposal facility or component of the disposal facility; in process design; in development of safety cases; and in establishing and applying management systems);
- Relevant experience from similar disposal facilities (national and international);
- Technical or safety concerns of other competent authorities.

CONDUCTING THE REVIEW AND REPORTING REVIEW FINDINGS

8.15. A regulatory review will normally have four phases:

(a) A pre-review phase, prior to the receipt of any documents from the operator, in which initial planning for the review should be carried out: This should normally involve meetings with the 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 should make an initial evaluation of the documents submitted 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: 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 should 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 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 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 include the involvement of independent experts and other interested parties.

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:

— Introduction: a brief description of the purpose and background of the review, the titles and developers of reviewed documents, summary information about the site, information on the organizations involved in the review, etc.
— Scope and objectives of the review: high level objectives of the review (including references to the applicable regulatory requirements) and 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, which will have other supporting review reports that have previously been completed, an overview of these reports should be described here with their general scope and applicability.
— Applicable regulatory requirements: a list of the regulations, established procedures and/or international recommendations against which the review was carried out. Summaries of the key points of the regulations, procedures and/or international recommendations should be included.
— Review methodology and process: a description of the procedure for regulatory review including the review plan and the steps in the process (primary review, main review, review of revised documents, etc.), interactions with the operator, categorization of comments, requirements about the format for comments and the manner of identifying comments, interactions within the review team, etc. and resolution of comments.
— Main results of evaluation: a description of each of the areas reviewed should be documented, with reference to the following areas (including the

degree to which the response of the operator to regulatory comments was able to resolve the related issues):

- Key comments: These are the general comments summarizing the main deficiencies of the documents reviewed, concerning high level issues such as the safety strategy, the context, approach and results for the safety case and safety assessment, the treatment of uncertainties (in scenarios, models and parameters), risk management and optimization, compliance with the main regulatory criteria and guidance, appropriate limits and conditions, and the programme for the future development of the safety case.
- Specific comments: These are more detailed review findings concerning the main technical areas of review, the characterization for the disposal facility, the waste inventory and the modelling of radionuclide migration from the disposal facility to the environment, with consideration given to aspects of engineering, geology, hydrogeology, chemistry, climate, biosphere and human intrusion.
- Unresolved issues and uncertainties: These are comments about issues that remain unresolved. Their relative safety significance should be noted together with the actions that will be taken to resolve the comments, if necessary. Any conditions for authorization of the disposal facility should be described and justified here.
- Conclusions: The conclusions of the review should be stated with regard to issues to be considered in licensing or authorization, such as further information to be provided by the 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. In addition, recommendations for conditions for authorization should be listed.
- References: A list of reference documents considered in the review, and underlying review reports that support the final review report. Any guidance documents used in the review should be documented.
- Appropriate information to demonstrate the credentials of the individuals making up the review team.

8.18. In the documenting of review comments and evaluations, the following should be ensured:

— The approach taken in the development of the safety case 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;
— Actions necessary to resolve the issues identified in the review comments should be clearly stated.

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