

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



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International Atomic Energy Agency



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IAEA SAFETY STANDARDS

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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**.

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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.

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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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Marketing and Sales Unit, Publishing Section
International Atomic Energy Agency
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fax: +43 1 2600 29302
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email: sales.publications@iaea.org
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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.



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THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish

fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures¹ have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

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

Safety Fundamentals

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

Safety Requirements

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

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

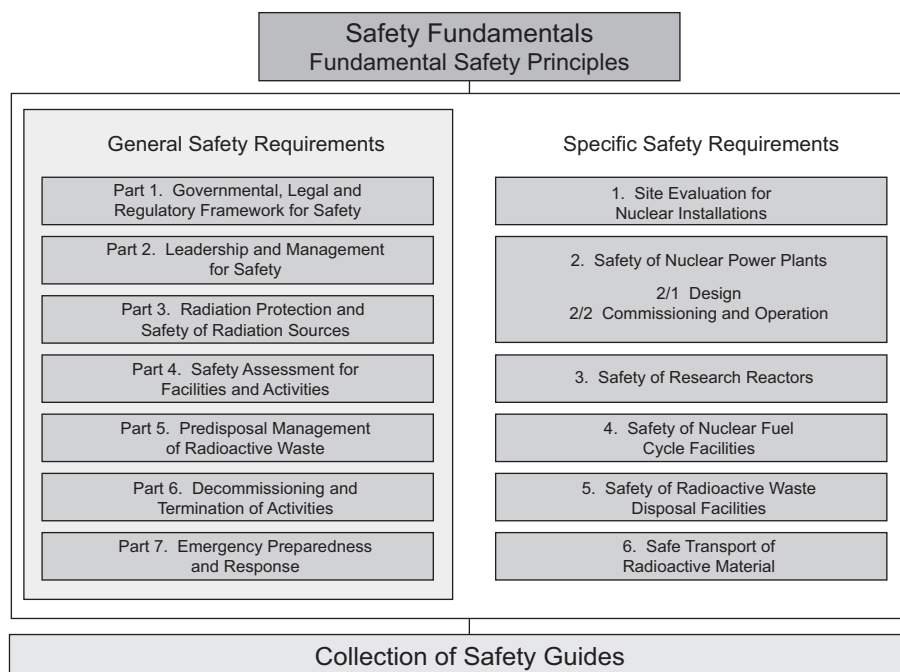


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

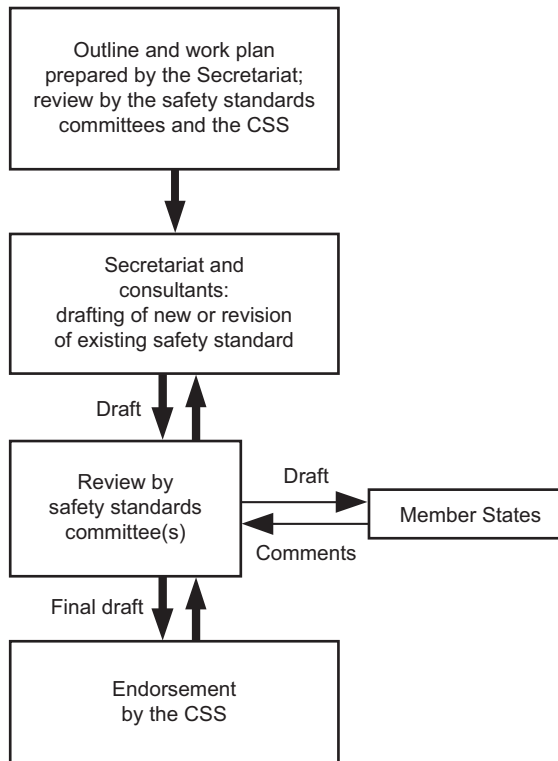


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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.

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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 isolation¹ 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 case² 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

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 operating³, 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 Guide⁴:

- 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.

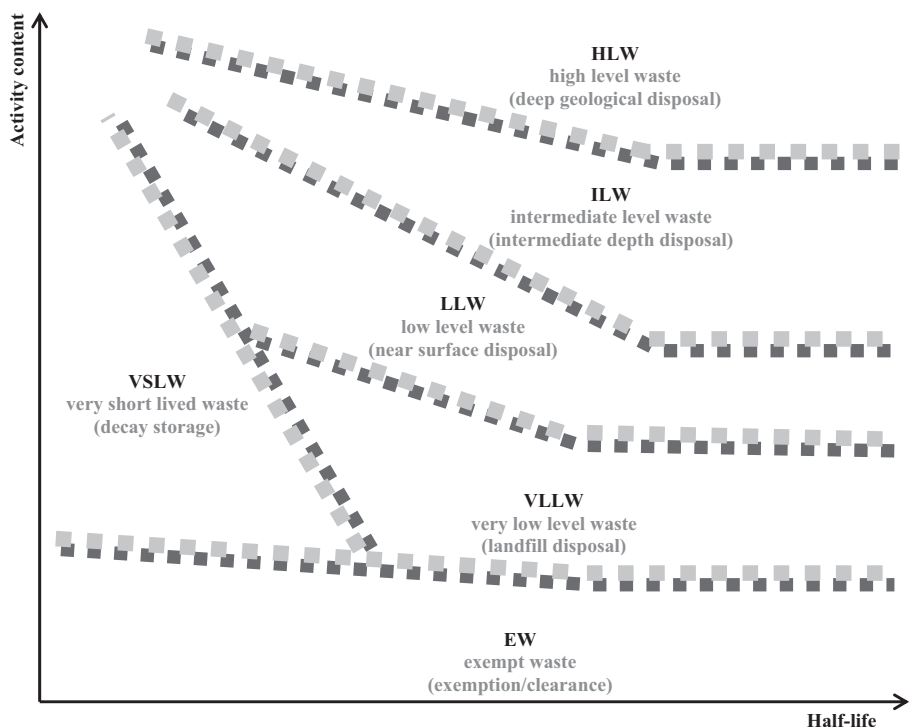


FIG. 1. Conceptual illustration of the waste classification scheme.

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 assessment⁵, 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

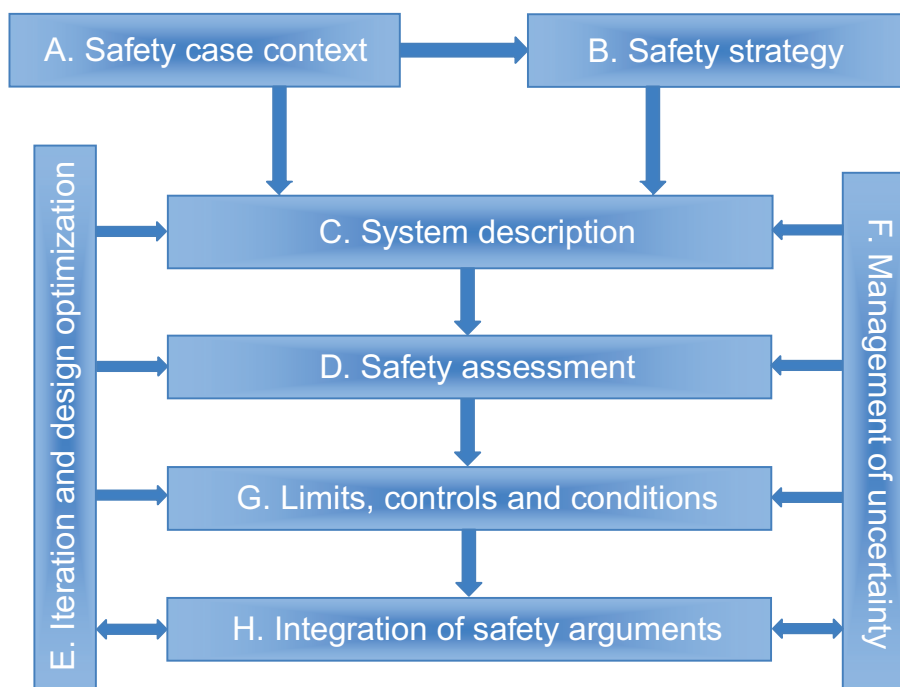


FIG. 2. Components of the safety case.

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

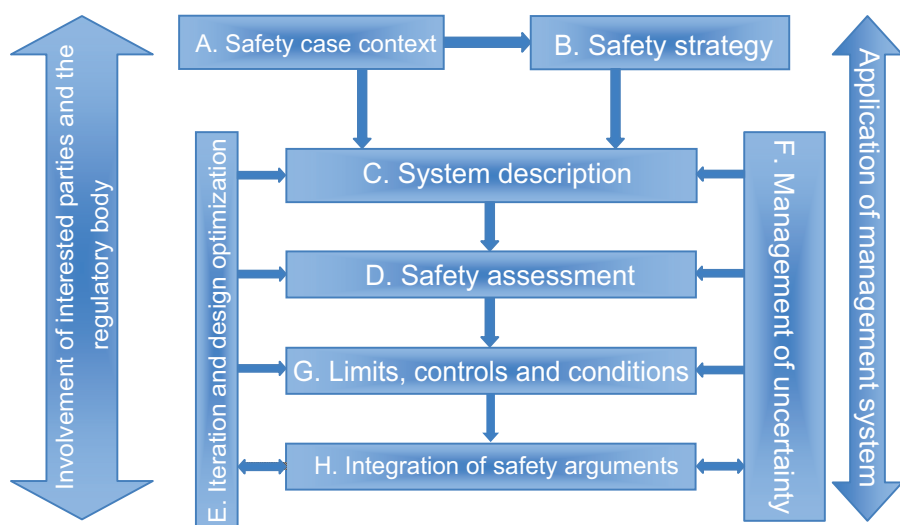


FIG. 3. Application of the management system and the process for interaction with the regulatory body and interested parties.

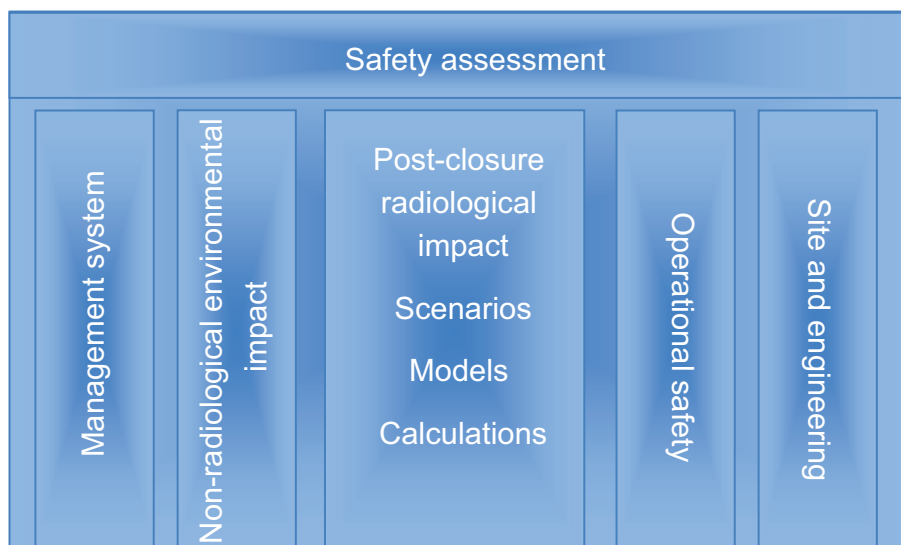


FIG. 4. Aspects included in safety assessment.

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 aspects⁸, 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 robustness⁹ 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.