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Safety Case and Safety Assessment for Predisposal Management of Radioactive Waste

DRAFT SAFETY GUIDE
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CONTENTS

BACKGROUND

1.1. The general principles of managing radioactive waste in a safe manner have been set out in the Safety Fundamentals publication entitled Fundamental Safety Principles [1]. The safety requirements for predisposal management of radioactive waste require that a safety case together with the necessary supporting safety assessment be developed and undertaken for each facility[1] or activity [2].

1.2. These facilities or activities will vary in size and complexity and have different existing and potential hazards. The level and content of radioactive inventory will also vary. In addition, a facility or activity could be one of several interdependent facilities or activities on a site. Similarly, the nature of the assessment facilities or activities will be subject to will differ depending on the stage in their lifecycle (construction, commissioning, operation, etc.). In view of these considerations, a graded approach should be applied to the development and review of the safety case and assessments. The guidance and recommendations contained in this publication is comprehensive and sufficient for the most complex and hazardous of facilities and their use in a graded manner is illustrated in a number of supporting safety reports which are being developed to cover a range of facilities from hazardous and complex to straightforward and of limited hazard potential.

OBJECTIVES

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

1.4. The Safety Guide aims to assist regulators, operators and supporting technical specialists in the application of a graded approach to the development and review of the safety case and supporting safety assessment. The Safety Guide provides guidance for a regulatory framework in which a safety case is developed and assessment is undertaken as part of the life cycle for a facility or activity. This Safety Guide contains guidance that can be used, irrespective of how the safety case and safety assessment process is addressed within individual national regulatory frameworks.

SCOPE

1.5. The Safety Guide is intended for application when developing or reviewing the safety case and supporting safety assessment prepared or undertaken for predisposal waste management facilities or activities. It covers all aspects of the safety case and safety assessment, including the use of a graded approach.

1.6. The Safety Guide should be used during planning and in particular, during the design, construction, commissioning, operation and modification of the facility or activity.

1.7. The Safety Guide provides recommendations and guidance on a systematic methodology for evaluation of waste management arrangements and the radiological impacts on workers, the public and the environment from planned activities and from potential accidents from predisposal waste management facilities or activities.

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

1.8. The Safety Guide supersedes the Safety Series No. 118, Safety Assessment for Spent Fuel Storage Facilities.

1.9. Assessing and demonstrating the safety of nuclear power reactors, decommissioning, and radioactive waste disposal are not included in this guide. With respect to nuclear reactors, decommissioning, and radioactive waste disposal facilities the reader is referred to companion Safety Guides respectively entitled, "Safety Assessment and Verification for Nuclear Power Plants," "Safety Assessment for Decommissioning Facilities Using Radioactive Material", and "The Safety Case and Safety Assessment for Radioactive Waste Disposal of Radioactive Waste" [12, 13, 11].

1.10. This Safety Guide applies to the predisposal management of radioactive waste of all types and covers all the steps in its management, from its generation up to its disposal, including its processing (pretreatment, treatment and conditioning), storage and transport.

1.11. The transport of radioactive waste is managed in the same way as the transport of any radioactive material. Safety in the transport of radioactive waste is ensured by complying with the IAEA Regulations for the Safe Transport of Radioactive Material [15].

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

1.13. Radioactive waste storage facilities include long term storage facilities, spent fuel storage facilities, and storage facilities for radioactive sources – both disused and those not in use..

1.14. In addition to processing, storage and transport, predisposal waste management activities include:

a) remediation of waste facilities,
b) retrieval of waste,
c) clearance, and
d) effluent discharge.

1.15. Such waste may arise from:

a) the commissioning, operation and decommissioning of nuclear facilities,
b) the use of radionuclides in medicine, industry, agriculture, research and education,
c) the processing of materials that contain naturally occurring radionuclides, and
d) the remediation of contaminated areas.

1.16. Clearance and control of discharges are addressed in IAEA Safety Guides GS-R-1.7 and WS-G-2.1 respectively.

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

STRUCTURE

1.18. (To be completed after development of the document)

2. DEMONSTRATING THE SAFETY OF PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

2.1. Whilst assessment and demonstration of safety for radioactive waste management facilities and activities has been widely undertaken in the past, limited efforts have been made to develop international consensus on approaches to such assessment and demonstration. The coming into force of the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management in 2001 gave increasing emphasis to demonstration of safety and supporting safety assessment which influenced the IAEA to establish an international intercomparison and harmonization project on the subject. The project is known as Safety Assessment Driven Radioactive Waste Management Solutions (SADRWMS). The framework for the work carried out within SADRWMS was developed at an early stage of the project and is included as Annex D.

2.2. In the broader context of safety demonstration, the safety case concept is used, the safety case being the collection of arguments and evidence, including the outcome of safety assessment, in support of the safety of a facility or activity. This will normally include the findings from the safety assessment work undertaken together with consideration of the level of confidence in these findings, the adequacy of the assessment work for the decisions to be taken and identification of further work necessary to reduce uncertainties if necessary. The safety case is the basis for the safe considerations in respect of sitting and locating facilities, their design, construction, operation and decommissioning, including the justification for changes with a significant impact on safety. It should provide the basis for interaction and dialogue between the operating organization and the regulatory body since it will comprise the main body of documents for granting the authorizations necessary under national legislative.

2.3. The safety assessment work undertaken in support of the safety case should employ a systematic methodology to demonstrate compliance with applicable safety requirements and criteria for the lifecycle of the facility, including the periodic review of the safety assessment. In addition, it should help ensure that interested parties are confident in the safety of the facility or activity. Once developed by the operator, the safety assessment work undertaken will be reviewed by the regulatory body to ensure compliance with relevant safety requirements and criteria.

2.4. A number of related Safety Standards have been agreed upon internationally, including the safety requirements for protection against ionizing radiation and for the safety of radiation sources [3]; for legal and governmental infrastructure relating to nuclear, radiation, radioactive waste and transport safety [4]; for nuclear power plants [5], disposal management [6], predisposal of radioactive waste [2]; decommissioning [7], release of sites from regulatory control on termination of practices [8] and management systems [9].

3. SAFETY FUNDAMENTALS AND REQUIREMENTS

3.1. This section lists the main requirements that have to be taken into account when preparing a safety case and a safety assessment for predisposal management of radioactive waste.

SAFETY FUNDAMENTALS

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. The safety principles to be applied in all facilities or activities including predisposal management of radioactive waste are set out in the IAEA Fundamental Safety Principles [1]. The principles set out in [1] form the technical basis for the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [16]. The relevant requirements for radiation protection are set out in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards) [3]. Many of the safety principles and concepts of protection adopted in these standards and in the Joint Convention are derived from the recommendations of the International Commission on Radiological Protection [17-20].

REQUIREMENTS FOR SAFETY CASE AND SAFETY ASSESSMENT

3.4. The following paragraphs identify the main requirements in [2] and [10] that are relevant for the preparation, updating/maintenance and use of the safety case and safety assessment. Other requirements in [2] and [10] are addressed in later sections of this guide. For remediation situations, the requirements stipulated in WS-R-3 would be applicable.

Responsibilities for Developing Safety Case and Safety Assessment

3.5. For predisposal facilities or activities, [2] specifies that *the operator shall prepare a safety case and a supporting safety assessment. In the case of a step by step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary.*

3.6. According to [10], *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.* This responsibility relates to the conduct of the assessment and for the quality of the results.

3.7. According to [2], *it is the responsibility of the regulatory body to derive and document in a clear and unambiguous manner the criteria on which the regulatory decision making process is based. It is important that any additional guidance provided by the regulatory body takes account of the wide range of predisposal radioactive waste management facilities that may be developed and the wide range of activities that may be conducted at these facilities.* These regulatory requirements and conditions will have to be addressed by the operator when preparing safety assessments and safety cases.

Requirements on the Safety Case and Safety Assessment

3.8. The following requirements on the safety case and safety assessment to be prepared for predisposal waste management facilities or activities are stated in [2]:

- *The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility, and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met.*
- *The design of the facility, the arrangements for operational management and the systems and processes that are used have to be considered and justified in the safety case. This has to involve the identification of waste arisings and the establishment of an optimal programme of waste management to minimize the amount of waste generated and to determine the design basis and operational basis for the treatment of effluents, the control of discharges and clearance procedures. The primary aim of the safety case is to ensure that the safety objectives and criteria set by the regulatory body are met.*
- *The safety case has to address operational safety and all safety aspects of the facility and activities. The safety case has to include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation and in possible accident conditions.*

3.9. A general requirement which is relevant for all facilities and activities including disposal facilities is stated in Ref. [10]:

- *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.*
- 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.*

3.11. The following requirements on safety assessment are stated in Ref. [10]:

- *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.*
- *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.*
- *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.*
- *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.

- *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.*
- *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.*
- *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.*

Maintenance of Safety Assessments

3.12. With regard to the maintenance of the safety assessment Ref. [18] specifies that *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.*

3.13. It is further stated in Ref. [18] that *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.*

3.14. More specifically for predisposal waste management facilities, [2] states in this context that *the safety case has to be prepared by the operator early in the development of a facility as a basis for the process of regulatory decision making and approval. The safety case has to be progressively developed and refined as the project proceeds. Such an approach ensures the quality of the technical programme and the associated decision making. For the operator, it provides a framework in which confidence in the technical feasibility and safety of the facility can be established at each stage of its development. This confidence has to be developed and enhanced by means of iterative design studies and safety studies as the project progresses. The step by step approach has to provide for the collection, analysis and interpretation of the relevant technical data, the development of plans for design and operation, and the development of the safety case for operational safety.*

3.15. The need for safety reviews which lead to an upgrading of safety assessment is required in [2]: *The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility.*

3.16. With regard to the process of such reviews, [2] states that *the safety assessment is reviewed periodically to confirm that any input assumptions that need to be complied with remain adequately controlled within the overall safety management controls.*

3.17. The time of reviews should, according to [2] be defined by the following considerations: *The safety assessment and the management systems within which it is conducted have to be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment has to be reviewed and updated:*

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

Documentation of the Safety Case and Supporting Safety Assessments

3.18. According to Ref. [18], *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.*

3.19. Detailed requirements on the documentation of the safety case are given in [2]:

- *The safety case and its supporting safety assessment shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support the decision at each stage and to allow for the independent review and approval of the safety case and safety assessment. The documentation shall be clearly written and shall include arguments justifying the approaches taken in the safety case on the basis of information that is traceable.*
- *Justification has to involve explaining why particular choices were made and stating the arguments in favour of and against the decisions made, especially those decisions that relate to the main approaches taken in the safety case.*
- *Traceability refers to the possibility of following the information that is provided in the documentation and that has been used in developing the safety case. For the purposes of both justification and traceability, a well documented record is necessary of the decisions and assumptions that were made in the development and operation of the facility, and of the models and data used in the safety assessment to obtain the set of results. Good traceability is important for the purposes of technical and regulatory review and for building public confidence.*
- *Clarity refers to good structure and presentation at an appropriate level of detail such as to allow an understanding of the arguments included in the safety case. This necessitates that the documents present the work in such a way that the interested parties for whom the documents are intended can gain a good understanding of the safety arguments and their bases. Different styles and levels of documentation may be necessary, depending on the intended audience for the material.*

Uses of Safety Cases

3.20. According to Ref. [10], "*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.*

4. OBJECTIVES AND DEVELOPMENT OF THE SAFETY CASE FOR PREDISPOSAL

4.1. This section identifies the components of the safety case as illustrated in Fig 1 and discusses its role during the development and operation of a predisposal waste management facility or when conducting a predisposal waste management activity. Since waste management activities in general are conducted within facilities, the term waste management facility is used in a general sense, also covering individual activities. Cases in which activities are not directly connected to a facility should be handled accordingly.

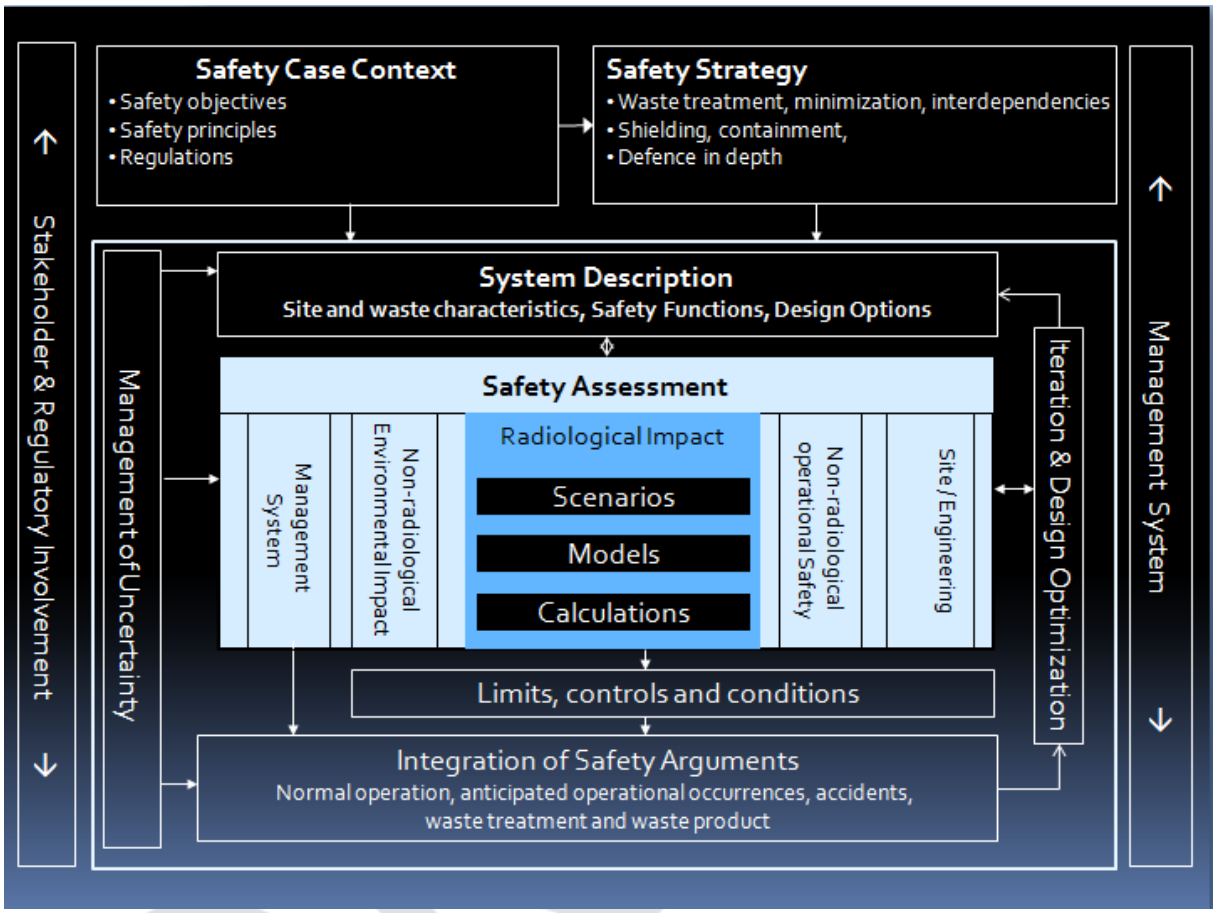

Figure 1: Components of the safety case

4.2. The safety case concept will be of particular importance and benefit for large predisposal waste management facilities such as national centres for the processing and storage of radioactive waste in countries with a nuclear programme. For smaller scale facilities such as storage facilities for disused sealed sources, the elements of the safety case process described below are still beneficial, but the actual process of conducting safety assessment will be substantially less demanding. Therefore, several of the aspects discussed below, such as the development in stages, will be less relevant for some types and sizes of facilities. This is an expression of the graded approach discussed in para. 4.27 and Section 6. In order to provide additional guidance on the level of depth and detail warranted for safety cases prepared for smaller facilities, safety reports with examples of safety cases are under development.

ROLE OF THE SAFETY CASE

4.3. In accordance with the requirements in [10] (see para. 2.12), a safety case should be developed. The role of the safety case for predisposal waste management facilities or activities includes:

- Presenting all the safety arguments and supporting evidence that demonstrates the safety of a waste management facility or activity.
- Providing a basis for the licensing or other authorization process for the facility or activity.
- Integrating relevant scientific (and other) information in a structured, traceable and transparent way and, thereby, developing and demonstrating an understanding of the potential behaviour and performance of the facilities.
- Demonstrating that consideration has been given to all steps of management of the waste under consideration from generation to disposal and their overall compatibility. Both short medium and long term aspects should be considered and the possible need for future handling and treatment of the waste and the risks and doses that may be associated with these activities. Compatibility with a disposal option should be demonstrated, in the event that a disposal option has not been identified at that stage, assumptions should be made about the likely options and clearly set down.
- Identifying uncertainties in the performance of the facilities, describing the possible significance of the uncertainties, and identifying approaches for the management of significant uncertainties.
- Demonstrating operational safety and providing reasonable assurance that the facilities will perform in a manner that protects human health and the environment, and fulfil relevant criteria.
- Aiding decision making on the authorisation / licensing of the facilities.
- Facilitating communication amongst stakeholders on issues relating to the facilities.

4.4. A specific role of the safety case in making decisions about treatment options is to ensure that suitable waste forms are produced. Thus, the safety case for a waste treatment facility does not only need to address safe operations within the facility, but also has to consider interdependencies with other waste management steps. The adequacy of waste forms to be produced has to be judged based on waste acceptance criteria for all downstream waste management activities, in particular storage, transport and eventually disposal. There are many aspects connected to these decisions, some of which are connected to quantitative assessments; others are more qualitative in nature. A more detailed discussion on relevant considerations and resulting implications for the safety case development is provided in Section 6.

4.5. The components of the safety case are indicated in Fig 1 and are comprised of; elements setting out the context of the safety case and the safety strategy, a descriptions of the facility including its design and the associated safety functions, safety assessment, the limits controls and conditions developed from the assessment, elements of iteration and optimization, uncertainty management and the integration of safety arguments. Interacting with the development and use of the safety case are the management system to ensure the quality of all safety related work, the regulatory process and the involvement with all other interested stakeholders. Safety assessment is the main element of the safety case and involves assessment of a number of aspects fundamental to which is the assessment of radiological impact in terms of radiation dose and risk. The other important aspects subject to assessment are the site and engineering, operational safety, non radiological impact assessment and the management system. Guidance on the various components of the safety case is provided in the sections below.

4.6. Development of the safety case should commence at the inception of the project and progress through all steps in the development and operation through to the decommissioning of the facility. The

safety case should also be used throughout the project to guide the site selection and location of facilities on sites, the facility design, excavation/construction activities, operation of the facility and its decommissioning. It should also be used to identify research and development needs, to identify and establish limits controls and conditions during these different steps and to provide the basis for the licensing process. It will also be the main vehicle of communication with stakeholders in terms of providing explanation of how safety is provided and how a reasonable assurance of safety is established.

4.7. The development of the safety case may be achieved in various ways and its content and structure are greatly influenced by country specific legislative and regulatory requirements and local concerns. Although some States may not use the term safety case in a formal way, the approaches and processes they use to demonstrate safety are compatible with and, in essence, similar to the safety case concept.

4.8. In accordance with the requirements, the development of a safety case should proceed within an iterative process that evolves with the development of the facilities. The formality and level of technical detail of the safety case depend on the stage of development of the project, the decision in hand and specific national requirements. This approach provides a basis for decisions relating to the development, siting, design, operation and decommissioning of the facilities, and allows the identification of areas on which attention needs to be focused to further improve the understanding of those aspects influencing the safety of the facilities or activities.

4.9. When developing the safety case it is important to identify and understand the needs of the key parties that will review, use and approve the safety case (e.g. government, regulators, stakeholders) – these will depend on the local and national situation. The safety case, including the supporting safety assessment is the responsibility of the facility operator, but it should be recognised that it may need to be presented according to the needs of the different parties. It is good practice, therefore, to gain as far as possible prior agreement through dialogue with those parties, particularly on what is to be included, assessed and calculated, given the stage of facility development and the relative level of hazard associated with the facility or activity. For example, expectations from safety assessment may increase as licensing decisions are approached.

4.10. The early development and adoption of a safety strategy is a key point in the development of the safety case. The safety strategy should be comprised of an overall management strategy for the various activities required in facility planning, implementation and decommissioning, including siting and design, safety case development, safety assessment, site and waste form characterization and research and development. More guidance on developing a safety strategy is given in paras. 4-28 – 4.37.

4.11. As outlined in Para. 2.12, predisposal waste management facilities or activities can be developed in a series of steps. Such a step by step approach enables: the systematic collection and assessment of the necessary scientific and technical data; the evaluation of possible sites; the development of concepts; iterative studies for design and safety assessment with progressively improving data; the incorporation of comments from technical and regulatory reviews; public consultations concerning specific decision points and political involvement at different stages. The process followed may depend on the type of facility and national practices.

4.12. The step by step approach, together with the consideration of a range of options for the design and operational management of predisposal waste management facilities, provides flexibility for responding to new scientific or technical information, advances in waste management and materials technologies, and enables social, economic and political aspects to be addressed.

4.13. The safety assessment and the safety case should be reviewed and updated prior to the major decision points and periodically as necessary to reflect actual experience and increasing knowledge (e.g. gained from scientific research), taking into account any relevant operational aspects which are

relevant for safety. Following commencement of facility operation revisions or updates to an assessment should be conducted as significant changes are identified in operational practices, waste forms, design, etc. The regulator may specify the types and/or magnitude of changes and time frames that would require an update. Typical periods range between five and ten years taking into account factors such as the turnover and training of personnel, improvements in knowledge and advances in computations capabilities.

4.14. During the site selection process, some assumptions will have to be made regarding the detailed characteristics of the site and the design of the facility and, therefore, the safety assessment will only provide preliminary estimates of how the facility performs. This is acceptable because the role of the safety case at this stage is only to determine whether a site is in principle suitable for a predisposal waste management facility. At later stages, more site-specific data will be necessary and details of the proposed design will be defined, allowing operational issues to be addressed in more detail. Throughout this process it is important that the safety case prepared for individual stages of the process provide sufficient depth of information and assessment to support the decisions required.

4.15. Principle 3 in [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." In accordance with this, [2, 10] require that the extent and complexity of safety assessment will vary with facility type and should be related to the hazard potential. Also, the level of depth of the safety assessments performed at the different stages of the development of a facility will vary depending on the magnitude of the risks and the stage of the disposal facility development and operation. As a consequence of the iterative approach to the development of the safety case, the arguments that are included in the safety case may carry different weight, and the level of scrutiny that they are subjected to by the regulatory body and other stakeholders may vary over time. Further guidance on the application of the graded approach to the development of the safety case is provided in Section 6.

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

SAFETY CASE CONTEXT

Safety Case Purpose

4.17. As indicated above the safety case will be developed as the project progresses and will be used as a basis for decision making, both regulatory and other decisions related to for example the design, supporting research work or site characterization activities. It is important that the context for a particular revision of the safety case is clearly set down and revised as necessary and appropriate for subsequent revisions.

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

- Testing of initial ideas for safety concepts;
- Site selection;

- Demonstration of predisposal facility or activity safety;
- Optimisation of predisposal facility design or activity arrangements;
- Evaluation of clearance and discharge activities;
- Identification and justification of the expected lifetime of the facility;
- Derivation of the maximum inventory that can be accepted (radiological capacity);
- Definition or revision of waste acceptance criteria;
- Input to monitoring and data acquisition programmes;
- Periodic re-assessment as required by law or regulation;
- Application to modify the facility or activity or to co-locate new facilities;
- Shutdown and decommissioning of the facility, either at the planned end of life or driven by non-compliance with the regulations;
- Determination of whether remedial action is necessary;

4.19. As already mentioned, the framework for safety assessment developed in the SADRWMS project is included as Annex D in this document. The overall process serves as a basis to develop guidelines for the application of safety assessment methodologies and the identification of what is needed in the way of safety justification. In support of this activity, flowcharts have been developed covering the main steps in pre-disposal waste management and a description of the individual elements and their relationships within the overall scheme.

Safety Case Scope

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

4.21. In the case of step by step development, the scope of the safety case should provide a clear definition of the lifecycle stage being considered, how the safety case has changed from previous safety cases, and how this safety case will support future safety cases. For example, it should be explained how the commissioning safety case can be justified from the construction safety case and how this will justify the operation of the facility once complete.

Approach to Safety Demonstration

4.22. The assessment philosophy refers to the approaches that are taken in conducting the assessment. The choice of approaches for the assessment is closely linked with the purpose of the assessment and the nature of the hazards being assessed. It further depends on the stage in the lifecycle they relate to, safety criteria, end points, available data and the treatment of the various sources of uncertainty (e.g. scenario, model and data).

4.23. The approach to safety demonstration refers to the safety objectives set down, the safety principles to be applied and the regulatory requirements that must be fulfilled. The safety objectives and principles may be mandated by the regulatory body. The regulatory framework governing conduct of the safety assessment should be documented as part of the assessment context, and the safety assessment should be conducted in a manner consistent with that framework. The safety criteria may vary in different countries and need to be specified in the assessment context.

4.24. If several facilities or activities exist or are planned at the same site, the impact of all facilities and activities should be taken into account in establishing which criteria to consider according to the scope of assessment and when comparing the results of the safety assessment with these criteria. This may not be straightforward if a mixture of existing and new facilities or activities exist at a site, or if the different predisposal facilities are used or different kinds of activity take place at the site. In such

situations, consultation between the operator and the regulatory authority will usually be required in order to define the criteria to be used in the assessments.

4.25. Safety requirements other than safety criteria as well as other requirements related to the safety case should be specified in the assessment context (e.g. industrial, environmental, clearance, site release criteria).

4.26. The approach to safety demonstration should also set down 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 guidance on the management of uncertainties is given in the following Chapter.

Graded Approach

4.27. A graded approach [2] should be considered when determining the scope, extent and level of detail of the safety assessment to be carried out, ensuring that these are commensurate with the hazards, the complexity of facilities or activities and the characteristics of the waste associated with a facility or activity. For example, in the case of a step by step approach, safety assessments for generic storage concepts being considered prior to site selection might be conducted in less detail than assessments for facility commissioning. Factors relevant to the graded approach for a safety assessment are given in [10]. Chapter 6 provides further discussion on the use of the graded approach for predisposal waste management facilities or activities.

SAFETY STRATEGY

4.28. 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 facility conceptualization. In the leter stages the strategy may develop and mature, but should be firmed up at as early a stage as possible to the extent that by the time the site is selected, the design concept should be well developed to provide an assurance that the overall system will provide and preserve the safety functions envisaged for the predisposal waste management facility. As the project develops, the safety strategy should be continually validated and any changes should be justified in the safety case. It is also important that any evolution of the safety strategy be carefully recorded and the records preserved for use in the future when staff may have changed.

4.29. The safety strategy should address a number of key elements namely; the provision of multiple safety functions and defence in depth, shielding and containment, and the adequate selection of waste treatment approaches. It should also be addressed how the principle of waste minimization is implemented and how interdependencies with other predisposal management steps and with disposal of the waste are taken account of. It should also addresses the approach that will be taken to uncertainty management with a view to ensuring that the safety approach set down above will be respected.

4.30. Reference [10] requires that multiple barriers are provided such that safety does not depend unduly on any single safety function and to ensure should one safety function not perform as intended, there are further safety function to compensate, for example if the integrity of waste packaging is compromised under certain accident conditions the facility itself is assigned a containment function The safety strategy should identify the intended safety functions, the timeframes over which they are intended to be available and how degraded performance will be compensated by another mechanism or component. 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 it is intended that an adequate level of defence in depth will be provided by the various safety functions, the adequacy may be expressed in quantitative and qualitative terms.

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

4.32. In addition, the safety strategy should address the degree of caution that will be exercised when making decisions and use of multiple lines of reasoning; the rationale for selecting the assessment methodology and assessment time frame and time windows, including a discussion on the various assessment approaches and tools used to verify, confirm and compare assessment findings; how peer reviews conducted and consistency demonstrated with international guidance and practices; and other high-level arguments as appropriate.

DESCRIPTION OF FACILITY OR ACTIVITY AND WASTE

Site Conditions

4.33. Site conditions and associated processes and events, of both natural and man-made origin, will impose certain demands and other requirements on the facility or activity and its equipment and components. The site characteristics form part of the input to the design. They may refer to the range of conditions under which the facility must be operated or the activity must be performed, such as meteorological conditions, or to the hazards to which it may be exposed, such as seismic hazards. Therefore, all site conditions, processes and events having relevance in this regard should be identified and considered consistent with the graded approach. The objective is to establish the normal or average situation and to identify any more extreme but credible events to be considered.

4.34. The effects of external conditions on the facility or activity should be identified and should describe the extent of their effects. This information should be compared to assumptions regarding the range of conditions and hazards that form the basis of the facility design. The safety assessment should ensure that the treatment of site conditions, processes and events has been adequate.

Facilities and Activities

4.35. The safety of predisposal facilities and activities, as with other engineered systems, depends in part on adequate design and construction. The most important design features of such facilities are those which provide the necessary assurances that the radioactive waste can be handled (processed, stored, retrieved, etc.) without undue risk to health and safety, or to the environment.

4.36. Therefore, the safety assessment should consider in depth the facility design and the fundamental assumptions upon which the design is based. This should include: a full description of the facility structures, systems and components and their importance for safety; the quantity and characteristics of the waste to be handled at the facility; the range of conditions under which the facility may operate; the hazards to which the facility may be exposed; and the performance criteria.

4.37. The safety assessment should also consider what fundamental design requirements have been applied and how the resulting design reflects these requirements. Typically, the fundamental design requirements will address such considerations as the need to ensure an adequate degree of redundancy, diversity, reliability and tolerance to faults, and the need to ensure that any failures which might occur are limited in scope and, to the extent possible, limited in consequence. It will also be expected that the design will respect the concept of defence in depth.

4.38. As appropriate, the design should be examined in the light of safety requirements to determine if the design, in conjunction with relevant operations, incorporates adequate measures to prevent

accidents and to limit the consequences of an accident should one occur. For example, for facilities or activities that handle fissile material, the design would need to ensure that issues associated with criticality are adequately addressed.

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

4.40. If there are any national and/or international systems for accounting and control of nuclear material [22, 23] that are applicable to the facility or activity, any provisions that are put in place for this purpose should be assessed from a safety point of view and any conflicts resolved.

4.41. In addition to issues related to the design and construction, the safety of a facility or activity also depends on operational aspects such as operating and maintenance procedures, controls and monitoring. The nature of the operating organization, particularly the aspects related to safety, the quality of training and the prevalent safety culture are often linked to the frequency of human-induced events.

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

4.43. For each safety-related operational issue, there should be an explanation of how the operator intends to address the particular issue with policies, procedures, controls and monitoring. The explanation should demonstrate the adequacy of the response from the operator to the underlying safety concern.

Waste

4.44. Data for each type of radioactive waste to be processed (pretreatment, treatment and conditioning) or stored, as well as material that is cleared/discharged at the facility or within the activity should be collected with respect to its volume and form, the radionuclides of concern, the levels of radioactivity, the presence of fissile materials, and other physical, chemical and pathogenic properties. Secondary waste streams that may arise from waste processing should be included.

4.45. Any non-radioactive hazardous constituents already present or introduced as process chemicals, etc. should be noted.

4.46. Variations in the expected characteristics of input materials (feedstock, source materials, receipts, etc.) should be considered, particularly with reference to their influence on anticipated operational occurrences and design basis accidents in the facilities or activities where the inputs originate.

SAFETY ASSESSMENT

General

4.47. The term safety assessment is used in this Safety Guide to refer to all assessment performed as part of the safety case (see Figure 2). This encompasses all aspects which are relevant for the safety of the development, operation and shutdown of the predisposal facility. Thus, the safety assessment also addresses qualitative aspects and non-radiological issues.

4.48. In earlier publications (e.g. [24]), the term safety assessment was used differently in two regards:

- The safety assessment was defined as the overall process to perform quantitative assessments of radiological safety. This included the development of the assessment context and the description of the facility and its environment as well as the interpretation of the results. In terms of the broader context of the safety case as illustrated in Figure 2, these elements are considered as part of the overall safety case and not limited to the quantitative assessments. Not including these steps into the definition of safety assessment as used in this document, therefore, does not represent any change of the actual methodology for performing quantitative assessments (as discussed for disposal facilities in [24). The approaches developed in these documents are only 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 radiological risks. This broadening of the term safety assessment is a logical consequence of adopting the broader concept of the safety case as basis for this Safety Guide.

4.49. The following sections provide an overview of the key elements of the safety assessment as shown in Figure 2.

Radiological impact assessment

4.50. The assessment of radiological impacts forms the core of the safety case for a predisposal waste management facility or activity. In addition to qualitative assessments, this involves a comprehensive quantitative analysis of perceivable challenges for safety and resulting potential radiological impacts. The implementation of this approach uses scenarios to describe possible situations occurring in the facility or during the activity and quantitatively analyzes the resulting radiological risks through the use of conceptual and mathematical models. A detailed description of this approach is presented in Chapter 5.

Site and engineering

4.51. The quantitative assessment of potential radiological impacts results in conclusions about the adequacy of the chosen or proposed site as well as of the intended design of the predisposal waste management facilities or activities. These conclusions based on quantitative assessments are supplemented by qualitative arguments and assessments. The overall set of qualitative and quantitative assessment results needs to be sufficient to demonstrate the adequacy of the site and engineering and the compliance with the relevant safety requirements summarized in Chapter 3 and that the safety strategy set down for the facility is fulfilled.

Engineering Analysis

4.52. The engineering analysis should identify where changes to the design could eliminate a hazard or reduce its frequency or consequence. The value of making the identified changes should be evaluated using the ALARA principle.

4.53. The safety assessment can then be used to identify the safety functions and associated structures, systems and components to mitigate the consequences from initiating events. This should be performed by applying appropriate engineering codes and standards, commensurate with the importance of the safety functions (e.g., the unmitigated consequences of their failure).

4.54. The safety assessment should determine if the existing structures, systems and components are suitable and sufficient to achieve all that has been assumed of them in the hazard analysis and that they

will achieve the required reduction of doses and risks to an appropriate level of confidence. The safety assessment should also confirm that existing structures, systems and components will continue to ensure associated safety functions for as long as is required by the lifecycle, taking account of ageing; other degradation mechanisms; invasive maintenance activities (e.g. demolition of supporting walls, creation of dusty environment), etc.

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

Passive Safety

4.56. The operator should demonstrate that, to the extent possible, passive safety features are applied as soon as possible. This is, according to [2], of particular relevance for the storage of waste, but provides also an important consideration for other types of predisposal waste management activities. This topic is discussed in more detail in Chapter 6.

Defence in Depth

4.57. The term 'defence-in-depth' derives principally from the field of nuclear reactor safety. The term has been used to refer to the hierarchical deployment of different levels of equipment and procedures in order to maintain the effectiveness of physical barriers placed between radioactive materials and workers, the public or the environment, in normal operation, anticipated operational occurrences and, for some barriers, in accidents at the facility. According to [10], an assessment of defence in depth is required, which should comprise an evaluation of the levels of defence provided by the predisposal facility or activity.

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

Scientific and Technical / Engineering Principles

4.59. The use of good science involves, amongst other things, making observations, developing and testing hypotheses, assessing reproducibility, and peer review. The application of good scientific principles in safety case development can be illustrated by considering an example of understanding the effectiveness of a proposed predisposal chemical waste processing activity. Such work might involve waste measurements, proposing hypotheses as to the effect of additives on physical and chemical behaviour of the waste, testing these hypotheses with models using the data collected, using more than one approach or team in the modelling work to examine alternative conceptual models and reproducibility, and subjecting the work to peer review.

4.60. The use of good technical / engineering principles is recommended in order to avoid complex or insufficiently characterized situations. The safety case should explain how good engineering practice has been applied and the operator should demonstrate that the materials, equipment and

processes foreseen for the facility or activity are well understood and that knowledge gained from similar applications confirms that they are well suited for the envisaged uses. Wherever possible, the operator should use well-established techniques and give due consideration to feedback from experiences gained in the use of these techniques.

Quality of the Site Characterization

4.61. The safety case should contain a clear description of the approach and criteria used in site selection and demonstrate that the selected site fulfils the approach and criteria. The safety case should integrate knowledge of the site location and its proximity to other facilities or population centres, and demonstrate an understanding of the possible behaviour of the system.

4.62. 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 measurement methodology, if safety assessment models can be developed that are consistent with the properties of the site and conceptual understanding 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 with only minor refinement.

Non-radiological operational safety

4.63. The assessment of non-radiological operational safety lies outside the scope of this Safety Guide. How requirements relating to non-radiological risks have to be accounted for will depend on the type of facility, the legal and regulatory environment, and the stage of facility development. Since the origin for radiological and non-radiological risks may be identical, an integrated assessment of such risks and required countermeasures may be beneficial.

Non-radiological environmental impact

4.64. The assessment of non-radiological impacts arising from the predisposal waste management facility or actitity will be required and governed by environmental protection legislation. This lies outside the scope of this Safety Guide. Nevertheless, the assessment approaches described in this Safety Guide may also be of use in the assessment of hazards from non-radioactive waste components and in optimization of safety and protection from all potential hazards.

4.65. The environmental protection legislation and its associated regulations will result in several requirements on the construction, operation and decommissioning of a predisposal waste management facility or on the implementation of a waste management activity. Examples are restrictions in terms of traffic or noise pollution which limit the construction and operation of the facility. Other examples are limits, controls and conditions required for the water management at the facility during construction. Such requirements arising from the environmental protection legislation will have to be adequately considered in the facility design. Thus, the integration of safety arguments (see Figure 2) has to take into account non-radiological impacts as well and demonstrate the overall safety of the facility or activity and the overall compliance with all relevant legislative and regulatory requirements.

Management Systems

4.66. In [2], the requirement is laid down that management systems be applied for all steps and elements of the predisposal management of radioactive waste (see Para. 2.19). General requirements for management systems are given in [9], and guidance on how to meet these requirements is provided in [21]. The application of suitable management systems contributes to confidence in the safety case

and an assessment should be carried out on the adequacy of the management system governing all work of a safety related nature.

4.67. The requirements on management systems influence the development of a safety case in two ways. Firstly, the description of management systems applying to the different phases of facility development should represent an important element of the safety case, contributing to the confidence that the relevant requirements and criteria for site characterization, construction, operation and decommissioning safety are met. Secondly, adequate programmes should be set up to assure the quality for all safety case and safety assessment activities, such as data collection and modelling. This aspect is discussed in paras. 4.103 to 4.108

MANAGEMENT OF UNCERTAINTIES

4.68. The importance of addressing uncertainties in safety assessment is reflected in the Safety Requirements [10], which state that "uncertainties in the safety analysis shall be characterized with respect to their source, nature and degree, using quantitative methods, professional judgment or both". Reference [10] further requires that "uncertainties which may have implications on the outcome of the safety analysis and decisions made on that basis shall be addressed in uncertainty and sensitivity analyses". Approaches to manage uncertainties are discussed in connection with the quantitative assessments in Chapter 5.

ITERATION & DESIGN OPTIMIZATION

4.69. The actual decision making process 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. This process will be iterative in most practical cases. These iterations will depend on the status of facility development, the required decisions as well as the availability of data and models.

4.70. Early iterations should be undertaken with available data and assessment capability. The iterations need only to proceed until the assessment is judged to be adequate for its purpose. Furthermore, additional knowledge needs only be acquired to the extent required to improve the basis for the decisions to be made. Iterations may only affect one specific aspect of the safety case (e.g. the improvement of the data requirements for a specific model). Larger scale iterations may involve revisions of all safety case elements, such as: The safety case context may be adjusted to, for example, treat uncertainties more realistically or to broaden the range of receptors considered. The safety strategy may be improved and refined. New data about the site may be 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 elements of the safety assessment may be revised and developed further.

4.71. The optimization of protection for a predisposal facility or activity is a judgemental process that is applied to the decisions made during the development of the facility's design. Most important is that good engineering and technical solutions are adopted and the principles of quality management are applied throughout the development, operation and decommissioning of the predisposal facility.

4.72. For some decisions on the optimum level of protection, a qualitative approach based on expert judgement and on the utilization of the best available and proven technology (BAT) may be sufficient. The more complex an issue is and the more interconnections it has with other aspects, the higher the requirements on demonstrating the optimization of protection become. Important arguments to demonstrate that protection can be considered optimized are:

- Due attention has been paid to the radiological safety implications of various design options at each step in the development, construction and operation of the disposal facility;

- The likelihood of events that might disturb the performance of the predisposal facility or activity, so as to give rise to higher doses or risks, has been reduced as far as is reasonably possible by siting or design.

4.73. It is important to show that the selected design option has been chosen by a well-defined, rational procedure. Confidence may be increased if alternative design options are presented in the safety case with an assessment of their advantages and disadvantages, and a justification for the preferred option. Consideration of alternatives is a regulatory requirement in some countries (e.g. [26]).

4.74. Substantially different options to a project are generally considered in the project design phase. However, the possibility of adopting alternative means to carry out a project should be realized at each phase of the decision making process. The safety case should describe the process used to select the most appropriate options based on a set of pre-determined criteria or considerations. The criteria used for the comparison of these alternatives should include, in addition to safety criteria, environmental and socio-economic factors (e.g. costs, public acceptance of certain options).

4.75. Examining 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?

4.76. Alternatives should be identified and described in sufficient detail, providing clear answers to these questions. For example, if alternative design options were being considered, then each alternative option would have to be described and the potential radiological effects, costs and benefits of each alternative defined. The criteria and analysis of the different options would then need to fully be documented to support the proposed design. Approaches for the decision making on alternative options are discussed further in Section 6. Records should be made of the design evolution and the basis for design related decision and these records should be maintained throughout the evolution of the safety case.

Identification of Safety Measures

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

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

4.79. The safety case should demonstrate that there are adequate safety measures in place commensurate with the likelihood of occurrence and the radiological consequences, to demonstrate compliance with safety criteria. Those measures can be:

a. Engineered measures: technical or physical measures in place during operations, such as the provision of shielding; and/or
b. Procedural measures: where engineering cannot fully eliminate a hazard administrative measures may have to be used, such as, restricting access to high-radiation areas, etc.

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

Derivation of Limits and Conditions

4.80. The safety case should be used to assist in the establishment of license conditions and other controls and requirements on the predisposal facility or activity. Examples include site- or process-specific limits on the types, activities and quantities of waste that may be accepted or processed in order to ensure operational safety, and in the case of long-term storage, longer term safety.

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

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

4.83. Limits and conditions of particular importance for predisposal facilities or activities are acceptable waste inventories and/or concentration levels for specific radionuclides in the waste and these should be defined based on the results of safety assessments.

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

INTEGRATION OF SAFETY ARGUMENTS

4.85. The safety case should provide a synthesis of the available evidence, arguments and analyses. The synthesis should explain how relevant data and information have been considered, how models have been tested, and how a rational and systematic assessment procedure has been followed. It should also acknowledge any limitations of currently available evidence, arguments and analyses, and highlight the principal grounds on which the author of the safety case has come to a judgement that the planning and development of the predisposal system should nevertheless continue. This includes the approach to be adopted 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 assessment or the facility design may need to be revised.

4.86. In general, the safety case will include all the different lines of evidence, arguments and analyses that are available to support the assessment of the quality and performance of the facility at a given stage of planning and development. Findings which are in contradiction to arguments of the safety case and uncertainties should also be discussed and analyzed. This requires a detailed discussion of:

- The treatment of uncertainty in the safety case and assessment;
- The quality and reliability of the science and design work that forms the basis for the safety case;

- The quality and reliability of the safety assessment, including the development of scenarios, the adequacy of the range of scenarios considered, assessments of their likelihood, and the adequacy of the methods, models, computer codes and databases used; and
- Management system requirements for performing safety assessment calculations to provide an assurance of their quality.

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

- The concerns and requirements of the intended audience;
- The time scale over which safety is being discussed, and the variation of hazard with time;
- The stage of project development;
- The possible evolution of the system; and
- The associated uncertainties and their implications for performance.

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

Comparison against safety criteria

4.89. A clear distinction needs to be made between protection objectives and criteria and the indicators used to demonstrate that these criteria are met and safety objectives are fulfilled. Protection objectives are expressed in general terms, and can be agreed internationally, while national regulations often provide standards and criteria relating to specific indicators (for example, dose or risk) expressed as targets, constraints or limits, which may differ from country to country.

4.90. One of the aims of safety assessment is to compare the assessment endpoints to the safety criteria. However, the indication of a level of protection such that calculated doses or risks are less than a dose or risk constraint is not in itself sufficient for the acceptance of the safety case for a predisposal facility, since other requirements have to be fulfilled such as the provision of multiple safety functions and protection is also required to be optimized.

Multiple Lines of Reasoning

4.91. Confidence in the safety case also may be enhanced by the use of multiple lines of reasoning. The use of multiple lines of reasoning may give added value 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.

4.92. Using multiple lines of reasoning to improve the confidence in the safety case can be done through the use of complementary arguments based on different approaches and sources of evidence, such as:

- Simple and direct approaches;
- Qualitative argumentations on how the safety of the facility or activities can be explained;
- Expert judgment (validity range, experience from other fields of activities); and
- International consensus.

4.93. In some case, multiples lines of reasoning can also be used for filling the gaps remaining from detailed and rigorous assessment or for supporting the safety case arguments. This can be achieved by the use of expert judgment in areas where the safety case is limited.

4.94. In any case, it is not required that multiples lines of reasoning (either qualitative or quantitative) ones, have to address all aspects of safety nor to be fully independent from each other. The appropriate types of arguments to use will depend upon the context and of the stage of the safety case.

Plans for addressing unresolved issues

4.95. The safety case for a predisposal waste management facility or activity will be developed and progressively updated throughout the lifetime of the predisposal facility or activity. Confidence in the safety case at any stage will be enhanced if each version of the safety case includes a plan for further work as necessary to address remaining issues and/or where possible reduce significant remaining uncertainties or to reduce/avoid their relevance, for example, through changes of the design of system components.

4.96. At the earliest stages of the facility development there may be many open questions and uncertainties, and the safety case should include clear plans for dealing with these in future stages, (e.g. by site characterization and optimization of system design), and set out the strategy by which these plans will be achieved. In the later stages and certainly by the time the safety case is presented as part of a license application, uncertainties and open questions with a potential to undermine safety should have been addressed in a manner appropriate for the decision at hand, and this will be reflected in the safety case.

INTERACTING PROCESSES

4.97. As indicated in Figure 2, there are a number of external processes which interact with the development of the safety case to ensure its quality and adequacy. Prime in this regard is the regulatory process which will set down standards to be complied with and regulatory guidance to meet the standards. It should also involve a process of structured interaction and dialogue to ensure that all the expectation of the regulatory authority for the safety case have been met and that issues needing resolution are identified and managed. Section 8 contains a discussion of how the regulatory review process should be structured and implemented to provide additional confidence in the safety case.

4.98. These interacting processes also encompass the involvement of independent experts and other stakeholders. In addition, the development of the safety case should be carried out under a comprehensive management system which ensures the quality of the safety case and its documentation.

Stakeholder Involvement

4.99. Early involvement of stakeholders should be part of the confidence-building process. A range of different models for stakeholder involvement has been applied in different States, and extensive research has been conducted on the methods of stakeholder engagement both in national and international research programmes. A key consideration is that stakeholder involvement should take place under an open and transparent stakeholder consultation framework, with clearly defined rules of procedure. This process should be supported by the safety case.

Independent Review

4.100. Independent peer review should play an important role in building confidence in the safety case. Peer review should entail a formally documented examination of a technical programme or specific aspect of work by a suitably qualified expert or group of experts who have not been directly

involved in the development of the safety case and have no direct interest (e.g. financial, political) in the outcome of the work.

4.101. Independent peer review should be an active and continuous part of work leading to development of the safety case, and should begin at an early stage in the project [33, 34]. It is important to fully document such peer reviews, including the scope and terms of reference for the review, the basis for selection of reviewers, the findings of the peer review, responses to peer review comments and reviewers' evaluations of the responses.

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

Management Systems

4.103. Regulators and operators should have appropriate management systems in place to assure the quality of all safety related work. The following aspects should be taken in to account in developing appropriate management systems designed to provide an adequate basis for the development and review of the safety case:

- The need for well-defined, consistent and transparent criteria by 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 systems and their implementation.
- The need to document and enhance the qualifications, competence and credibility of assessors and reviewers, for example, through training programmes and participation in international projects.
- The need for transparency and public involvement in the safety case development and review processes.
- The need to ensure consideration of international recommendations, safety objectives, safety assessment methodologies, time frames, disposal concepts etc.
- The need to develop and maintain the competence and knowledge of the operator and the regulator over the whole project timeframe.

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

4.105. 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 regulatory authorities are likely to look for (Section 8). Other stakeholders may also wish to see issues important to them addressed. It is advisable, therefore, to use various methods to show that the safety case addresses all of the relevant issues including the relevant uncertainties. The range of issues to be addressed is dependent on the stage of development of the facility and may derive from several sources, including legislation, regulations and stakeholder concerns. Methods for showing completeness may, therefore, include structured cross checks or mappings that link from these sources to the safety case.

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

and assumptions were made, how these decisions and assumptions were implemented, what versions of modelling tools were used, and what are the ultimate sources of the data etc.

4.107. Transparency requires openness, communication, and accountability. This implies that the safety case and safety assessment should be documented in a clear, open and unbiased way that, for example, recognizes both the features of the facility that provide safety benefits and the uncertainties. The aim should be to provide a clear picture of what has been done in the assessment, what the results and uncertainties are, why the results are what they are, and what the key issues are, that can be used to inform decision making by those accountable to the community. Transparency also suggests that the safety case documentation is publicly available and prepared in a manner and at a level of detail that is suitable for the intended audience.

4.108. Further guidance concerning the documentation of the safety case is provided in Chapter 7.

5. SAFETY ASSESSMENT

INTRODUCTION

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

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

5.3. Depending upon the point in the lifecycle of the facility or activity, the safety assessment will not necessarily be performed for all the stages at the same level of detail (e.g., because of lack of design information at the site selection stage). So the safety assessment should be updated at appropriate intervals (e.g., at least before the beginning of each new phase, or as required by the regulatory body) taking into account new data, such as feedback from operating experience.

OVERALL APPROACH

5.4. A methodology for preparing safety assessment for predisposal waste management facilities or activities has been addressed within the the IAEA SADRWMS project [reference]. The recommended approach to safety assessment includes the following key components:

i. Specification of the assessment context;
ii. Description of the predisposal waste management facility or activity and waste;
iii. Development and justification of scenarios;
iv. Identification of models and data needs;
v. Calculation and evaluation of results;
vi. Analysis of safety measures and engineering, comparison against assessment criteria;
vii. Independent verification of safety assessment results, and
viii. Review and modification of the assessment if necessary (iteration).

5.1. Some of these components (assessment context, system description, evaluation of results) overlap with the respective components of the safety case described in Chapter 4. This is a natural consequence of embedding the radiological impact assessment into the broader safety case. The respective discussions in this chapter relate to the specific aspects of the quantitative assessment and supplement the more general presentation of these components in Chapter 4.

ASSESSMENT CONTEXT

5.5. The assessment context comprises the following key aspects: the assessment purpose, the assessment philosophy, the regulatory framework, the assessment endpoints, the assessment philosophy, and the assessment time frame. In addition to the general aspects discussed in Chapter 4, the following guidance is relevant for quantitative assessments of radiological impact.

Assessment Philosophy and Approaches

5.6. The assessment philosophy, i.e. the choice of approaches taken in conducting the assessment, which has been discussed generally in Chapter 4 already. With regard to the quantitative assessments, some specific aspects are relevant.

Use of Different Assessment Approaches

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

Probabilistic and Deterministic Approaches

5.8. Reference [10] provides requirements on the use of probabilistic and deterministic approaches. Combining probabilistic and deterministic approaches in the safety assessment may contribute to increased confidence in the assessment. It is, however, important to be aware of the benefits and limitations associated with these two approaches.

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

5.10. A strength of the probabilistic approach lies in its ability to provide a more comprehensive and explicit representation of the system under consideration and of the remaining uncertainties. Such approaches also provide for more thorough and systematic sensitivity analyses, and can be used to derive risk estimates. Weaknesses of probabilistic approaches include the difficulties involved in obtaining or defining appropriate probability distributions for the parameters, the possibility that the statistical sampling method may choose parameter combinations outside their range of validity, the difficulty in communicating probabilistic assumptions and results, and the additional resources needed.

Conservative and Realistic Assessments

5.11. Reference [10] discusses the role of conservatism vs. realism in relation to the use of deterministic vs. probabilistic analyses. A realistic assessment aims at providing an indication of the most likely behaviour of the predisposal facility or activity. In general, this requires complex conceptual and mathematical models. A conservative assessment, on the other hand, aims at

simplicity by deliberately overestimating the likelihood and magnitude of exposures and/or underestimating the ability of the engineering and safety measures to provide protection.

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

5.13. The use of one or other, or both, approaches depends on a number of factors such as the nature and objective of the assessment, the regulatory requirements, the availability of data, the complexity of the site and the facility or activity, and available resources.

5.14. If the safety assessment is to be used for optimizing the design of the facility or demonstrating a detailed understanding of its behaviour, then the safety assessment should be as realistic as possible, given the availability of data with which to parameterize the models. Undertaking a realistic assessment may, however, involve 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 system performance. It supposes the use of relevant available data, including radiological and environmental monitoring results, operating experience and information on historical events relevant to safety (e.g. from facility operation, or operation of similar facilities at the national or international level).

5.15. If the safety assessment is to be used for demonstrating compliance with a numerical performance measure or standard, it may be appropriate to undertake a conservative analysis based on relatively simple models. Such approaches are feasible if there is a large margin of safety. Caution is required, however, because, if misused, results from overly conservative or worst case representations of the predisposal facility or activity may lead to poor decision making, based on assessment results that bear little resemblance to actual facility or activity performance.

Assessment Endpoints

5.16. A clear description and justification of the assessment endpoints corresponding to the associated regulatory safety requirements and criteria, taking into account assessment assumptions such as timescales, and receptors to be used in safety assessment should be provided. They can include:

- the assessment endpoints considered for radiological protection such as dose or risk, which usually relate to the regulations applicable to the facility or activity and should be consistent with the purpose of the assessment, relevant regulatory requirements and guidance;
- other safety indicators such as dose rate, radionuclide releases, radionuclide concentrations in the environment, concentrations and releases of non-radiological contaminants, impacts on non-human species and others;
- a description of how the assessment endpoints have been used, for example, to determine compliance with radiological or environmental standards, etc.

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

Receptors

5.18. The receptors associated with the different endpoints should be clearly identified and described. A range of potential receptors should be considered, including individual, population and non-human species.

5.19. The ICRP recommends in [17] the use of the concept of "representative individuals" for assessment of the public exposure. Both the dose and risk to representative individuals of potentially exposed groups can be used as assessment endpoints depending on the regulatory requirements.

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

DESCRIPTION OF THE FACILITY OR ACTIVITY AND THE WASTE

5.2. The description of the waste, the facility or activity and its surroundings has been discussed already in paras. 4.33 to 4.46 because this is needed, to a certain extent, for all elements of the safety case. The quantitative analysis of risks will pose many additional data requirements. These are determined by the scenarios defined and models used. Therefore, the collection of these additional data required for the quantitative analysis usually proceeds within an iterative process proceeding in parallel to the development and refinement of scenarios and models.

DEVELOPMENT AND JUSTIFICATION OF SCENARIOS

5.21. Scenarios are postulated or assumed sets of conditions and/or events [10] that can lead to human exposure or environmental contamination.

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

5.23. The set of safety assessment scenarios for predisposal facilities or activities should account for all relevant existing and potential hazards arising from the facilities or activities, and their interrelation and evolution over the lifecycle [1] according to the safety case and the assessment context.

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

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

5.25. The hazard identification and screening process should consider the complexity of the facility or activities, as well as the evolution of hazards and risks over the lifecycle, and should be consistent with the regulatory framework.

Potential Hazard Identification

5.26. When identifying the hazards, consideration should be given to the status of the process during normal operation, during maintenance and during recovery from failure. The hazard identification process also needs to consider how failure of one process can affect associated processes. For example, the hazard identification process for a crane emplacement of wastes should consider the faults that could occur during normal operation of the crane; maintenance of the crane; recovery of the crane for maintenance following a failure during emplacement; and the effect of the crane outage on upstream processes.

5.27. The set of identified hazards should include those that could occur as a consequence of human error. This could range from incorrect or incomplete maintenance operations to incorrect settings of control equipment limits or wrong operator actions. These identified hazards will not necessarily be similar to identified hazards caused by equipment failures because they could involve common cause failures in addition to the initiating event.

5.28. Many remotely operated components depend upon computer codes. The software reliability should be covered in the hazard identification process.

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

5.30. The identified hazards should be quantified and screened in order to direct the safety effort towards all significant and relevant hazards for the facility or activity. Hazards lacking the potential to create harm to human health and/or the environment to an extent exceeding relevant safety requirements or criteria, or which cannot be realized given the scope of the facility or activity being assessed can be screened out from the subsequent hazard analysis. During the re-evaluation of a safety assessment screening arguments should be reviewed to check that they are still valid.

Hazards screening

5.31. The hazards should be quantified taking no benefit from any protective or mitigating safety measures to be used. However benefit from intrinsic (passive) features of the facility (e.g. walls for shielding, engineered safety features), which are not affected by the initiating event, should be taken into account. Hazards with the potential to cause significant harm through any identified pathway or those of high risk, when compared to relevant criteria should be considered further.

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

5.33. Where hazards are eliminated or grouped, a justification for the approach should be included within the safety assessment. In subsequent safety assessments these justifications should be reviewed to check that they remain valid

5.34. The hazard screening process should involve consideration of all relevant exposure pathways to workers at the facility or involved in the activity and to potentially affected members of the public.

This aspect of the process should take into account radioactive releases and exposures from normal operations and anticipated operational occurrences (as these releases/exposures may occur continuously over a relatively long time interval) and accident conditions, which are typically single events.

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

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

5.36. Exposure pathways to members of the public and releases to the environment should be considered wherever applicable (e.g. lack of containment or fires could lead to an inadvertent spread of radioactive substances beyond the site). In addition to the pathways listed above for workers, the potential for off-site exposure pathways through water, airborne courses and/or the food chain should be considered.

Identification of Scenarios

5.37. Assessment scenarios for screened hazards should be generated in a systematic manner (e.g. using potential initiating event identification).

5.38. When identifying potential initiating events (PIEs) one should consider all potential initiating events (PIEs) through which harm could be realized, in particular:

a. External initiating events; (i) natural events such as adverse meteorological conditions (e.g. wind, snow, rain, ice, temperature, flood, lightning), earthquakes or biological intrusion; or (ii) inadvertent human events such as aircraft crashes (with or without subsequent fires), explosions, fires, loss of electrical power or other services, and inadvertent intrusion;
b. Internal initiating events at the facility or the site, e.g. fire, explosion, structural collapse, leakages or spillages, failures of ventilation, drop of heavy loads, failures of protective measures (e.g. of shielding, personal protective equipment);
c. Human initiating events such as operator errors and violations, misidentifications performing incompatible activities. The process should also consider the potential for new initiating events to be caused by the actions taken during the evolution of an accident to mitigate the consequences of the accident

5.39. For predisposal facilities or activities, special attention should be given to human factor and technological procedures as this often can represent the main scenario generating component.

5.40. The identification of initiating events and their evolution should be carried out using an appropriate technique (e.g. operability analysis, event tree, fault tree) and sources of information, such as checklists, potential dose rates for the facility or activity, radioactive waste inventories, and feedback from other facilities or activities.

5.41. Assessment cases should be specified for normal activity or operation conditions (including start up and shutdown where appropriate), anticipated operational occurrences, and accidents. The safety analysis should address both, the consequences arising from all normal activity or operational

conditions and the frequencies and consequences associated with all anticipated activity or operational occurrences and accident conditions. The degree of detail of the analysis should depend on the magnitude of the radiation risks associated with the facility or activity, the frequency of the events included in the analysis, the complexity of the facility or activity and the uncertainties inherent in the processes that are included in the analysis.

Scenarios for normal operation

5.42. Scenarios for normal operation should address all conditions under which the facility systems and equipment are being operated or activity is carried out as expected, with no internal or external challenges. This includes all the phases of operation for which the facility was designed to operate in the course of normal operations and maintenance over the life of the facility as well as all stages of activity. The effects of variations in the input materials (feedstock, source material, receipts, etc.) on normal operations should be considered.

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

Scenarios for anticipated operational occurrences and design basis accidents

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

5.45. Anticipated operational occurrences are those events which exceed the bounds of normal operation and have the potential to challenge the safety of the facility and which might be expected to occur at least once during the lifetime of the facility. Anticipated occurrences should also be considered for waste management activities.

5.46. A design basis accident, as the name implies, is an accident condition against which a plant is designed according to established design criteria, and for which the damage to the plant and the release of radioactive material would remain within defined acceptable levels. Design basis accidents have a lower frequency than the anticipated operational occurrences. They would not be expected to occur during the lifetime of the facility but have been considered in the design of the facility.

5.47. The safety analysis should identify the anticipated operational occurrences and accident conditions that challenge safety. This needs to include all internal and external events and processes that may impact on physical barriers to confine the radioactive material or otherwise give rise to radiation risks. The selection of events and processes to be considered in the safety analysis should be based on a systematic, logical and structured approach and should provide justification that the identification of all scenarios relevant for safety is sufficiently comprehensive. The analysis should be based on an appropriate grouping and bounding of the events and processes and should consider partial failures of components or barriers as well as complete failures.

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

(a) control the potential for release of radioactive material or loss of shielding and thus fulfil the safety requirements;
(b) ensure that any operational effluent discharges are below prescribed limits;

(c) ensure that limiting criteria for design basis accident conditions will be met;
(d) show that radiological limits applied are not exceeded; and
(e) demonstrate that some or all of the barriers put in place to limit exposures and limit the release of radioactive material from the facility will maintain their integrity to the extent required.

5.49. In addition, the aim of the design basis assessment should be to provide a robust demonstration of the fault tolerance of the engineering design and the effectiveness of the safety features and protective measures. This is achieved by carrying out a conservative assessment that should take account of the uncertainties associated with the assessment. Further, the analysis of scenarios addressing design basis events is used as the basis for design specifications related to reactivity control of fissile material, the safety features (for example, containment boundary, fire protection system, ventilation system, cooling system etc.) and the electric power system (if necessary for safety).

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

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

(a) the original design basis and the acceptance criteria are no longer adequate;
(b) the safety assessment tools previously used have been superseded by more sophisticated methods; or
(c) the original design basis is no longer met.

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

Scenarios for beyond design basis accidents

5.53. Accidents beyond design basis are those which the facility is not explicitly designed to withstand. They may be considered in two general groups:

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

5.54. The distinction between design basis accidents and accidents beyond design basis is based upon consideration of the probabilities of occurrence and the consequences. It is very facility or activity and site dependent. If the probability of occurrence of an accident is high, the design should be able to accommodate the accident without significant consequences from the point of view of safety. If the probability of occurrence of an accident is much lower but the consequences from the point of view of safety would be significant, it may be advisable to incorporate features into the design to accommodate this eventuality.

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

(a) those which fall within the envelope of the conservative acceptance criteria for the design basis accidents, although an assessment may be needed to demonstrate this;
(b) those which exceed the conservative acceptance criteria for the design basis accidents but would not result in significant facility damage or releases beyond discharge limits; and
(c) those in which there has been significant facility damage, the safety features have malfunctioned and some of the barriers to the release of radioactive material have failed or have been bypassed.

5.56. The accident described in (c) of paragraph 4.79 above is a severe accident in the context of the facility or activity. However, the term "severe accident" has acquired a particular meaning related to core damage and other effects of a reactor accident. The term will therefore not be used in this document but instead, reference will be made below to "serious accident" to denote such accidents.

5.57. In the case of accidents described in (a) and (b) of paragraph 4.79 above, the assessment should aim to quantify a facility or activity safety margin and demonstrate that a degree of defence in depth is provided for this class of accidents. This would mean that the facility design and operation includes measures where reasonably achievable to:

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

Serious Accidents

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

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

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

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

FORMULATION AND IMPLEMENTATION OF MODELS

5.62. Once the scenarios have been developed, the corresponding assessments should be carried out. This is commonly done using assessment models. An assessment model includes the following components:

- A conceptual model, which is a representation of the system under consideration. In predisposal waste management facilities or activities, this system can represent a certain component or process during normal operation (e.g. when evaluating the effectiveness of shielding) or during and after an accident (e.g. to estimate releases from waste forms during a fire). The system under consideration may also represent other parts of the facility (e.g. acting as barriers) or parts of the biosphere (e.g. if the modelling has to assess the consequences of releases over atmospheric or aquatic pathways). In all these cases, 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 system geometry, the chemical, physical, biological, and mechanical behaviour of the system, consistent with the available information and knowledge.
- A mathematical model, which is a representation of the features and processes included in the conceptual model using mathematical equations. The mathematical model can be used for performing quantitative analyses.
- A computer code, which is a software implementation of the mathematical model that facilitates performing the assessment calculations. The computer code may include numerical schemes for solving the equations in the mathematical model.

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

5.63. During model development the assessor should as far as possible ensure that:

- models are developed at a level of detail that is fit-for-purpose, given the status of the assessment context and existing knowledge of the predisposal system;
- the conceptual model provides a reasonable representation of the system under consideration, and that 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;
- for mathematical models, model verification and validation exercises are conducted and documented to a sufficient degree to build confidence in the fitness of the model for its intended purpose [10].

5.64. Once the models have been developed it is necessary to assign values to the different parameters, a process which is here called model parameterization. During model parameterization it should be ensured that:

- Parameter values used as inputs to the models and codes used in assessment calculations are documented. The model parameterisation process should be traceable to source data.
- Records are kept of how site and system specific characterization data has been used to derive parameter values used in the assessment calculations.
- Where a probabilistic approach has been used in the assessments, a justification of the selected probability distributions is provided.

PERFORMING CALCULATIONS AND ANALYZING THEIR RESULTS

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

5.66. The calculation cases should adequately address the appropriate scenarios using appropriate site, facility or activity design information. A sufficient range of sensitivity and uncertainty analyses have to be performed to demonstrate system understanding, and to show that parameter correlations have been treated in an appropriate way.

5.67. When presenting the output from safety assessment calculations, sufficient results should be provided, both needed for comparison with the ultimate assessment endpoints and with any alternative or sub-system performance criteria. Guidance on the use of the safety assessment results should be provided. For example, it should be explained whether the safety assessment results (endpoints) will be compared directly with regulatory criteria (e.g. safety targets) or whether these will be used for illustrative or other purposes.

Management of Uncertainties

5.68. In view of the complexity of certain radioactive waste predisposal systems, efforts should be undertaken during the assessment to understand the significance of the uncertainties and to reduce or bound uncertainties.

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

Sources of Uncertainty

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

5.71. *Model uncertainty* could arise from imperfect knowledge of the processes, which leads to imperfect conceptual models (e.g. when estimating the amount of radioactivity released from a waste form during a fire). The mathematical representation of the conceptual models may be approximate or over-simplified, also contributing to model uncertainty. Imprecision in the numerical solution of mathematical models is another source of uncertainty falling into this category.

5.72. *Data/parameter uncertainty* refers to the uncertainty in the values of the parameters used in the safety assessment models. This category often includes uncertainty in the intrinsic characteristics of the components of the system, e.g:

- *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, waste form composition, records, etc.
- *Process characteristics* – chemical and physical characteristics during processing, additive-to-waste ratio
- *Measurement procedures* - clearance/discharge measurement procedures
- *Receptor characteristics* – exposure times

Uncertainty and Sensitivity Analyses

5.73. Some uncertainty has to do with events or phenomena that occur in a random manner such as random failures of equipment. These aspects of uncertainty are inherent in the logic structure of the probabilistic model. Other uncertainties are associated with the state of knowledge relating to a given problem under consideration. In any analysis or analytical model of a physical phenomenon, simplifications and assumptions are made. Even for relatively simple problems, a model may leave out some aspects that are deemed unimportant to the solution. Additionally, the state of knowledge within the scientific and engineering disciplines may be incomplete. Simplifications and lack of knowledge lead to uncertainties in the prediction of outcomes for a specified problem.

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

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

5.76. When defining a strategy for the treatment of uncertainties, it is convenient to differentiate between scenario uncertainties and model and data/parameter uncertainties. Possible approaches for their treatment are outlined below.

Treatment of Model and Data/Parameter Uncertainties

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

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

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

o The graded approach to safety assessment applies equally to the treatment of uncertainty. For example, a commonly used approach to treat uncertainty is to use conservative (cautious) assumptions (when simplifying the models used, a conservative view can be taken). Another example is to assign conservative values to model parameters. This approach has several advantages, in particular for the demonstration of compliance with regulatory criteria. However, it should be taken into account that in some cases the conservative assumptions may lead to assessments representing situations that are extremely unrealistic or impossible and, therefore, difficult to interpret and communicate. Also, when conservative values are assigned to several parameters, the results of the calculations might be over-conservative due to magnification of errors, and would provide a poor basis for decision making. Another important consideration is that an assumption that is conservative in one scenario, or for one nuclide, might not be so for another. The conservatism of the assumptions should be justified in relation to their impact on the assessment endpoints.

o Probabilistic Safety Assessments (PSA) can be used to quantify the risks associated with each scenario. PSA should avoid realizations with impossible combinations of the parameters or combinations corresponding to very unlikely states of the system. Impossible combinations may be generated, for example in Monte Carlo simulations, when sampling from the probability distributions of the different variables, for example if correlations are not taken into account. PSA should also be conducted so as to avoid undue risk dilution.

ANALYSIS OF ASSESSMENT RESULTS

Comparison against Assessment Criteria

5.80. A clear distinction needs to be made between protection objectives and the indicators used to demonstrate that these objectives are fulfilled. Protection objectives are expressed in general terms, and can be agreed internationally, while national regulations often provide standards and criteria relating to specific indicators (for example, dose or risk) expressed as targets, constraints or limits, which may differ from country to country. One of the aims of the safety assessment is to compare the assessment endpoints to the specific indicators. This is significantly aided by adopting a systematic approach such as reflected in the SADRWMS work (see Annex D)

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

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

Review and modification of the assessment models

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

5.84. In accordance with the graded approach [2], the extent and complexity of the safety assessment will vary with facility or activity type and should be related to the hazard potential. Also, the level of depth of the safety assessments performed at the different stages of the development of a facility or activity will vary.

5.85. The level of detail to which the models are developed and the associated amount and quality of data required will be a function not only of the assessment context but also of the stage of iteration of the assessment process (see Section 3). For example, during early iterations (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 implement them using more sophisticated computer codes. Models and data for later iterations, especially for the final safety case, may need to be even more comprehensive.

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

6. SPECIFIC ISSUES

6.1. This section expands on several issues that may require particular consideration when undertaking safety assessments for radioactive waste predisposal facilities or activities. The issues considered are:

- Determining when a safety assessment required
- The graded approach;
- Defence in depth;
- Reliability;
- Facility and Activity Lifetimes;
- Long Term Storage;
- Waste acceptance criteria and interdependencies;
- Comparison of options.

EVOLUTION OF THE SAFETY CASE

6.2. In Annex D, a framework for the overall processes of predisposal waste management is developed and illustrated in a series of flowcharts. This framework is used to identify those facilities and activities requiring safety assessment and provides an overview of the scope and objectives of these safety assessments.

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

- Concept and design development;
- Construction;
- Commissioning – both inactive and active;
- Operations;
- Shutdown and decommissioning; and
- Review of the safety assessment.

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

Concept and Design Development

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

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

6.7. Looking at the transposition of the adopted safety strategy to the facility or activity and its components, the safety case should address specifically how individually and together the components of the system will ensure implementation of all safety requirements. In general, the safety case should include a description of the functions assigned to each component of the system and assess the ability of these components to fulfill their given role. The safety case should also address construction feasibility and reliability. In all these respects, the performance of the system should be justified and the uncertainties remaining at the particular stage of the project identified.

6.8. The safety case should explain how the characteristics and properties of each component of the system are intended to provide for the allocated safety functions and how this will evolve with time. This should be supported by:

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

6.9. Radiological impact assessments can only be very preliminary at the conceptualization step. Nevertheless, it is desirable to carry out such preliminary assessment in order to provide a broad order of magnitude estimate of possible impacts, based on generic considerations of site performances, and to begin to identify the features of the facility and environment that are likely to be important to safety.

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

- Other activities on the site;
- The affect of the facility or activity on any neighbouring populations.

6.11. Consideration also needs to be given to:

- the effect of other activities or facilities on the proposed facility or activity;
- the management, predisposal, discharges or clearance of any wastes generated.

6.12. The safety case should also contain information about the management systems. Amongst the topics related to the management system, at this early step, the safety case should address the organizational structure and required resources to undertake the project, the programme for the project planning and the information management system. It is also necessary at this stage to develop and implement plans for regulatory and stakeholder dialogue.

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

Construction

6.14. During the design development and construction step, it is expected that the safety case will be further developed so that it demonstrates that the:

- facility or activity is required;
- that the adopted design will meet all safety requirements;
- that the facility can be safely constructed or the activity can be safely carried out.

6.15. The safety case should demonstrate that the likelihood of a component of the system failing is low and that, in the event of degradation, the loss of a safety function of one component does not jeopardize the safety of the whole system. Thus, the safety case should provide a mature assessment of the engineering and of the impact of the facility or activity.

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

Commissioning

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

6.18. A Safety Commissioning Schedule should be prepared detailing the test to be undertaken and the expected results to ensure that all aspects of the facility important to safety are adequately tested.

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

- The organization and procedures that are in place to assure the quality of the design and construction work performed, its linkage to the outcome of R&D activities and safety assessment work.
- The record keeping and tracking system covering data, information and the records of decision is implemented. Design basis information including information on design modifications should be captured together with validations.
- That there is sufficient expertise to carry out tests and operate the facility or activity.

6.20. Operations and events and occurrences in other comparable facilities or activities should also be used to identify the potential need for a re-examination of the safety case or structures, systems and components important to safety. It is advisable that all the appropriate information should be available

in order to support decision making including references to outputs from other projects results and substantiations.

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

Operations

6.22. The initial operational safety case will justify that the facility has been constructed and commissioned safely. Information acquired during the commissioning should be used to verify the validity of the safety assessment conducted before the respective stages, particularly regarding to key assumptions and predictions. Any significant differences between the actual and predicted performance of the facility or activity should be identified and the reasons investigated. All discrepancies should be justified. If there are safety implications, then a re-examination of the related structures, systems and components important to safety should be carried out.

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

- The organization and procedures that are in place to assure the safety of operations.
- The record keeping and tracking system covering data, information and the records of decision.
- That there is sufficient expertise to operate the facility or activity.

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

6.25. The safety case should justify that the facility can be safely decommissioned. Where a treatment facility is developed for all decommissioning waste then it should be recognized that the treatment facility will also generate decommissioning waste that will need some sort of treatment facility.

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

Shutdown and Decommissioning

6.27. The design of any waste management facility will eventually be closed and decommissioned. From the very earliest stage of the safety case development this must be addressed to justify its safety. The justification should be based upon techniques that are currently available and commensurate with the level of resources likely to be available at the time of closure.

Review of the safety assessment

6.28. During the operational life of a facility there maybe a need to modify some aspect. Where these have a potential impact on safety an appropriate safety assessment should be conducted or the current assessment updated before implementation to assure continuing compliance with established safety requirements. The resulting safety assessment should be justified against the operational safety case and the approved documentation appended to the safety case.

6.29. There may be time dependent processes and events both internal and external to the facility or activity, which will eventually modify certain assumptions, parameters and boundary conditions. Because the processes and events may be gradual or may occur at unpredictable times, the operational

safety case should be reviewed periodically in order to detect significant changes to the underlying assumptions, parameters and boundary conditions. If necessary, the safety case should be revised accordingly. This periodic review should be mandatory at periods determined by the regulatory body.

6.30. Periodic safety reviews may also be required to justify the life extension of the facility beyond its original design life; changes in the ownership or management of a facility; or changes in regulations.

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

GRADED APPROACH

6.32. This Safety Guide applies to a wide range of facilities or activities, and characteristics of waste processed, which may pose different degrees of hazard and risk. A graded approach to safety assessment should be used, therefore, which recognizes these different levels of hazard and risk. Thus, it could be expected that greater levels of effort should be put into developing safety cases and safety assessments for a large treatment facility than for a small low-level waste storage facility. The degree of detail required in the safety assessments should be determined by first undertaking relatively simple safety assessments that provide an indication of the potential levels of risk.

6.33. When undertaking a safety assessment, it is necessary to ensure that the assessment is based on an appropriate level of understanding of the system and its potential behaviour, and that all safety relevant issues are considered and addressed. Various criteria may be used to help in determining the level of understanding that should be expected for a particular facility or activity. Reference [10] identifies the following criteria: safety significance, complexity, and maturity. The potential use of these criteria in safety assessment for predisposal waste management facilities or activities is discussed in the following paragraphs.

6.34. According to [10], safety significance will usually be the most important criterion. Use of this criterion will necessitate consideration of facility or activity performance in terms of releases from normal operation, potential consequences of anticipated operational occurrences and reasonably foreseeable accidents, and the potential significance of low probability events with potentially high consequences.

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

6.36. Maturity of the facility or activity, as well as the technologies employed, may also be used to inform decisions regarding the level of effort in assessing or reviewing a predisposal waste management facility or activity. The use of proven practices and procedures, proven designs, data on operational performance of similar facilities or activities, uncertainties in the performance of the facility or activity, and the availability of experienced manufacturers and constructors typically require less consideration than with the use of novel approaches. The graded approach process is fostered by the systematic hierarchy captured in the SADRWMS work as attached in Annex D.

6.37. As a consequence of applying the graded approach, the development of a safety case for a comparatively simple waste management facility such as a storage facility in a hospital may require only a few weeks of time and may be conducted using a checklist approach. The development of a safety case for a large centralized waste processing facility, on the other hand, may require a large team with several different specializations and require serveral years of work.

6.38. A specific example for the application of the graded approach concept is the decision when to apply probabilistic modeling as opposed to conceptually simpler conservative deterministic assessment. Three main decisive factors can be identified determining the necessity of probabilistic assessments:

- Complex situations with many factors of influence which can lead to an exposure usually require an adequate treatment of possible evolution paths of each relevant system component and internal or external factor of influence; this is, in most cases, only possible by setting up an appropriate probabilistic model which adequately addresses and combines the individual probabilities to arrive at an overall probability distribution for the possible consequences.
- Large spreads of parameter values determining the likelihood and/or magnitude of exposure usually require a probabilistic treatment because setting each parameter conservatively may result in grossly overestimating exposures and, thus, may not yield an adequate basis for the assessment of the system and of required safety provisions;
- Potentially high consequences of an accident usually require a thorough analysis in order to ascertain sufficient confidence in the results.

While these aspects determine the necessity of probabilistic assessments from the point of view of the graded approach, there may be other situations in which probabilistic assessments are conducted for convenience or because of preferences of the safety assessor.

6.39. Probabilistic assessments vary in complexity and details. Determining the required level of complexity and detail again depends on the factors indicated in paragraph 6.36 and, thus, is also driven by the graded approach.

DEFENCE IN DEPTH

6.40. According to [10], an assessment of defence in depth is required, which should comprise an evaluation of the levels of defence provided by the facility or activity (see Section 2). The defence in depth concept is centered on several levels of protection including successive barriers and other safety functions preventing the release of radioactive material to the environment and minimizing exposures. The concept includes protection of the barriers by averting damage to the facility and to the barriers themselves. It includes further measures to protect the public and the environment from harm in case of unexpected malfunction or degradation of these barriers. Consideration should be given to combining physical barriers and administrative controls into an effective defence in depth strategy.

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

6.42. Safety assessment should take into account existing or justify projected levels of defence in depth. This can be made clearly by:

a) identifying barriers and other safety functions;
b) explaining the diversity of such barriers and other safety functions;
c) explaining the resilience of such barriers and other safety functions under normal and abnormal conditions;
d) if appropriate, making a quantitative estimate of their contribution to the margin of safety; and
e) showing that if any single safety barrier fails then the safety of the facility is not unacceptably compromised.

6.43. The assessment process should pay special attention to internal and external hazards which could have the potential to adversely affect more than one barrier.

RELIABILITY

6.44. When selecting components for use in a facility it is important to know their reliability. The safety case should justify the level of reliability demanded of any component. This will depend upon the safety demands made of the component and the defence offered by other components in the system.

6.45. In the safety assessment, consideration also needs to be given to the reliability of the component over the lifetime of the facility. Components should be designed to have a lifetime commensurate with the demands that will be placed upon them. This should be complemented by an appropriate maintenance regime to ensure the continued reliability of the component. Older components may well have lower levels of reliability, unless they have been well maintained.

EXPECTED LIFETIME OF THE FACILITY

6.46. The safety case will have to justify the expected lifetime of the facility. The expected lifetime of the facility needs to be sufficient for the activity being undertaken. For storage this lifetime may need to include some contingency i.e. for unloading of the wastes or for delay in the availability of disposal facilities.

6.47. For facilities or activities with long lifetimes it will be necessary to use well-proven and well-documented materials so that there is confidence that they will last for the duration of the facility or activity life. Special consideration needs to be given to long term storage, and are discussed later on in this section.

6.48. For facilities planning for extensions beyond their original planned lifetime expectancy, it is necessary to update the safety case (including the safety assessment) to consider the potential impacts on safety. The update should consider the degradation of barriers or components, and should be performed well in advance of the end of the original license to facilitate regulatory review.

LONG TERM STORAGE

6.49. Long-term storage (facility or activities), by definition, involve a period of time which will exceed the normal design life of civil structures including short term storage facilities and this will have implications for the choice of materials, operating methods, quality assurance and quality control requirements, etc. Specific issues that require special consideration in the safety case for long term storage include the assessment time frame of the storage facility or activity, the importance of passive safety features, retrievability, and management systems.

Timeframe

6.50. The assessment timeframe is the longest period considered in the safety assessment calculations. The rationale for selecting the assessment time frame should be explained and justified. Depending on the purposes of the assessment for long-term storage, it might be convenient to divide the overall time frame of the safety assessment into shorter time windows with different endpoints for modelling or presentational reasons.

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

- For most long-term storage systems (including waste packages, engineered constructions and surrounding environment) and waste types, potential impacts will rise for a period of time

after commissioning of the facility. In the longer term, depending on the nature of the waste, impacts may decrease, in particular through decay of the radioactive inventory of the storage facility. Usually, the safety assessment calculations should cover a period that is sufficient to determine the maximum, or peak, dose or risk associated with the facility or activity.

- Another consideration which may influence decisions on time frames or time windows is the return period of natural external hazards such as extreme meteorological events or earthquakes.
- Several factors that can significantly affect safety assessment results may change with time. The assessment should consider these changes. As a means to assess the possible evolution of the long-term storage facility, assessments may consider one or more scenarios to reflect different evolution paths. Assessment time windows may be defined as appropriate to reflect the potential changes that could impact upon the storage facility.
- The habits and characteristics of the receptor group, as well as the conditions in which they are located, may change over time. Consequently, such receptors should be considered as hypothetical, but receptors and populations in the future should be afforded at least the same level of protection as is required at the present day. The habits and characteristics assumed for the group should be chosen on the basis of reasonably conservative and plausible assumptions, considering current lifestyles as well as the available site or regional environmental conditions.

Passive Safety

6.52. The operator should demonstrate that, to the extent possible, passive safety features are applied as soon as possible. This is, according to [2], of particular relevance for the storage of waste. The assessment of long-term safety should account for the degradation of passive barriers over time.

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

6.54. Similar to disposal situations, the environment may also offer additional protective barriers (e.g. clay layers which would provide a sorption capacity for contaminants in cases of any leakages of the facility). Such aspects should be taken into account during the siting of the facility and considered in the safety assessments for the different time periods.

Retrievability

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

6.56. The safety case should consider a plan for safe handling of the waste following long-term storage and assess the potential effects of degradation of containment on the ability to retrieve and handle the waste.

6.57. Unlike for near surface disposal facilities, the possibility of inadvertent human intrusion normally would not be considered relevant when assessing the safety of a long term storage facility because the facility will require continued surveillance not only during but also after the waste placement phase. The situation after the waste placement terminates is somewhat analogous to a near surface disposal facility within an institutional control period, although the level of control in terms of intensity and frequency of surveillance measures likely will be substantially higher for the long term storage facility (e.g. because of involving

inspections of waste packages). Since safety assessments for near surface disposal facilities normally do not address human intrusion during the institutional control phase, this does, even more so, not appear necessary for long term storage facilities so that the safety assessment should not consider inadvertent human intrusion scenarios.

6.58. A relevant aspect, however, is the prevention of intentional human intrusion. This requires adequate security arrangements. These need to be addressed in the safety assessment and confidence in their long term efficiency needs to be built.

Management Systems

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

6.60. Because of the long time frames potentially involved with long-term storage, the safety case should also consider a plan for adequate record keeping over the expected time frame for storage.

6.61. Periodically, the safety case should be reviewed to consider the continuing adequacy of the storage capacity, with account taken of the predicted waste arising, both for normal operation and for possible incidents, the expected lifetime of the storage facility and the availability of disposal options. Waste acceptance criteria and interdependencies. It is important to notice that there are interdependencies among and between the different steps of radioactive waste management. Decisions made at one step may affect subsequent steps or foreclose viable alternatives. It is therefore of great importance to identify such interdependencies in the safety assessments for each predisposal waste management activity and to ensure that no conflicting requirements arise that could compromise safety.

6.62. Given that disposal is the last step in radioactive waste management, it also needs to be taken into account when any other upstream radioactive waste management activity is being considered. However, in many Member States disposal facilities are not yet available in general or only for specific types of waste. Independent of this, all radioactive waste arisings must be dealt with, requiring decisions on waste forms to be produced which, in this situation, must be made before all radioactive waste management activities are finally established.

6.63. Such circumstances emphasize the importance of preparing adequate waste form specifications which define the requirements on waste to be accepted by a facility (e.g. a storage facility) as well as requirements on waste forms to be produced by waste processing facilities. Such waste form specifications may either address radiological, physical and chemical properties of a broad range of different waste or be established for individual waste types.

6.64. The specifications for acceptable waste forms are derived within the safety assessment for the facility or activity. Specification development should focus on assessing or controlling the radiological, physical and chemical properties of waste packages in order to be accepted for transport, storage and disposal. In order to achieve this objective, the specifications need to consider the intended storage facility and the transport regulations and incorporate any relevant parameters from waste acceptance requirements, if available.

6.65. Various methods are applied for processing the different types of radioactive waste. Consideration is given to identifying suitable options and to assessing the appropriateness of their application. Decisions are taken within the overall approach to radioactive waste predisposal management as to what extent the waste has to be processed, with account taken of the quantities, activities and physical and/or chemical nature of the radioactive waste to be treated, the technologies available, the storage capacity, and the availability of a disposal facility. When the waste form and package concept have been decided upon, all relevant parameters should be quantified in terms of

ranges that may be achieved in producing the waste package. Maximum values for each parameter and factors of safety can then be determined.

6.66. When deriving requirements on the waste forms within a safety assessment, the situation arises that a comparison of different treatment options has to find a balance between possible further increases in safety and economic aspects. In such situation, methodologies for the comparison of options (see para. 6.69. and the following) can be utilized.

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

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

OPTIONS APPRAISAL

Framework for the Decision-Making Process

6.69. The planning and development of facilities or activities is usually faced with the necessity of making decisions of various kinds. For example decisions on the facility design. Decision making in all cases requires to compare different management options to each other and to identify the option which complies with all applicable regulatory requirements and provides an optimal level of performance, factors such as costs and other detriments taken into account.

6.70. The actual decision making process depends on the legislative and regulatory framework. The safety case represents one key input to this process and, therefore, should assist in reaching decisions on how to ensure the safety of a new facility or activity or to upgrade the safety of an existing facility or activity. Consequently, the whole range of activities required to develop a safety case, including all steps of conducting the underlying safety assessment, should satisfy the following requirements:

- All safety aspects relevant for the eventual decision making should be addressed in the safety case. This includes the assessment of radiological risks as well as of other factors of influence for deciding about the practicability and acceptability of intended activities.
- Relevant factors of influence for the decision making should be investigated with a sufficient level of depth, using adequate methodologies. Main considerations are that relevant impacts should not be underestimated, but that also, in particular in existing situations, an overestimation of risks and other important detrimental factors should be avoided to the extent practicable in order not to trigger unnecessary measures.
- It should be avoided to invest substantial efforts (e.g. for data collection and modelling) to address factors of no or only minor relevance for the eventual decision making, resulting in a waste of time and financial resources.
- The assessment results as well as the additional arguments and considerations presented in the safety case should be sufficient to derive and justify a decision on the action to be taken. A

sufficient basis should be provided for the assessment of compliance with regulatory standards, for the inclusion of other relevant factors, for the balancing of benefits and detriments from available options as a basis for selecting an option to be implemented (in particular relevant for existing situations), and for the building of confidence in the reliability of the assessments performed and in the adequacy and safety of the action proposed in the safety case.

Methodology

6.71. In view of the overall goals of the decision making process, it is evident that it influences all parts of the development of a safety case. In particular, all key components of the safety assessment methodology presented in Section 4 will be affected by considerations derived from decision making goals and requirements. Important considerations are:

- As the basis for the definition of the assessment context, required decisions should be identified, which depend on the purpose of the assessment. On this basis, potential factors of influence for the decision making issues to be addressed have to be compiled.
- A decisive part of setting up the assessment context consists in the 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, cautious), the type of data to be used (site-specific or generic) and the approach to the treatment of uncertainties (probabilistic or deterministic). It is evident that defining these boundary conditions of the assessment inappropriately with regard to the decision making requirements would preclude the ability to make adequate and defendable decisions.
- Apart from the range of decisions to be made, the assessment context will also be determined by the decision making methodology to be adopted. If quantitative decision-aiding methodologies are to be applied, requirements to address specific end-points arise (such as collective doses if a cost-benefit analysis is to be used). Also, other components of the assessment philosophy such as the treatment of uncertainties may depend on the eventual decision making methodology.
- Scenarios should be set up by considering all Potential Initiating Events that could directly or indirectly influence the system and the radioactive inventory. To the extent that non-radiological factors are relevant for the decisions to be made, these will also require consideration in the scenario development.
- The results need to be analyzed and interpreted in view of their relevance with regard to the decision making requirements. If they are not considered to be sufficient for this purpose, refinements of scenario definitions and/or models and possibly the collection of additional data will be necessary.

6.72. The actual decision making process is multi-faceted in that several varied and sometimes competing factors have to be brought together and reconciled to reach a decision as to whether the system and the assessment are adequate. The assessment process will be iterative in most practical cases. Early iterations should be undertaken with available data and assessment capabilities. The iterations need only to proceed until the assessment is judged to be adequate for its purpose. Furthermore, new data need only be collected to the extent required to improve the basis for the decisions to be made.

6.73. 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 within a qualitative process, involving deliberation of all relevant factors. Quantitative methods such as cost-benefit analysis (CBA) or multi-attribute utility analysis (MAUA) are applied to address and balance the various factors relevant for the decisions to be made.

6.74. If quantitative methods are being applied, their function should be seen as tools to aid the decision making process, not as a substitute for it. Results should be used as input to discussions with involved parties like regulators and stakeholders. The main role of these decision-aiding methodologies lies in analyzing and presenting assessment results in a conceivable and comprehensive way, allowing for judgments of their respective importance and implications on the decisions required.

6.75. The decision making process should consider all relevant factors. In case of several nuclear facilities or activities present or planned at a site, the cumulative radiological impacts from these facilities or activities should be considered in the decision making process (see Para. 4.22).

6.76. The decision making process in general includes, beyond the technical aspects, other relevant factors and considerations. Although the assessment of other than radiological factors is not part of the methodology outlined in Section 4, activities required to estimate, for example, non-radiological risks are analogous to those required for the estimation of radiological risks. Therefore, it will be possible to integrate the assessment of all relevant factors into this methodology, providing a consistent and transparent description of all assessment activities required in order to be able to compare the options and to select a preferred option for achieving safety (or to justify to do nothing in cases of existing facilities or activities). It is possible to apply quantitative decision-aiding methodologies such as MAUA also to such additional factors of influence, even if they are qualitative in nature (such as public acceptance of different options).

Application to Existing Facilities or Activities

6.77. The approach to support the decision making process outlined in the previous section is directly applicable to existing facilities or actvities as well. However, there are some specific requirements arising in such situations from the fact that the facility or activity and possibly radiological risks are already present and that, therefore, management options are limited to deciding whether corrective action is necessary and, if this is the case, which type of corrective action to choose.

6.78. A decisive part of setting up the assessment context consists in the definition of the assessment philosophy. Assessments performed with the intention of comparing the resulting doses to regulatory limits, constraints and other criteria will have to be performed with a sufficient level of conservatism. Assessments for the comparison of option involving optimization, however, should be based on more realistic assumptions. Due to the importance of the optimization principle in existing situations, this distinction becomes more relevant for existing facilities or activities.

6.79. For an existing situation, assessments usually should in general be conducted in two distinct steps. In the first assessment step it should be determined whether corrective action has to be considered at all or whether the current condition of the facility or activity is considered acceptable. The second assessment step, performed only if required by the results of the first step, should identify and evaluate options to improve the situation.

6.80. In particular for existing facilities or activities with several feasible options for corrective actions, their comparison should usually be performed iteratively:

- It may be possible to disregard some options very early on, e.g. because of prohibitive costs or because it becomes evident soon that basic regulatory requirements cannot be complied with. For such options, a detailed analysis of impacts would not make sense and result in a waste of efforts.
- The assessment of implications of the remaining options with regard to the factors to be considered in the decision making can be very time and resource consuming. It may even face fundamental difficulties if a basis for precise estimates does not exist (e.g. with respect to the durability of structures). Instead of investing great efforts in trying to improve the estimates for such factors, first of all their relevance for the decisions to be made should be examined. It may turn out that prevailing uncertainties for such factors do not influence the decisions, because these are dominated by other factors. If this is the case the uncertainties can be accepted and further assessment efforts are not required in this respect. Because a justification for this decision can be given based on the assessment results, it does not interfere with the overall requirement to build confidence in the assessments.
- In correspondence with the graded approach, the level of effort invested in improving the data basis and the modelling should be in line with the importance of the various factors for the

decisions to be taken. Within an iterative process implications of results and their uncertainties for the decision making can be 'tested' to identify those aspects which warrant further refinement based on their decision making relevance.

7. DOCUMENTING AND USING THE SAFETY CASE

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

DOCUMENTING THE SAFETY CASE

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

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

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

7.5. Whatever documentation structure is adopted, there are key attributes and considerations that should be considered throughout the documentation process. 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 performance story should remain the same and not be changed to suit the expectations of a particular audience. All consultation and promotional documents should always be consistent with the main safety case document(s).

- The main safety case documents should provide sufficient information for the key safety arguments and the evidence supporting them to be clearly understandable.
- The foundation of the safety case should always be consistently based on sound scientific evidence and arguments using established using technical experience and analyses.
- The documentation should be open and acknowledge uncertainties and limitations as well as their safety implications.
- The safety case documentation should be well structured, transparent and traceable.

- The documentation should be transparent by making the information readily available to stakeholders, being clear and understandable and by clearly presenting the justifications and rationale behind key assumptions.
- The documentation should be traceable by showing how follow-up actions and programs are put forward at early stages to confirm assumptions or how unresolved uncertainties have been and/or will continue to be followed. It should also be shown how key decisions have been documented and recorded by including a clear referencing system.
- The safety assessment methodology should be well structured, transparent and traceable. It should allow the regulators 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 identify the assumptions and uncertainties that impact the most on safety.

7.6. Safety case documents should be updated periodically in accordance with a systematic and considered plan. The operator should implement proper controls over the safety case report approvals process and over updates to the set of data and parameter values on which the safety case is based and that are used in the safety assessment. It is advisable not to feed documents of low maturity into formal review processes.

Executive Summary

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

7.8. For most readers, the summary will provide the first and most lasting impression of the project. Often this is all that members of the public will read. As a result, this section should be clear, complete and concise. Summary tables, graphics and flow charts should be considered as effective ways to present information clearly and accurately. The use of complicated technical terminology should be avoided as much as possible. The executive summary can be presented under a separate cover and it may get greater distribution than the rest of the documentation. It could also be presented in different languages to suit local communities' linguistic characteristics.

Introduction and Safety Case Context

7.9. The safety case documentation should be introduced by clearly presenting the purpose and context of the safety case in order to provide the reader with a clear understanding of the project and the decision making process, and of the various issues that are to be considered. The introduction should outline the following main aspects:

- A brief description of the project which provides the specific objectives, background, various phases involved and current status;
- The policy and regulatory contexts under which is safety case has been prepared and presented;
- The roles and responsibilities of the different 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 adequacy of development of the technologies that will be used;
- A statement on the need for, and importance of the project, in order to support and justify the safety case;
- A discussion of alternatives that have been considered and reasons for the preferred alternative;

- The key decisions that have been and will have to be made during the course of the proposed project;
- A description of critical timing considerations associated with the project;
- An overview of how compliance with regulatory requirements will be ensured and verified by both the regulator and the operator,
- Overview of the operator's quality control procedures and its ability to adequately address the challenges associated with the project.

Safety Strategy

7.10. Once the purpose and context of the safety case have been clearly presented, the safety case documentation should provide an overview of the high-level safety approach that will be used to achieve safety. The objective of this section is to demonstrate that the overall approach and methods adopted to design, assess the safety of, construct, operate, shutdown and decommission the predisposal waste management facility or activity are adequate to ensure safety. The section should also include confidence building arguments that are relevant to the safety strategy. The main aspects to be considered include:

- Strategy and approach to manage the different development phases of the facilities or activities (e.g. site evaluation, construction, operation, shutdown, decommission);
- How the adopted strategies adhere to good engineering principles and practices;
- Handling and reduction of uncertainties;
- Basis for making decisions and the use of multiple lines of reasoning;
- Safety features included in the design of the facility and defence in depth used;
- Rationale for selecting the assessment methodology and assessment time frames, including a discussion on the various assessment approaches and 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

7.11. This section documents the details of the safety assessment, forming the scientific and technical basis for the safety case (including all of the aspects discussed in section 4). This is the section that will be scrutinized by technical reviewers and the regulators. Documenting the safety assessment involves detailed description of the safety assessment context, each step of the assessment, the assessment findings and the conclusions. Due to the large amount of details that are involved, it could be more practical and traceable to document detail descriptions, modeling and calculations in annexes. The main document should focus on the assumptions, the approaches and methodologies used in assessment, discussion of the most relevant features that affect safety, the assessment findings and supporting the conclusions. Confidence building arguments should be documented within each step of the safety assessment documentation as well as for the overall safety assessment.

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

7.13. The quantitative and qualitative outcomes of the safety assessment form the basis of the safety case. These are supplemented by supporting evidence for and reasoning about the robustness and reliability of the safety assessment and its assumptions, including information on the performance of individual system components as appropriate.

Synthesis and Conclusions

7.14. Once the details of all supporting evidence for the safety case have been documented, a synthesis section should be developed to support conclusions and recommendations. This section should:

- Draw together the key findings from the safety assessment;
- Highlight the main evidence, analysis and arguments that quantify and support the claim that the predisposal facility or activity is safe;
- Present an evaluation of uncertainties and unresolved issues and discussed planned steps to resolve them;
- Present statements of confidence in the form of additional evidence and arguments on the main components of the safety case.

Follow-up Programmes and Actions

7.15. In particular when the safety case is developed within a step-by-step approach, it is important to put the current version of the safety case into the context of the overall development process. Required activities for the next phase of developing the eventual safety case should be described, such as acquisition of additional data or planned improvement of modelling. If certain activities can only proceed after decision making hold points (for example, on the site of the facility or activity), these should be identified.

Traceability and Transparency of the Safety Case and Safety Assessment Documentation

7.1. Whatever documentation structure is adopted, there are key attributes and considerations that should be considered throughout the documentation process. These include the following:

- All documents produced in the context of the safety case, whether for regulatory approval, for information or promotion should convey a consistent message about safety issues. In other words, the message should remain the same and not be changed to suit the expectations of a particular audience. All consultation and promotional documents should always be consistent with the main safety case document(s)[2].
- The main safety case documents should provide sufficient information for the key safety arguments and the evidence supporting them to be clearly understandable.
- The documentation should show that the foundation of the safety case is based on sound scientific evidence and arguments using established technical experience and analyses.
- The documentation should be open and acknowledge uncertainties and limitations as well as their safety implications.
- The safety case documentation should be well structured, transparent and traceable.
- The documentation should be transparent by making the information readily available to stakeholders, being clear and understandable and by clearly presenting the justifications and rationale behind key assumptions.
- The documentation should make the procedure followed and key decisions taken in the development of the facility and of the safety case traceable. This should include showing how follow-up actions and programmes are put forward at early stages to confirm assumptions or how

[2] Note, however, that the consistency required here does not preclude emphasizing different arguments to a different degree for different audiences as or different people may be convinced by different arguments.

unresolved uncertainties have been and/or will continue to be followed. It should also be shown how key decisions have been documented and recorded by including a clear referencing system.
- The safety assessment methodology should be well structured, transparent and traceable. It should allow the regulators 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 identify the assumptions and uncertainties that impact the most on safety.

7.2. Safety case documents should be updated periodically in accordance with a systematic and considered plan. The operator should implement proper controls over the safety case report approval process 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. It is advisable not to feed documents of low maturity into formal review processes.

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

- The assessment methodology should be clearly structured and presented, and the assumptions and basis for assumptions should be clearly presented. Well-defined and documented methods should be used in identifying features and processes, designing and instrumenting tests and experiments, interpreting test results, constructing conceptual models, and analyzing and evaluating the models.
- Consistency between assumptions should be sought, along with the range in which the assumptions are appropriate.
- Consistency should be achieved among all stages of safety assessment, and with the main objectives and approach.
- The evolution of the assessment from one iteration to the next must be transparent to stakeholders (e.g., explanation of new data or reasons for changing components of the conceptual or mathematical model), in order to avoid giving impressions that the assessment is being manipulated to give more favorable results.
- Confidence should be increased by choosing an assessment methodology which is compatible with international experience and guidance.
- A formal set of QA procedures should be developed, and evidence provided that these procedures have been applied.
- As part of the QA procedures, a comprehensive system of records 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 appropriate literature should be provided.

7.4. Various stakeholders will have different interests and will scrutinize the arguments provided in the safety case that are more related to their interests and concerns. The levels of traceability and transparency to be reached therefore may depend on the expectations of the stakeholders. For example, technical reviewers will pay close attention to safety assessment aspects while members of the general public may be more interested in the other more qualitative arguments such as the managerial aspects. For this reason, a simplified version of the safety assessment documentation could be sufficient for the public, whereas regulators expect more complete information.

7.5. 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. 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 are the ultimate sources of the data etc. Traceability therefore requires the highest standards of quality assurance. Traceability further implies that the regulator or other technical reviewers should be able to reproduce part or all of the assessment results from the safety assessment documentation. Traceability will be greatly increased by presenting the safety case in a hierarchically structured set of documents.

7.6. To ensure traceability of a safety assessment, the following issues should be taken considered:

- It is essential that all information comprising the safety case and safety assessment can be traced to source. Such information sources may include records of observations, measurements, research work, modelling studies as well as decisions and assumptions made during the safety case and safety assessment development projects. Such decisions and assumptions may rely on expert judgment or expert elicitation processes, for which appropriate procedures and documentation are required.
- Expectations related to traceability depend on the audience of the safety assessment. Traceability in safety assessment intended for scrutiny by the regulator should be higher than in a document intended for internal use by the operator organization.
- If safety assessment is undertaken iteratively, there may be a tendency for the referencing to become "sedimentary", with each successive iteration simply referring to decisions made in a prior iteration. This may refer the reviewer 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 process may lead to a reduction in confidence in the operator organization by the reviewer. Consequently, direct citation of primary references should be emphasized, and each iteration of the documentation should permit straightforward evaluation of its traceability.
- It should be avoided to reference reports form the grey literature or proprietary or classified documents. Self citations (e.g. decisions made in earlier reports by the operator to be cited as the source for important information) should be avoided, except where the self citation is to an accessible primary reference. If referenced documents are unavailable to the reviewer, their use as a reference would break the chain of traceability.
- The need to keep the chain of traceability intact back to primary references tends to make documents large and difficult to read. Consequently, there is frequently a tradeoff 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

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

Licensing

7.17. A principal function of the safety case is in the license application and approval process. In the case of step by step development, such safety cases may be required for regulatory purposes at various stages in the licensing process, including approval to construct, operate and shutdown the facility, and whenever there are significant changes in the facility or activity. In other cases, the license could cover all of the lifecycle stages of the facility. When required by the licensing authority, the safety case is also updated at periodic intervals or to reflect new information.

7.18. For predisposal facilities and activities within other facilities operated for other purposes, such as nuclear power plants or spent fuel reprocessing plants, the license for the predisposal facility or activity may be approved within the framework of the license procedure of the other facility or activity.

Construction and Commissioning

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

Operation

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

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

Monitoring

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

Management Controls

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

8. REGULATORY REVIEW PROCESS

8.1. The regulatory decision making process may involve one or several regulatory authorities and may also be scrutinized by the public and other stakeholders. The credibility of the process is enhanced if the regulators take a coordinated approach so that stakeholders perceive that regulatory decisions are based on a careful and comprehensive examination of risk. This should be achieved by an adequate plan for the regulatory review process in accordance with requirements laid down in Ref. [4] and the guidance provided in Ref. [25]. Some important elements of the regulatory review of the safety case and safety assessment for predisposal facilities and activities are discussed in the following sections.

OBJECTIVES AND ATTRIBUTES OF THE REGULATORY REVIEW PROCESS

8.2. The objectives of a regulatory review of the safety case and safety assessment should take account of the status of the facility development (e.g. whether the facility is proposed, under development, operational, undergoing re-assessment or closed) and the associated assessment context.

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

- To determine whether safety assessment has been conducted in an acceptable manner (quality, level and depth) and whether it is fit-for-purpose.
- To verify that the results of safety assessment and the assumptions on which the assessment and the wider safety case are based, comply, or are in accordance, with accepted radioactive waste management principles, and regulatory requirements and expectations.
- To determine whether the safety assessment provides an appropriate basis to support the safe operation of the proposed facility or activity, in particular by identifying any limits, conditions and controls that will need to be applied to support safe operation of the facility or activity.
- To ensure that relevant measures and contingencies to mitigate unlikely potential effects have been identified and considered, and that adequate follow-up plans for their implementation have been developed.
- To determine whether issues to be addressed by other regulatory bodies, if any, have been clearly identified.
- To determine unresolved issues and to ensure that plans for resolving these issues have been adequately identified.

8.4. In order to assist with evaluating safety assessment work against the primary review objectives, it is common for a number of secondary objectives to be specified. These may include evaluating whether the safety assessment:

- Is based on an appropriate assessment context.
- Is sufficiently complete, given the status of the waste management programme and the facility or activity under consideration, and consistent with the planned activities.
- Is sufficiently transparent in its presentation of data and information and has been prepared by competent personnel applying a suitable management system providing confidence in the quality of the operator's safety assessment.
- Is based on appropriate assumptions and on the use of adequate techniques and models and contains satisfactory arguments supporting the adoption of those assumptions and parameter values and the use of the models.
- Provides an adequate identification and screening of hazards and related scenarios such that all relevant safety functions and all potential safety concerns are adequately considered and an adequate understanding of the facility or activity is demonstrated.
- Describes adequately how the identification, justification and optimization of (procedural or engineered) safety measures, limits, controls and conditions were performed and that adequate defence in depth is provided.
- Clearly identifies the uncertainties associated with the understanding of the operation and performance of the facility or activity as well as with input data and models used in the assessments and addresses them adequately.
- Provides an adequate analysis and supporting justification that the proposed facility or activity will minimize doses and risk as low as reasonably achievable (ALARA) and that accidents are prevented, appropriate protective measures are identified and the consequences of accidents will be mitigated appropriately.
- Includes an adequate consideration of the justification and optimization of remedial measures, if applicable.
- Appropriately applies the graded approach to the facility or activity;
- Addresses all relevant factors of the management system to be applied for the siting, construction, commissioning, operation and shutdown, as appropriate (e.g. internal and external audits, verification and validation; use of suitably qualified and experienced personnel; training; control of subcontractors; implementation of conclusions and recommendations).

- Provides an adequate planning of emergency preparedness measures.
- Provides an adequate planning of surveillance and maintenance measures.
- Demonstrates that good engineering practice has been used in developing the design of the facility or activity.
- Defines an appropriate programme for improving safety assessment for the facility or activity.

8.5. When defining the objectives and scope of the review, relevant points to consider include:

- The important safety issues for the site.
- The extent of the safety information provided by the developer / operator, and the resources available to the regulator.
- Whether the review will consider only radiological impacts on humans or will consider other impacts as well, for example impacts related to hazardous waste materials.
- Whether the review will consider impacts to the public, to workers, to non-human species, to the environment.
- What parts of the developer's / operator's documentation should be the focus of the review.
- The use to be made of the review results, for example whether they will be used as part of licensing dialogue with the operator and other stakeholders, for facility licensing, or to establish conditions on 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 regulatory requirements and expectations, 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 cases and safety assessment often depend on the clarity of the regulatory requirements, expectations and approach. Annex B contains an example checklist of aspects that are likely to be of importance to the regulatory review.
- The regulatory review process should be independent, and the team of reviewers should not be unduly influenced during the review process by internal and external consideration that are outside the scope and terms of reference of the review. Any such considerations should be taken into account into the broader safety case context by the decision makers along with the regulatory review findings.
- The regulatory review process should be structured and traceable with clearly defined roles and responsibilities and decision making steps.
- Regulatory authorities should possess or have access to internal expertise and hands-on experience in safety assessment of radioactive waste facilities (see Ref. [4]).
- The regulatory review should be conducted using a level of resource that is adequate and commensurate with the level of complexity of safety assessment and the risks associated with the facility or activity under consideration.
- The regulatory review should involve communication between the operator and the regulatory body.
- The regulatory review process should include a stakeholders consultation framework with well defined consultation steps, rules of procedure and decision making.
- The regulatory review should document the rationale and judgments as to whether or not the arguments presented in the safety case and safety assessment are adequately supported by the underlying science and technology, and whether those arguments are in accordance with regulatory requirements and expectations.

MANAGING THE REVIEW PROCESS

8.7. The management of a safety case/assessment/ review should be treated as a project, to which the standard principles of good project management apply (see Section 3). Depending on the scale of

the review to be conducted, it may be necessary to establish a team of reviewers. Regulatory reviews may be conducted by the regulatory authority with or without support from external organizations, but the results of the review must be fully "owned" by the regulatory authority.

8.8. The regulator should have clear and consistent regulatory requirements, guidance and expectations on safety assessments. A well defined regulatory process including appropriate decision points should exist and independency of the regulator should be ensured. The regulator should have well established and documented regulatory procedures for reviewing safety assessment.

8.9. The following aspects are important for the management of the review process:

- Defining the objectives and scope of the review as well as all national and international regulations, guidance and recommendations that apply to the safety assessment process;
- Developing a review plan that identifies the review tasks and addresses other relevant topics listed here;
- Assembling a review team of competent personnel possessing the necessary expertise and experience to undertake the review;
- Defining the project schedule and allocating resources for the conduct of project tasks, including consideration of review conduct when resources are limited;
- Identifying the responsibilities of review team members and ensuring that they receive adequate training and guidance in the review method;
- Co-ordinating the conduct of the review tasks, and ensuring sufficient communication between review team members;
- Identifying early on during the review any areas of regulatory guidance that are important to regulatory decision making but that may be open to interpretation;
- Co-ordinating dialogue with the operator of the facility, and with other stakeholders during the review process;
- Reviewing and integrating documents generated during the review process;
- Synthesis, documentation and communication of review findings.

8.10. The review procedures applied should allow the regulatory authority to demonstrate that the review of safety assessment work has been performed by competent people, and recorded in a traceable and auditable manner. Project-specific procedures might 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 views or review comments arise on the safety case. Further procedures may be necessary if the review includes tasks such as audits or independent regulatory assessment calculations.

8.11. For each regulatory review, a review plan will be required to provide guidance on 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 safety assessment. This document can therefore serve as a template from which a project-specific plan can be developed.

8.12. To the extent practical, it may be useful for a regulatory review team to 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 assessment under review.
- The review team should have experience of conducting relevant safety assessment and review of safety assessment work.
- The review team should understand the context of the review to be conducted (e.g. knowledge of the facility and of the regulations governing its authorization).
- The review team should have knowledge of waste management practices and programmes in other States.

- The review team should comprise individuals whose advice will be viewed by stakeholders 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 assessment work to be reviewed or in any supporting work, or be directly involved in the management, financing or operation of the facility.

THE USE OF A GRADED APPROACH BY THE REGULATORY BODY

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

- The likelihood and magnitude of exposures of workers and/or members of the public arising from planned processes, incidents or accidents;
- The complexity and novelty of the proposed processes;
- Operator aspects (e.g., the operator's or contractor's track record and relevant experience in designing or operating the facility or activity or other similar facilities or activities; in producing safety assessments; and the complexity of the organization);
- Relevant incidents and events at similar facilities or activities (national and international);
- The scope of the facility or activity being assessed (e.g. a stage of a larger project, a single large project, a modification, etc.);
- Technical or safety concerns of other competent authorities;

8.14. To assist with the implementation of such graded approach, the regulatory body should consider establishing a set of deterministic screening criteria to categorize facilities or practices according to their safety significance based on the criteria listed in para. 8.13.

CONDUCTING THE REVIEW AND REPORTING REVIEW FINDINGS

8.15. A regulatory review will normally have four phases:

1. An inception phase, prior to receipt of any documents from the developer / operator, in which initial planning for the review will be conducted. This will normally involve meetings with the developer / operator to understand the extent of the information that will be provided.
2. An initial review phase, during which the regulator will make an initial evaluation of the submitted documents to assess the completeness of the assessment and the availability of supporting documents, and to make a preliminary identification of those issues that are most important to safety (e.g. in order to 'risk-inform' the review). Evaluating the completeness of the assessment includes checking that the information submitted addresses all of the regulator's expectations for safety assessment. This checking will be documented and a series of detailed review comments may be prepared requiring additional information. The regulator will review and assess any additional information provided by the developer/operator in response to the review comments.
3. A main technical review phase, comprising the bulk of the effort. This will include the development of detailed review comments, and may include evaluation of additional information provided by the developer / operator in response to comments.
4. A completion phase, in which the main conclusions of the review are identified and used to inform the decision making process.

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

8.17. The completion phase of the review will include the development of a final review report. There is no single correct way in which such a report should be organized, and each such report will

inevitably need to be tailored to the review conducted. General guidance on what a regulator should consider including in such a report is provided below:

- Background to the review, including summary information on the site, the regulatory framework in which the review was conducted, purpose of the review, approach to the review and process of review followed.
- Key review findings concerning high-level issues such as the safety approach, the assessment context, approach and results, the treatment of uncertainty (scenarios, models, parameters), risk management and optimization, radiological capacity, appropriate limits and conditions, and the forward programme.
- Key review findings concerning the main technical areas of review, such as the characterization and modelling of waste inventories and waste streams, engineering, chemistry, geology, hydrogeology, climate, biosphere..
- Key review findings concerning compliance with the main regulatory criteria and guidance.
- Conclusions of the review with regard to issues to be considered in licensing or authorization, such as further information to be provided by the developer / operator, revised safety assessment work, monitoring and other controls on the site or the waste, inventory restrictions, risk management, and waste acceptance criteria.
- List of unresolved issues and uncertainties.
- List of references, including reference to documents considered in the review, and underlying review reports that support the final review report.
- Appropriate information to demonstrate the credibility of the review team.

An example template for the review report is provided in Annex C.

8.18. When documenting review comments and assessments it is good practice to ensure that:

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

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, Safety Standards Series No. SF-1, IAEA, Vienna (2006).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, Safety Standards Series No. WS-R-5, IAEA, Vienna (2008)

[3] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 15, IAEA, Vienna (1996).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Requirements, Safety Standards Series No. GS-R-1, IAEA, Vienna (2000).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Operation, IAEA Requirements No. NS-R-2. IAEA, Vienna (2000).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, (Draft Safety Requirements - DS354 in preparation).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Nuclear Facilities, IAEA Safety Standards Series No. WS-R-5, IAEA, Vienna (2006).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Sites from Regulatory Control upon the Termination of Practices, IAEA Safety Standards Series No. WS-G-5.1, Vienna (2006).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series, IAEA, GSR Part 4, Vienna (2009).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Case and Safety Assessment for Radioactive Waste Disposal, IAEA Safety Standards Series No. (Draft Safety Guide DS355 in preparation)

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment and Verification for Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-1.2, Vienna (2001).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, IAEA Safety Standards Series No. WS-G-5.2, Vienna (2008).

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

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2005 Edition, IAEA Safety Standards Series No. TS-R-1, IAEA, Vienna (2005).

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, INFCIRC/546, IAEA, Vienna (1997).

[17] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the ICRP, ICRP Publication 60, Pergamon Press, Oxford and New York (1991).

[18] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection Policy for the Predisposal of Radioactive Waste, ICRP Publication 77, Pergamon Press, Oxford and New York (1997).

[19] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Protection Recommendations as Applied to the Predisposal of Long-lived Solid Radioactive Waste, ICRP Publication 81, Pergamon Press, Oxford and New York (2000).
[20] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Assessing Dose of the Representative Person for the Purpose of Radiation Protection of the Public and the Optimisation of Radiological Protection, ICRP Publication 101, ISBN 0702029270 / 9780702029271, Pergamon Press, Oxford and New York (2006).
[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, Safety Guide, Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006).
[22] INTERNATIONAL ATOMIC ENERGY AGENCY, The Agency's Safeguards System, INFCIRC/66/Rev.2, IAEA, Vienna (1968).
[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Model Protocol Additional to the Agreement(s) Between State(s) and the International Atomic Energy Agency for the Application of Safeguards, INFCIRC/540, IAEA, Vienna (1997).
[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment Methodologies for Near Surface Predisposal Facilities (ISAM), Vol. I – Review and enhancement of safety assessment approaches and tools; Vol. II – Tests Cases, IAEA, Vienna (2004).
[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Staffing of the Regulatory Body for Nuclear Facilities, IAEA Safety Standard Series No. GS-G-1.1, IAEA, Vienna (2002).
[26] ENVIRONMENT AGENCY AND SCOTTISH ENVIRONMENT PROTECTION AGENCY, Guidance for the Environment Agencies' Assessment of Best Practicable Environmental Option Studies at Nuclear Sites, UK (2004).

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Annex A

EXAMPLES OF HAZARDS AND INITIATING EVENTS

In making use of this list it should be recognized that the initiating event in the table would not necessarily be applicable to all facilities and all sites. The list is provided as an aide-memoire and is intended to be used as such.

1. Meteorology and climatology of the site and region both average and extreme conditions (e.g. Precipitation; Wind; Temperature; etc.)
2. Hydrology and hydrogeology of the site and region both average and extreme conditions (e.g. Flooding; Surface runoff; Groundwater conditions; Wave action; etc.)
3. Geology of the site and region both average and extreme conditions (e.g. Lithology and stratigraphy; Seismicity; Historical mining and quarrying; etc.)
4. Geomorphology and topography of the site (e.g. Stability of natural materials; Collapse due to tunnelling or mining; Surface erosion; dust or sand storms; etc.)
5. Terrestrial and aquatic flora and fauna of the site (e.g. blockage of inlets; natural fires; etc.)
6. Explosion
7. Fire
8. Aircraft crash
9. Interactions with surrounding installations (e.g. Missiles due to structural/mechanical failure; Ground vibration; etc.)
10. Release of any corrosive, toxic and/or radioactive substance
11. Geographic and demographic data (e.g. Population density; Industrial installations; Transport infrastructure; etc.)
12. Power supply and potential loss of power
13. Criticality
14. Release of activity from containment
15. Loss of shielding
16. Physical hazards (e.g. dropped loads, etc.)
17. Human and organizational factors
18. Effects of ageing (e.g. corrosion, etc.)

Annex B

TOPICAL ISSUES FOR SAFETY CASE REVIEW FOR RADIOACTIVE WASTE PREDISPOSAL FACILITIES OR ACTIVITIES

I. Legal and Regulatory Framework:

- The Regulatory Body should be sure that there is a clear and unequivocal allocation of responsibility for safety during the entire process of radioactive waste predisposal management and if the operator, in the documentation presented, assumes the prime responsibility for safety within the whole process.
- In those cases where the predisposal management of radioactive waste might involve the transfer of radioactive waste from one operator to another, the responsibility for safety should be guaranteed throughout the whole process.
- The Regulatory Body should ensure observation of the relevant article of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management in the event of transfer of radioactive waste beyond national boundaries.
- The Regulatory Body should be sure the predisposal strategy proposed by the operator is aligned with the national policy and strategy for radioactive waste management and the preferred options for radioactive waste management defined in this policy.
- The Regulatory Body should be sure that all safety requirements for the development of radioactive waste management facilities or activities and all procedures for meeting the requirements for the various stages of the licensing process are in place.
- The Regulatory Body should review and assess the safety case and the environmental impacts of predisposal facilities or activities, as prepared by the operator, both prior to authorization and periodically during operation.

Regulatory process

- The Regulatory Body should be sure that the operator takes into consideration adequately the relationship between the operator himself, the Regulatory Bodies involved in the licensing process of the installation and other stakeholders in the process of development of safety requirements and authorizations for predisposal management of radioactive waste.
- The Regulatory Body should be sure the operator is acquainted with the regulatory process, especially as related to the specific characteristics of the operators own facility.
- The Regulatory Body should be sure the operator is acquainted with the specific requirements and criteria developed by the regulatory body for:
  - handling and transportation of waste;
  - acceptance of waste packages for disposal; and
  - any other issues related to the operators own facility.

Preparation of the safety case and safety assessments

- The Regulatory Body has to be sure that, for each step of the licensing process of the facility or activity, a safety case and supporting safety assessments are prepared and updated.
- The Regulatory Body should provide the operator with guidance on the definition of the end-points for analysis and other relevant output information necessary to support the authorization request and to serve as the basis for the decision making and regulatory approval and control processes.

- The Regulatory Body has to be sure the operator checks and considers all provisions that have been made for the development of safety cases in previous phases of the facility as basis for the regulatory decision-making and approval process.
- The Regulatory Body has to be sure that, as the project proceeds, these safety cases are progressively developed and refined.
- The Regulatory Body has to be sure the operator holds all the responsibility for the development of the safety case and safety assessments that will be submitted for analysis by the Regulatory Body.

Scope of the Safety Case and Safety Assessments

- The Regulatory Body has to be sure that the operator, within the development of the safety case, understands and represents towards the Regulatory Body all the safety aspects of the site, the facility design and the managerial controls to comply with the regulatory criteria.
- The Regulatory Body has to be sure that, within the development of the safety case, the operator demonstrates that the safety requirements will be met.
- The Regulatory Body has to be sure the operator demonstrates how the results of the safety assessments are used to bring appropriate safety related improvements to predisposal waste management facilities or activities.
- The Regulatory Body has to be sure the operator indicates how the safety case addresses and justifies the facility design, operational management arrangements and system processes which are used to ensure that the safety objectives and criteria set by the Regulatory Body are met.
- The Regulatory Body has to be sure the operator demonstrates, within the safety case presented, what considerations are included for reducing risks to workers, members of the public and the environment under both normal operation and anticipated incidents and accidents.
- The Regulatory Body has to be sure that the operator demonstrates that the safety case developed is sufficiently comprehensive and detailed as to address the complexity of the operations and the magnitude of the risks associated with the predisposal management facility or activity.

The Documentation of the Safety Case and Safety Assessment

- The Regulatory Body has to be sure that the safety case and the supporting safety assessments developed are adequately documented (at a level of detail and quality) as to demonstrate safety and support the decision-making process as well as to allow for independent review, justification, traceability and clarity.
- The Regulatory Body has to be sure that the documentation submitted by the operator for analysis in each step of the licensing process is adequate in scope and structure to clearly set out the safety case and the supporting of the safety assessments in order to adequately support the regulatory approval process, also taking into account considerations such as justification, traceability and clarity.
- The Regulatory Body has to be sure the documentation submitted for analysis by the operator addresses adequately justification issues, i.e. explains why choices were made and the arguments in favor of and against the decision, especially those decisions that relate to the main safety arguments.
- The Regulatory Body has to be sure the documentation submitted for analysis by the operator includes traceability considerations, i.e. that the documentation allows for an independent reviewer to follow within the documentation what has been done.
- The Regulatory Body has to be sure the documentation submitted for analysis by the operator allows for adequate clarity i.e. allows for adequate understanding of the safety arguments and presents the work that has been done.

Step-by-step Development and Evaluation

- The Regulatory Body has to be sure the operator describes the different phases of the development of the predisposal facility and presents the different analyses carried out in each phase to support the overall system performance and safety.
- The Regulatory Body has to be sure the operator relates the step-by-step approach used in the design of the facility with the phases imposed by the regulatory process.
- The operator has to demonstrate the impact of the step-by-step approach in the confidence building process of the safety analysis, providing support for safety analysis outcomes, such as:
  - collection, analysis and interpretation of relevant scientific and technical data;
  - development of engineering designs and operational plans;
  - development of the safety case itself for operational safety.

II. Basic Elements Associated with Predisposal Management of Radioactive Waste

- The Regulatory Body should be sure the operator carries out safety assessments and develops the necessary supporting safety cases for siting, design, construction, commissioning, operation, shutdown and decommissioning of facilities. The safety cases shall be carried out in compliance with legal and regulatory requirements established within the regulatory framework.
- The Regulatory Body should be sure the operator demonstrates the commitment of senior management to safety and the establishment and maintenance of a safety culture within the installation.
- The Regulatory Body should be sure the operator demonstrates the implementation of an integrated approach to safety and security in the installation for predisposal management of radioactive waste.
- The Regulatory Body should be sure the operator takes into account the interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option..
- The Regulatory Body should be sure the operator applies an effective management system to all steps and elements of the installation for predisposal management of radioactive waste. Features that are important for the safe operation of the facility or activity and that are considered in the management system should be clearly identified in the safety assessment and supporting safety cases.
- The Regulatory Body has to be sure the operator adequately contemplates in the safety cases and supporting safety assessments basic elements of sound predisposal management of radioactive waste, such as:
  - Identification and control of all radioactive waste streams;
  - The use of measures to keep secondary waste generation to the minimum practible;
  - Reuse and recycling of materials, provided that protection objectives are met;
  - The authorized discharge of effluent and clearance of materials from regulatory control, according to the regulations in place.

III. Technical Requirements for Predisposal Management of Radioactive Waste

Waste characterization and classification

- The Regulatory Body should be sure that radioactive waste is adequately characterized and classified, in accordance with the requirements established and approved by the regulatory body, at the various steps of the predisposal management process within the installation.

Pretreatment of radioactive waste

- The Regulatory Body should be sure the pretreatment of waste in the facilities or activities under operator responsibility considers appropriately the characteristics and properties of the waste and the requirements imposed by subsequent steps in the predisposal management program of radioactive waste (treatment, conditioning, transport, storage and disposal).
- The Regulatory Body should be sure that, within the facilities or activities under the operator's responsibility, the purposes of pretreatment, i.e. (1) to reduce the amount of radioactive waste that would be subject to additional processing and disposal, and (2) to adjust the characteristics of the remaining radioactive waste that might require treatment, conditioning and disposal to make it more amenable to additional processing and disposal are adequately achieved.
- When carrying out pretreatment operations such as waste collection, segregation, chemical adjustment and decontamination, the Regulatory Body should be sure that the appropriate characterization of the waste serves to enable the appropriate allocation of treatment and conditioning processes.

Treatment and Conditioning of Radioactive Waste

- The Regulatory Body should be sure for the facilities or activities under the operator´s responsibility that, in making decisions with respect to the treatment of radioactive waste, the interdependences between the basic steps in the predisposal management of radioactive are adequately taken into account.
- The Regulatory Body should be sure for the facilities or activities under the operator´s responsibility that an appropriate conditioning for radioactive waste is being chosen in order to ensure a waste form compatible with the selected storage, disposal or anticipated disposal option.
- The Regulatory Body should be sure that the conditioning process selected produces a waste package that complies with the established waste acceptance criteria for transport and disposal
- The Regulatory Body should be sure that the packaged solid waste form is compatible with the selected or anticipated disposal option and which also meets the requirements for safe handling, transport and storage.
- The Regulatory Body should be sure that the selected materials and processes chosen for the conditioning process are compatible with the radioactive waste form.
- The Regulatory Body should be sure that processing of waste and selection of containers are carried out so as to ensure operational safety, sufficient stability between the waste, waste form and the container, and the compatibility of waste packages with the storage and disposal environment.

Storage of Radioactive Waste

- The Regulatory Body has to be sure that the safety case developed for the storage facility takes into consideration normal operation aspects and appropriate scenarios for the potential accidents and incidents in the installation.
- The period of storage has to be taken into account in the safety case and the design of the facility has to consider the use of passive safety features that could handle the natural degradation of any safety barriers considered in the containment of the waste.
- The Regulatory Body has to be sure that the safety case also considers any natural site characteristics (geology, hydrology, climate) that could impact the performance of the safety features of the installation, making sure that no radiological impact beyond the established limits will occur.
- The installation has to incorporate design characteristics in order to allow for regular inspection of the waste packaging conditions, development of maintenance actions, retrievability, reconditioning and transport, if necessary, and adequate radiological surveillance.

- For nuclear materials, special attention has to be given to avoid (1) the risk of criticality, even in the case of natural phenomena, and (2) the risk of heating beyond the design safety limits.
- The Regulatory Body has to be sure that the operator understands the role to be accomplished by the storage installation within the waste management process, proving for features that allow for:
  - proper containment of the waste during the storage period;
  - the monitoring of the waste as required;
  - the facilitation of the next steps to be accomplished within the waste management process: decay until clearance, authorized discharge or authorized disposal.
- The Regulatory Body should ensure that the design of the facility has taken into account the type of radioactive waste to be stored, its characteristics and associated hazards, its inventory and anticipated storage period and has provided the appropriate technical and engineered features.
- The Regulatory Body has to be sure that the design of the installation has taken into consideration the intention of the storage, making possible the retrievability of waste for authorized discharge, authorized use or clearance, for processing or disposal at a later time.
- The Regulatory Body has to be sure that provisions have been made by the operator for regular monitoring, inspection and maintenance of the waste packaging and the storage facility to ensure continued integrity.
- The Regulatory Body has to be sure that procedures are in place to deal with adequacy of storage capacity (taking account of the predicted waste arisings including from any accidental situations), the expected lifetime of the storage facility and the availability of disposal options.
- The Regulatory Body has to be sure that in those cases when the storage facility has been proposed to store radioactive waste for an extended period of time, provisions (technical and managerial) have been made in order to ensure the protection of present and future generations.
- The Regulatory Body has to be sure that provisions have been made in the design of the facility to adequately deal with liquid waste and gases arising from the waste;

Radioactive Waste Acceptance Criteria

- The Regulatory Body has to be sure that the actual characteristics of the waste accepted for storage in the facility (packed or unpacked) meet those characteristics taken into account in the development of the safety case.
- The Regulatory Body has to be sure that the operator is acquainted with the classification system and acceptance criteria for disposal of radioactive waste established by the Regulatory Body and applies it to the installation.
- The Regulatory Body has to be sure the operator knows the waste acceptance criteria in terms of radiological, mechanical, physical, chemical and biological properties or any other applicable characteristics, either for waste packages or unpackaged waste.
- The Regulatory Body has to be sure that the operator knows the role of the waste acceptance criteria to ensure the safe handling and storage of waste packages and unpackaged waste, in normal and abnormal conditions, and for disposal.
- The Regulatory Body has to be sure that the operator is acquainted with the process of approval of the waste acceptance criteria by the Regulatory Body. The Regulatory Body has to be sure the operator knows and applies the provision to be made for identifying, assessing and dealing with waste or waste packages that do not meet process specifications or disposal criteria.
- The Regulatory Body has to be sure the operator has adequate procedures and instructions in place to determine the need for waste processing after storage to meet the acceptance criteria and is properly trained to operate these procedures.
- The Regulatory Body has to ensure that the operator has adequate provisions in place for identifying, assessing and dealing with waste acceptance criteria (radiological, mechanical, physical, chemical and biological) established by the Regulatory Body.

- The Regulatory Body has to be sure that the operator has adequate procedures and instructions in place to certify that the final product arising from waste processing meets the acceptance criteria (radiological, mechanical, physical, chemical and biological) established by the Regulatory Body.
- The Regulatory Body has to implement procedures (onsite surveillance, package testing) in order to ensure that the waste or the waste packages meet the required acceptance criteria for storage.
- The Regulatory Body has to be sure the operator is acquainted with IAEA Transport Regulations and other international or national standards applicable, and meets their provisions adequately, where applicable.

Facility Siting and Design

- The Regulatory Body has to be sure the operator demonstrates, through the analyses carried during the siting and design phases, that safety standards will be met both during the operational and decommissioning phases. Emphasis should be made on the use of defense-in-depth concepts in the design of the installation.
- The Regulatory Body has to be sure the operator clearly identifies those features that have been incorporated to the design of the predisposal waste management facility to deal with (and are largely dependent upon) the properties, total inventory and hazard potential of the radioactive waste and the requirements of the Regulatory Body.
- The Regulatory Body has to be sure that the need for operational maintenance, testing, examination and inspection from the concept design stage onwards is adequate to meet the safety requirements..
- The Regulatory Body has to be sure the operator understands the overall process for siting of storage facilities for radioactive waste and the issues it should consider, such as:
  (1) the investigation of the proposed region to evaluate its present and foreseeable future characteristics, the distribution of the population and the present and future uses of land and water;
  (2) the determination of ambient radioactivity in the region as a baseline for future investigations;
  (3) estimates of expected and potential releases of radioactive material over direct and indirect pathways;
  (4) radiological exposure of the population in operational states of the facility as well as under accident conditions;
  (5) evaluation of potential effects from natural and human induced external events (e.g. seismic events, meteorological events, geotechnical impacts, aircrafts crashes, explosions); and
  (6) the likely period of storage, the use of passive safety features, the potential for degradation during that period and consideration of natural site characteristics that could impact performance as geology, hydrology and climate.

Facility Construction and Commissioning

- The Regulatory Body has to be sure the operator has in force the technical and managerial systems necessary to ensure that the predisposal waste management facility is constructed according to the design approved by the Regulatory Body and described in the approved safety case and safety assessments. The operator has also to demonstrate that the construction of the installation will be carried out in such a way as to provide reasonable assurance of safety during the operational period and decommissioning.
- The Regulatory Body has to be sure the operator demonstrates that the responsibility of the operator for constructing the facility and performing any verification or test that needs to be performed (welds, foundation, etc) is clearly allocated. The operator has also to demonstrate that it is responsible for and is acquainted with the evidences required by the Regulatory Body to prove it complies with its responsibility during the construction.

- The Regulatory Body has to be sure the operator knows and demonstrates towards the Regulatory Body how the process of commissioning has been organized in the predisposal waste management facilities under his responsibility. The operator is supposed to describe the stages - i.e., as applicable, construction completion and inspection; equipment testing; performance demonstration; non-active (without radioactive waste) commissioning and active (with radioactive waste) commissioning - carried out within the frame of the commissioning process for facilities under his responsibility.
- The Regulatory Body has to be sure the operator has appropriately documented in the final commissioning report the predisposal waste management facility under his responsibility:
- This documentation should include:
  - the as-built status of the facility which, in addition to providing information to facilitate operation, is important when considering possible future modifications, shutdown and decommissioning of the facility;
  - all testing carried out and evidence of its successful completion and of any modifications made to the facility or procedures during commissioning;
  - the evidences providing assurance that all the conditions of authorization have been satisfied.
- The operator should also represent towards the Regulatory Body the arrangements that have been made for this report to be maintained by the operator as part of the documentation needed for the operation and the development of the decommissioning plan of the installation and that the Regulatory Body is regularly updated in the process.
- The Regulatory Body has to be sure the documentation presented by the operator contemplates clear information on the codes and standards that are used to choose structural materials, fabrication and construction techniques, and testing procedures.
- The operator should also clearly present the considerations given to the potential effects that the waste, any associated material and the environmental conditions may have on the capabilities of any safety related features of the facility to perform their intended functions (prevention of high temperature corrosion of material and mitigation of adverseconsequences of irradiation in high radiation fields).

Facility Operation

- The Regulatory Body has to be sure that the operational procedures proposed for the predisposal waste management facilities or activities comply with the requirements in force and the conditions approved by the Regulatory Body, both during the operational period and decommissioning phase. The operator has also to provide for regular updating of these operational procedures in the light of operational experience.
- The Regulatory Body has to check that the operator:
  - ensures that all operations and activities important to safety are subjected to documented limits, conditions and controls and are carried out by trained personnel;
  - describes how and where the operational limits, conditions and controls for the operation of predisposal waste management facilities or activities are documented;
  - ensures that positions with responsibility for safety are properly qualified and authorized;
  - describes how documented operating procedures and emergency plans are developed (by himself) and approved by the Regulatory Body;
  - ensures that a program of periodic maintenance, testing and inspection of systems that are essential to safe operation is included in the documented procedures.
- The Regulatory Body has to be sure the operator puts in place a technical/managerial system to ensure active control over safety by the operator for as long as the facility or activity remains under regulatory control.
- The Regulatory Body has to be sure the operator takes into consideration in the safety features proposed for the facility and the safety assessment carried out, the prevention of criticality and adequate heat removal in the management of HLW.

Facility Shutdown and Decommissioning

- The operator has to be sure the documentation presented by the operator for licensing already contemplates the life-cycle of the facility, including all phases, from design to shut down and decommissioning. The Regulatory Body has to be sure the operator is aware of the need to obtain approval for such steps and to periodically update the shutdown and decommissioning plans.
- The Regulatory Body has to be sure the operator is aware of the need to take into consideration in the planning and design of the predisposal facility the decommissioning phase, addressing specifically:
  - the procedure for the development of the decommissioning plan;
  - the demonstration that the decommissioning plan can be accomplished safely;
  - how *the need for decommissioning was taken into account during the planning and construction phases of the facility.*
- The Regulatory Body has to be sure that the shutdown and decommissioning of the facility occurs in accordance with the conditions set by the Regulatory Body.
- The operator should demonstrate to be aware of his responsibility within this process and to have adequate procedures in place for clear allocation of responsibility in the case of transfer of ownership of the installation.
- The Regulatory Body has to be sure the operator reports to the Regulatory Body of any updating of the decommissioning plan and that this updating should particularly contemplate changes in the facility or regulatory requirements, advances in technology and needs of the decommissioning operation.

Nuclear Safeguards

- The Regulatory Body has to be sure that the operator takes into consideration nuclear safeguards requirements, when applicable, in the design and operation of the waste predisposal management facility or activity.
- The operator has to demonstrate how it is ensured that nuclear safeguards requirements are implemented in such a way as not to compromise the safety of the facility or activity.
- The Regulatory Body has to be sure that the operator, when applicable, puts in place in the facility an adequate nuclear safeguard system, contemplating, among other issues:
  - provisions for accountability for nuclear material through the implementation of nuclear safeguards requirements, in order to allow for the promptly detection of its diversion to unauthorized or unknown purposes in the short and medium term;
  - how active surveillance and controls on which nuclear safeguards depends are organized in the facilities or activities;
  - how safeguards surveillance for waste containing fissile materials is implemented in the facilities under the operator´s responsibility for ensuring continuity of knowledge of the fissile materials and the absence of any undeclared practices at the site related to such material.

Existing Facilities or Activities

- The Regulatory Body has to be sure the operator performs all the regulatory steps to ensure adequate safety levels for existing facilities or activities and the compliance with the safety requirements established by the Regulatory Body.
- The Regulatory Body has to check that the facilities or activities under the operator's responsibility are within a regulatory process, which should include the review of an existing safety case or the elaboration of a new one, as well as all the supporting safety assessments. This process should be started by the Regulatory Body, in order for the existing installation to comply with all safety requirements established for predisposal waste management facilities or activities.
- The operator has to demonstrate the additional operational restrictions, modification or decisions that have been identified or implemented based on the regulatory process in force.

- The regulatory body has to be sure the operator carries out, for the facilities or activities under his responsibility, regular safety reviews and safety upgrades in accordance with the requirements specified by the Regulatory Body.

Annex C

TEMPLATE OF REGULATORY REVIEW REPORT

1. INTRODUCTION

Brief description of the purpose and background of review, titles and developers of reviewed documents, information on organizations involved into review, etc.

2. SCOPE AND OBJECTIVES OF REVIEW

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

3. APPLICABLE REGULATORY REQUIREMENTS

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

4. REVIEW METHODOLOGY AND PROCESS

Description of review procedure including the review plan and possible steps (primary review, main review, review of improved document), interactions with developer, categorization of comments, requirements on comment format and indication, interactions within review team, etc. Any guidance documents used by the review should be documented.

5. 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 applicant response resolved those issues):

6. KEY COMMENTS

These are the general comments summarizing main deficiencies of reviewed document.

6.1. Specific comments

These are more detailed comments on specific chapters of the reviewed documents or areas of investigation.

6.2. Unresolved comments

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

7. CONCLUSIONS AND RECOMMENDATIONS

The conclusions of the review should be stated. In addition, recommendations for authorization conditions should be listed.

Annex D

SADRWMS

Framework for the Overall Process

1. INTRODUCTION

In the following, a framework for the overall processes of predisposal waste management is developed. This will serve as basis to develop guidelines for the application of existing safety assessment methodologies and the identification of what is needed in the way of safety justification. The emphasis lies on waste orientated activities, not considering aspects such as political considerations, engineering aspects, etc.

In support of this activity, flowcharts have been developed covering the main steps in pre-disposal waste management. A description of the individual elements and their relationships within the overall scheme is provided in Section 2.

In Section 3, for each pre-disposal activity shown in the flowcharts the following aspects are addressed:

- Identification of necessary safety assessments;
- Compilation of decisions which have to be made based on these safety assessments and for which, consequently, the safety assessments have to provide a basis;
- General aspects for the assessment context of these safety assessments (to be further detailed as part of subsequent activities within SADRWMS).

2. FRAMEWORK

Figures 1 to 6 provide an overview of pre-disposal waste management activities. Figure 1 describes the general process. Figures 2 to 6 provide details for the individual process steps defined in Figure 1.

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

In the following, a description of the activities indicated in the flowcharts is provided. The purpose and scope of the required safety assessments is described in Section 3.

Fig. 1: Overall Process

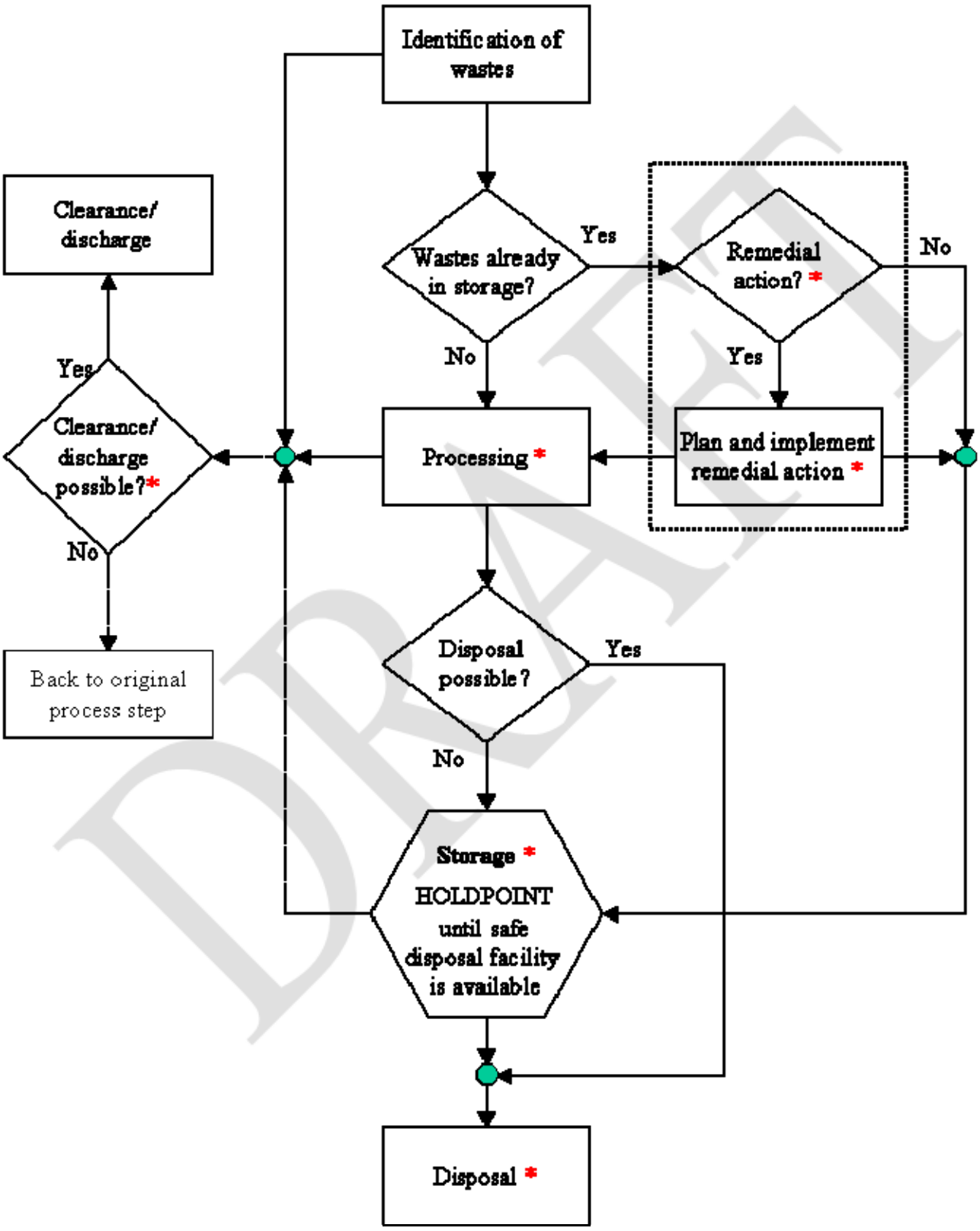


Fig. 2: Remedial Action?

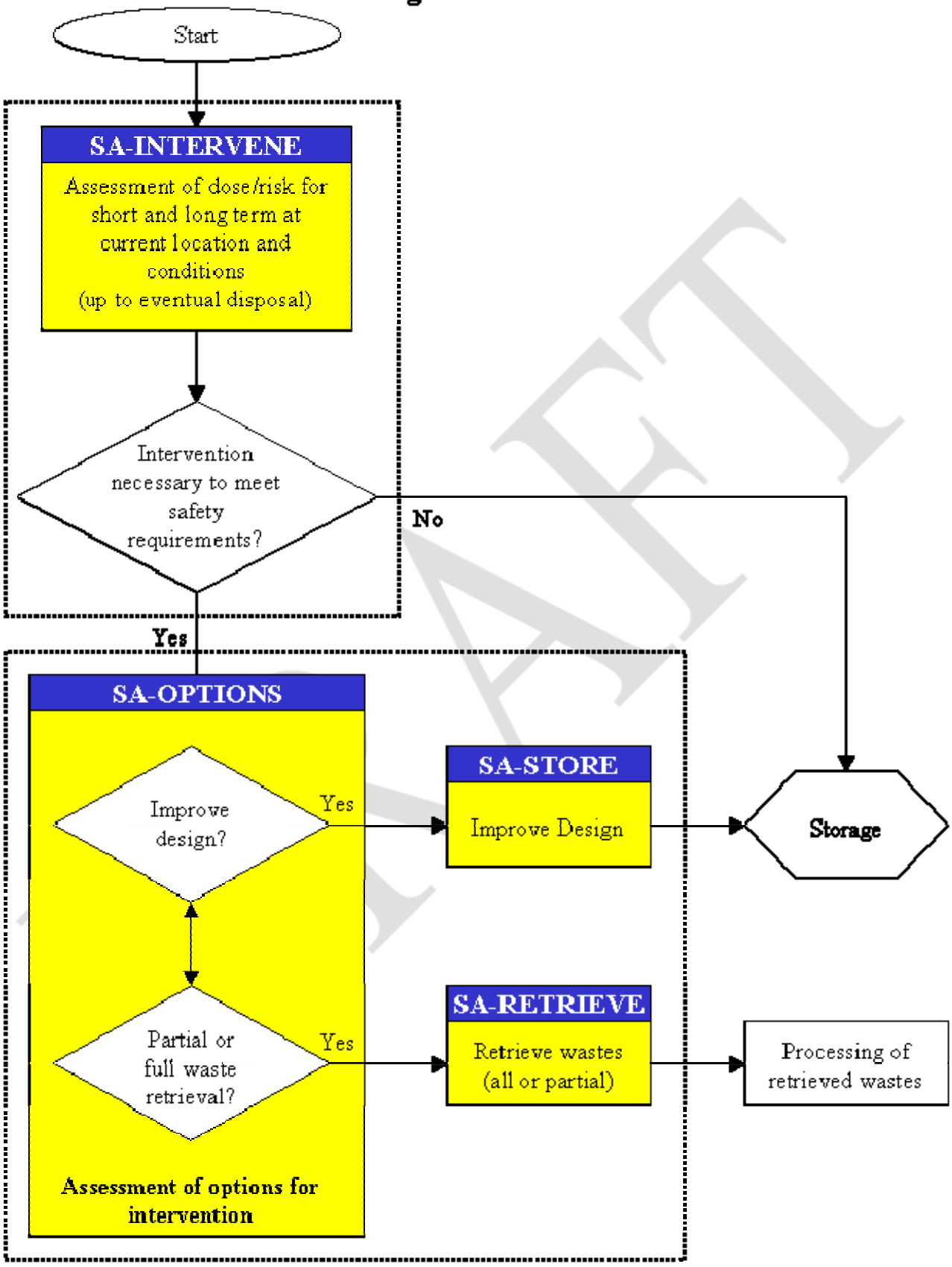


Fig. 3: Clearance/Discharge Possible?

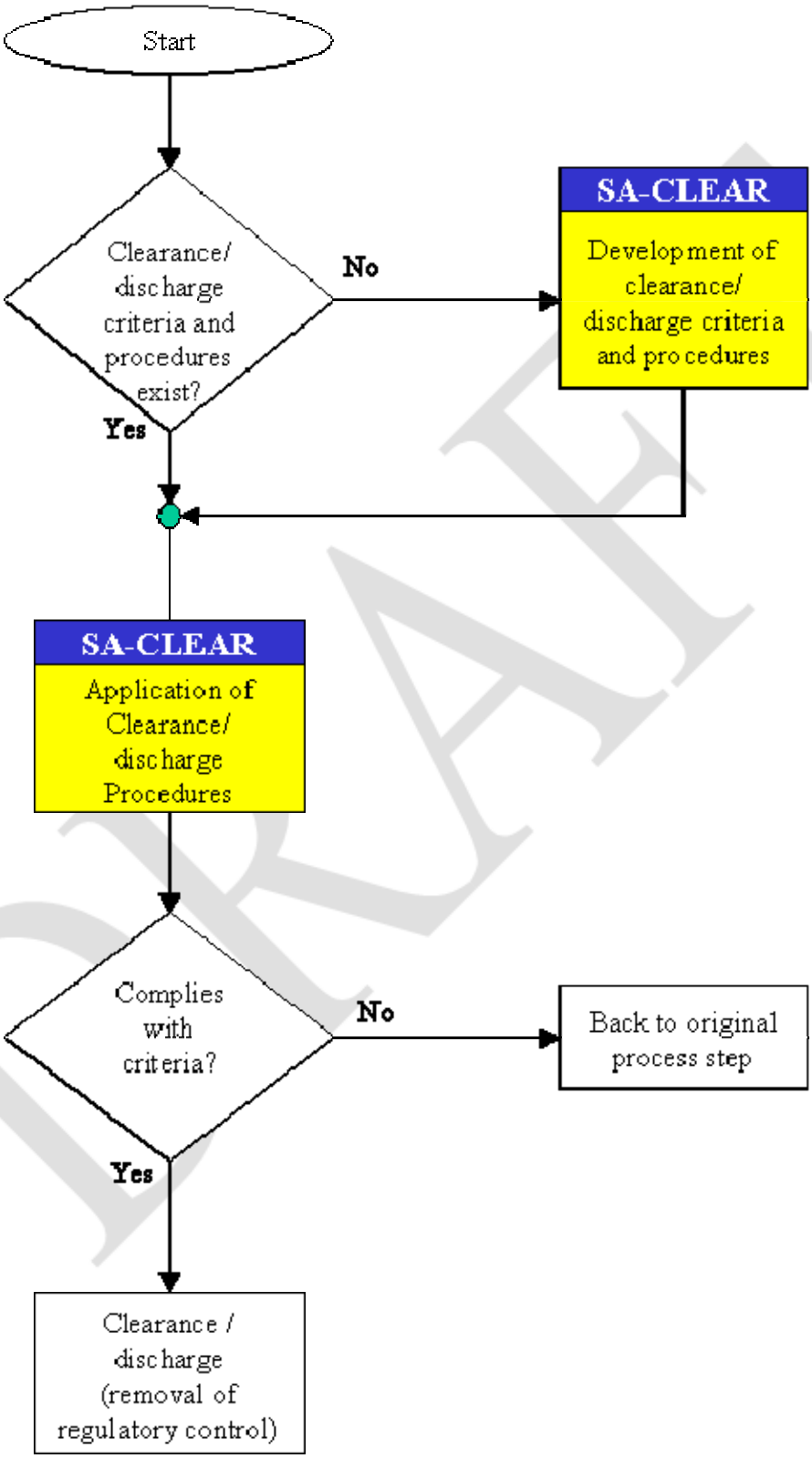


Fig. 4: Processing

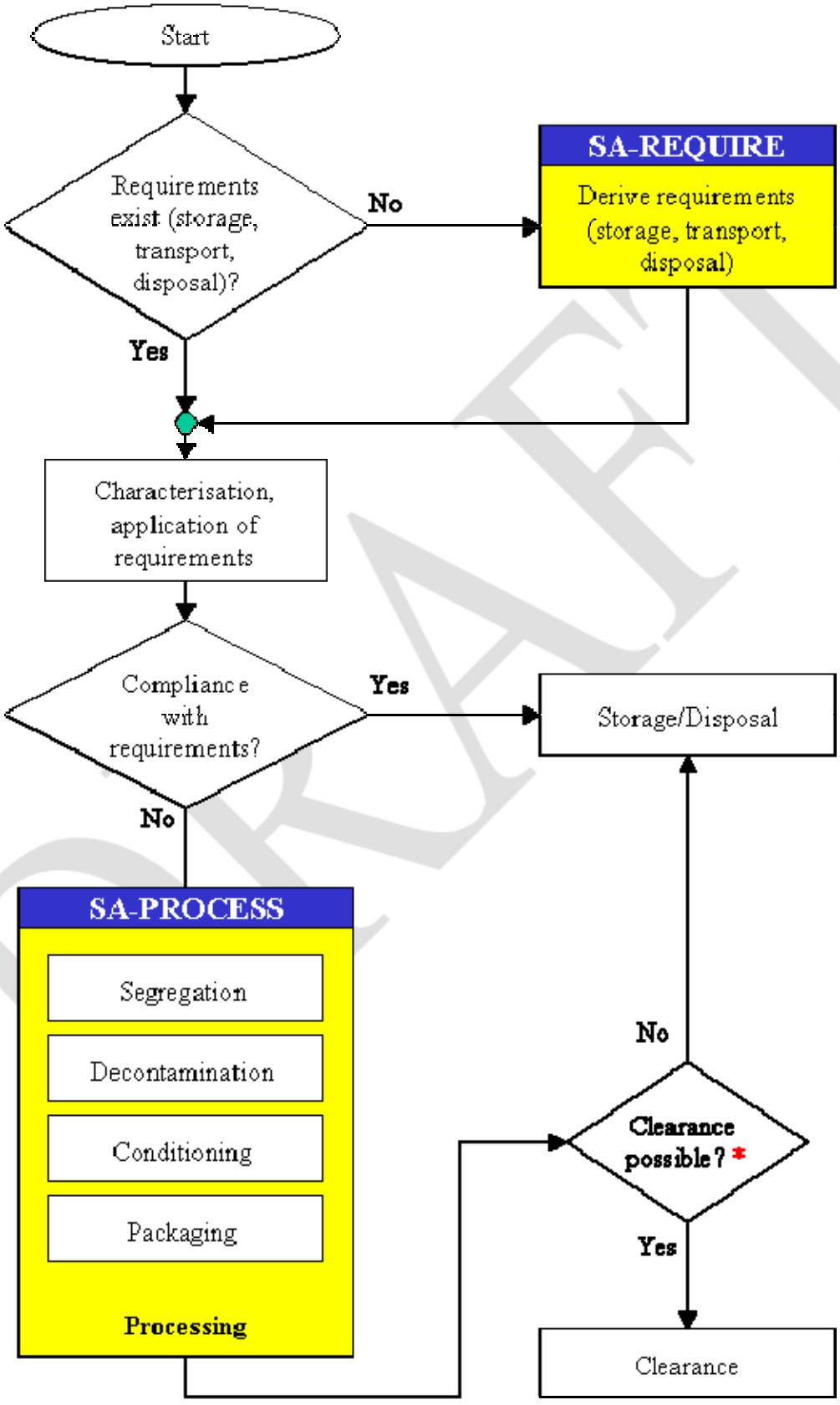


Fig. 5: Storage

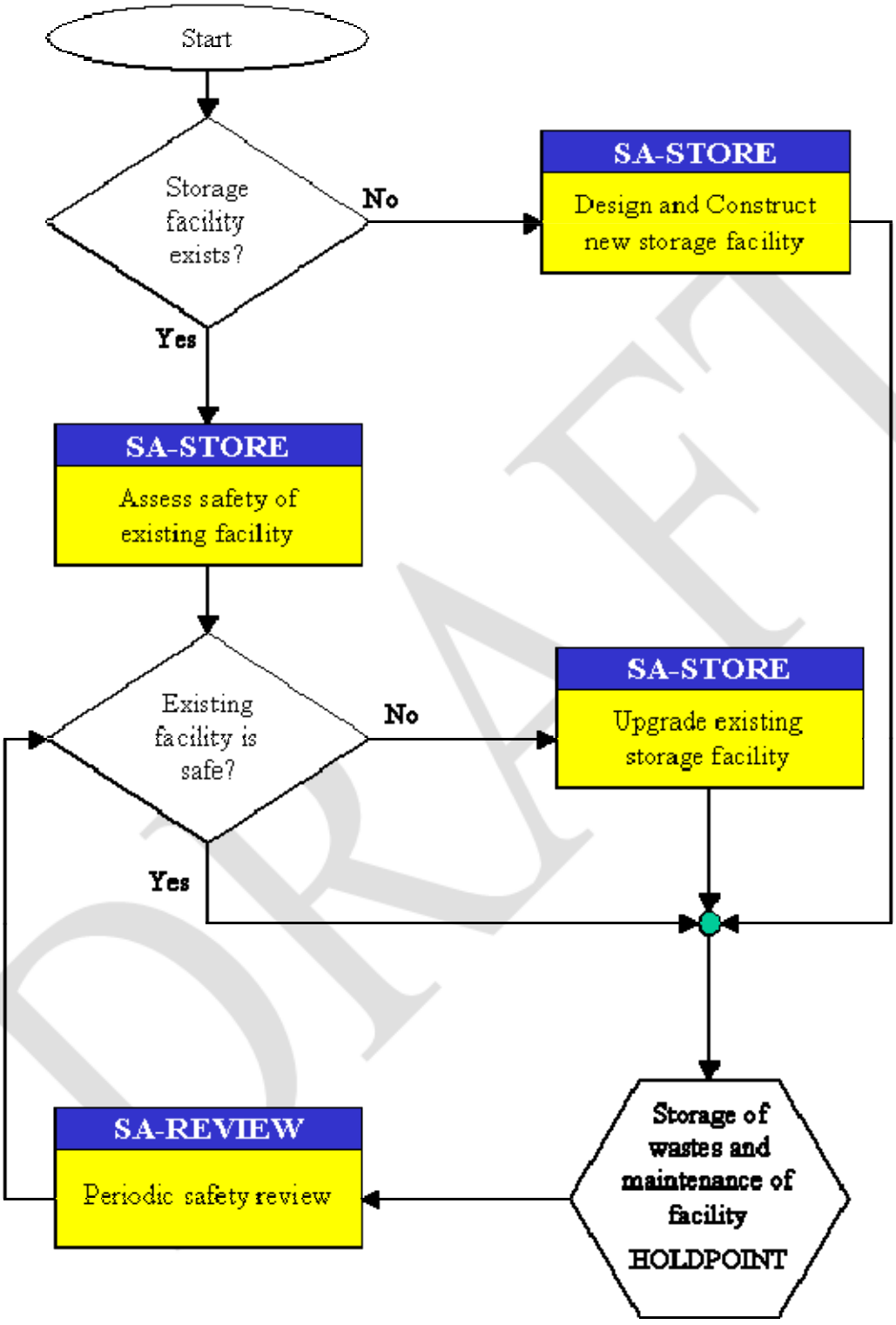
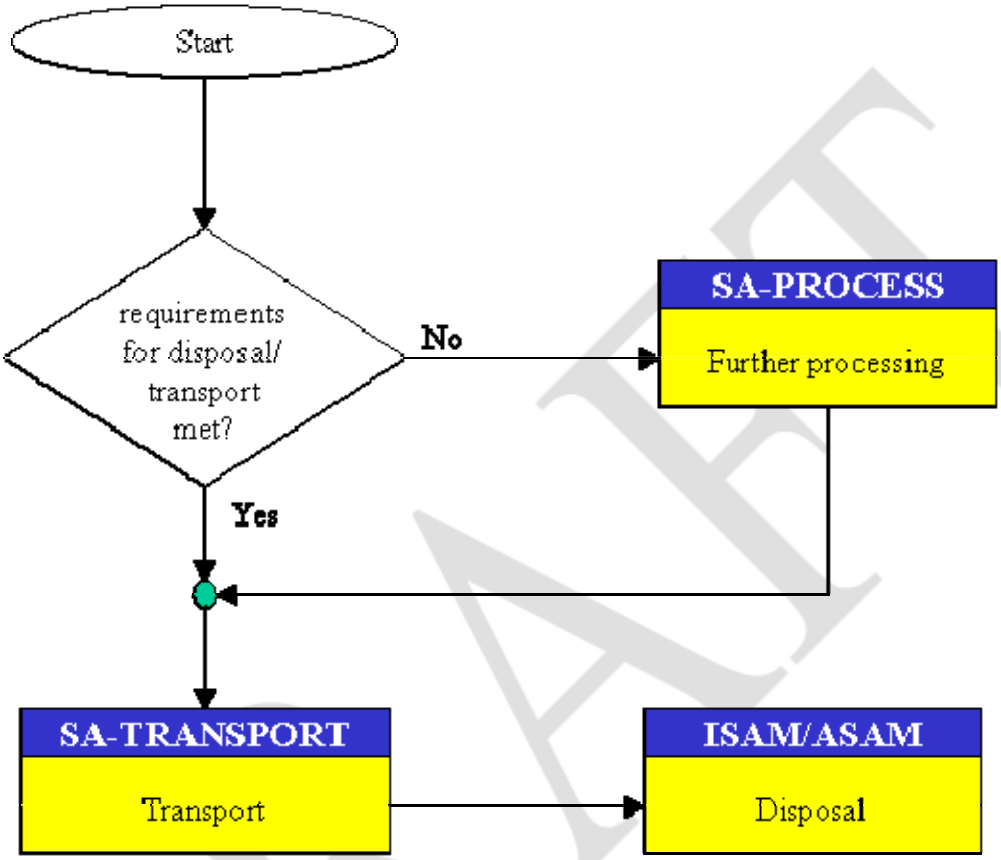


Fig. 6: Disposal



2.1. Overall process

The first activity in the overall chart (Fig. 1) is the identification of wastes. This has to address all parameters for the particular type of waste required to decide about its classification in terms of the flowchart.

An important distinction arises between wastes which already exist and which are kept in a storage facility as opposed to wastes which are newly generated. In cases of existing wastes which have been put into a storage facility in the past, safety and security of these storage arrangements may not be adequate based on current standards. This may require remedial action to upgrade safety and security by changes of the waste conditions, improvements of the storage facility and/or retrieval of the wastes and storage in another facility.*)

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

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

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

For liquid or gaseous wastes, an analogous waste management option consists in their discharge. As described for clearance above, discharges can be considered at all stages of the overall process. Practically important examples for discharges at later stages are liquid or gaseous wastes arising during waste management activities (in particular processing) and liquids being discharged after decay storage.

2.2. Waste identification

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

- Liquid, solid, or liquid/solid mixture?
- High/low dose rate?
- Radioisotope dominance - long lived/short lived?
- Flammable/non-flammable?
- Explosive/non-explosive?
- Alpha containing/non-alpha containing?
- Corrosive/non-corrosive?
- Gas evolver/non-gas evolver ?
- Fissile/non-fissile?
- Contained/uncontained?
- Well-contained/poorly contained?
- Records available?

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*) The decision to consider remedial action, i.e. an intervention, for wastes already in storage in Fig. 1 does not apply to wastes which are in interim storage pending processing within a practice. Rather, it applies to wastes for which the decision to store them in their current form already has been made, so that any changes would be considered as an intervention. Wastes in interim storage would be treated like newly arising wastes within a practice and it would be decided within the processing box whether processing is required.

- Wastes properly labelled?

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

2.3 Remedial action

In case of wastes in an old storage facility (not in interim storage as part of a current practice, see footnote in Section 2.1), remedial action may be required to upgrade safety and security (Fig. 2).

The first question to be addressed is whether the existing situation is acceptable from a safety and security point of view or whether corrective actions to upgrade safety and security are required. This means that only the question of the necessity to consider corrective action is addressed, not the question which corrective action should be taken (in case that this is considered necessary). The safety assessment required at this stage (SA-INTERVENE) considers in particular doses and risks arising from the current location and conditions of the waste. The time span to be considered reaches up to the anticipated time at which a disposal facility for the wastes becomes available.

If this safety assessment indicates the need for an intervention, it is required to identify and evaluate options to improve the situation (SA-OPTIONS). This may involve improvements of the design of the storage facility and/or the full or partial retrieval of wastes.

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

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

For the storage of wastes after retrieval and processing, the existing facility may be used, normally after the implementation of measures to upgrade its safety and security. Alternatively, these wastes may be stored in another existing or in a new facility. The safety assessment SA-STORE required at this stage is in principle identical to the safety assessment required for storage in the case of newly arising wastes which is discussed in Section 2.6.

2.4 Clearance / discharge

Clearance (mainly for solid wastes) and discharge (for liquid and gaseous wastes) are important options to reduce the volume of wastes which have to be stored and eventually be disposed of. In some cases (e.g. stainless steel) the economic value may also provide incentives to clear wastes. The first question shown in Fig. 3 is whether criteria and procedures for clearance or discharge, as appropriate, exist. If this is not the case these need to be developed (SA-CLEAR[*)]).

With regard to clearance levels, this can either utilise generic approaches as recommended by the IAEA in RS-G-1.7 [Ref.]. Alternatively, specific clearance criteria and procedures can be developed for certain waste types or for certain disposal or recycling options. In the latter case, criteria

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

for conditional clearance may be derived, i.e. regulatory control will only be removed if the waste producer can ascertain the regulatory body that certain restrictions on the disposal or recycling of waste are being complied with.

Guidance on the development of criteria and procedures for discharges is given in WS-G-2.3 [Ref.].

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

If the wastes comply with these criteria, the wastes can be cleared or discharged. Otherwise, the wastes remain with the overall scheme of radioactive waste management and will be subject to the appropriate process step according to Fig. 1.

In the case of unconditional clearance, regulatory controls will be removed. For conditional clearance and discharges in general some regulatory requirements will remain, ensuring that clearance and discharge are performed according to the specified restrictions and prescribing, in particular in the case of discharges, monitoring activities.

2.5 Processing

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

If such requirements do not exist, they will need to be developed before any decision about waste processing can be made (SA-REQUIRE). As already stated in Section 2.1, ideally at this stage requirements for all further waste management steps, including transport and disposal will be derived. This avoids the necessity of further processing of the wastes at a later stage, which would be economically unfavourable and which would also, if avoidable, conflict with the overall optimization requirement. In practice, however, this will not be possible in all situations such as in the frequently occurring case that a disposal facility and planning for such do not exist.

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

If the wastes in their current form do not comply with the requirements, processing has to be undertaken. This may involve the following main steps:

- Segregation of wastes which are subject to different types of treatment, clearance and/or discharge;
- Decontamination of wastes to facilitate their treatment or allow for clearance or discharge;
- Conditioning and packaging of wastes.

After processing, the wastes will be sent to storage/disposal. Segregated or decontaminated portions of the wastes potentially meeting clearance or discharge levels will be subject to the application of clearance or discharge procedures (see Section 2.4).

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

2.6. Storage

As already discussed in Section 2.1, storage of waste is considered only as a hold point until a disposal facility becomes available. However, since in many countries disposal facilities are not

available and will not be available in the short term, safe and secure storage arrangements play an important role in the overall management of radioactive waste (Fig. 5).

The first question arising is whether a storage facility already exists. In the case of an existing facility it is required to assess whether this facility allows for a safe and secure storage of waste. If this is not the case, upgrading of the facility will be required. In so far, the situation is comparable to Fig. 2, assessing the adequacy of storage arrangements for existing wastes.

If no facility exists so far, it will be required to design and construct a new facility, taking account of the safety and security requirements for the particular types of waste which have to be stored.

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

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

2.7. Disposal

The eventual target for radioactive waste is safe disposal. After an adequate disposal facility exists, wastes will be transported to this facility directly after processing or following a storage period. This may require further processing in order to meet transport and disposal criteria, although this necessity should be avoided to the extent possible (see Section 2.5). If, however, additional processing is necessary, the type of activities and the safety assessment SA-PROCESS required are identical to those described in Section 2.5.

For the transport of wastes a safety assessment SA-TRANSPORT will be required. This may be very simple for unproblematic wastes by just demonstrating that criteria on activity contents, dose rates etc. stipulated in the transport regulations are complied with. For more problematic wastes (in particular HLW) more detailed assessments of the transport risks may be necessary.

The eventual disposal will require a thorough safety assessment covering the operational phase of the repository as well as the long term safety. A methodology for this purpose has been developed in the ISAM co-ordinated research project [Ref.] and its continuation project ASAM [Ref.]. Consideration of this phase of radioactive waste management, therefore, is outside the scope of the SADRWMS project.

3. PURPOSE AND SCOPE OF SAFETY ASSESSMENTS

Based on the description of relevant waste management steps in Section 2, the safety assessments identified as necessary for the individual process steps are characterized in the following with regard to the following aspects:

- Purpose, i.e. questions which need to be addressed and answered and
- General aspects of the assessment context for each assessment.

The identification of the different safety assessments uses the acronyms defined in Section 2. The following tables indicate for these safety assessments key elements of their

- purpose,
- endpoints,
- philosophy, and
- timeframes.

In addition, remarks concerning their contents and their relationship to other safety assessments are provided.

Some general aspects of these safety assessments are not mentioned in the tables, such as the regulatory framework as part of assessment context and their function to contribute to public confidence. These will strongly depend on the specific conditions under which the assessments are undertaken.

Based on the identified general functions of the safety assessments, Appendix A summarizes key questions which have to be addressed in their preparation.

Table 1: Assessment context of SA-INTERVENE

Assessment of safety of wastes stored in existing facility	SA-INTERVENE
Purpose of assessment	1. Determine whether the existing situation is acceptable from a safety and security point of view or whether corrective action to upgrade safety and/or security is required. Note: The identification of the required corrective action is not part of this assessment (see SA-OPTIONS).
Assessment end points	1. Assessment of impacts from facility in current conditions and from possible changes (e.g. degradation of barriers, external or internal events); possible end points include: a. Radionuclide releases from the storage facility; b. Radionuclide concentrations in environmental materials; c. Doses and risks to workers for activities such as maintenance, surveillance etc.; d. Doses to public (potential or real exposure group member); e. Doses to non-human biota; f. Level of security of facility.
Assessment philosophy	1. Use of cautious assumptions, but in view of the intervention situation these should be as realistic as possible; i.e. the existing situation should be addressed realistically and cautious assumptions should only be used to the extent that impacts from events and processes potentially affecting the assessment endpoints need to be assessed. 2. Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site-specific data are not available (e.g. data concerning the impact of potential events and processes or data such as the contents of waste packages which cannot be measured at this stage) or to cases in which site-specific sampling and measurements are not warranted by the importance of the data for the assessment results.
Assessment timeframes	1. Anticipated timeframe for establishing a disposal facility and for starting the retrieval of wastes. Note: Frequently existing uncertainties in this respect should be accounted for by using a contingency allowance.
Remarks	1. This assessment intends only to determine whether there is a need for intervention. If this exists, SA-OPTIONS will compare available intervention options and lead to the identification of the upgrading option to be implemented.

Table 2: Assessment context of SA-OPTIONS

Assessment of options to upgrade safety	SA-OPTIONS
Purpose of assessment	1. Identify options to improve the existing situation of wastes stored in the facility and/or the facility itself by a. improving the design of the facility and/or b. retrieving part or all of the wastes from the facility. 2. Compare identified options and determine optimal option with regard to all attributes relevant for the specific situation (doses, risks, costs etc.).
Assessment end points	1. Assessment of the retrieval of wastes and/or upgrading of the facility (to the extent that these are within the scope of options considered), possible end points include: a. Radionuclide releases caused by the retrieval and upgrading operations; b. Radionuclide concentrations in environmental materials; c. Doses and risks to workers during waste retrieval and upgrading of the facility; d. Doses to public (potential exposure group member); e. Doses to non-human biota. 2. Assessment of impacts from upgraded facility (i.e. improved design and/or partially retrieved wastes); possible end points include: a. Radionuclide releases from the storage facility; b. Radionuclide concentrations in environmental materials; c. Doses and risks to workers for activities such as maintenance, surveillance etc.; d. Doses to public (potential exposure group member); e. Doses to non-human biota; f. Level of security of facility. 3. Assessment of processing/storage/disposal of retrieved wastes (to the extent that waste retrieval is within the scope of options considered). Note: The necessity and scope of this part of the assessment will be very case-specific and depend on whether capacities for waste processing, storage or disposal already exist. In any case, it is important to include the fate of retrieved wastes (in particular, doses, risks and costs incurred by their management) into the comparison of options for intervention.
Assessment philosophy	1. Use of cautious assumptions, but in view of the intervention situation these should be as realistic as possible (see Table 1): a. The comparison of options should in general be based on realistic assumptions; b. The assessment of compliance with regulatory standards within each of the considered options will require sufficiently cautious assumptions. 2. Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site-specific data are not available (see Table 1).
Assessment timeframes	1. Assessment of the retrieval of wastes and/or upgrading of the facility: duration of these activities. 2. Assessment of impacts from upgraded facility: anticipated timeframe for establishing a disposal facility and for starting the retrieval of wastes (including contingency allowance, see Table 1). 3. Assessment of processing/storage/disposal of retrieved wastes: case

Assessment of options to upgrade safety	SA-OPTIONS
	specific (see above).
Remarks	1. This assessment will only be required if SA-INTERVENE results in the need for intervention. 2. The actual planning of the measures to upgrade the facility and/or to retrieve the wastes is not part of this safety assessment (see SA-STORE, SA-RETRIEVE). Therefore, assessments of these activities are only required to the extent and depth of allowing for a comparison of options. Detailed planning will only be necessary for the option identified as optimal (which is going to be implemented).

Table 3: Assessment context of SA-RETRIEVE

Assessment of waste retrieval	SA-RETRIEVE
Purpose of assessment	1. Assessment of the safety of retrieval operations, allowing for their detailed planning. 2. Establishment of a. limits (qualitative or quantitative restrictions to any part of the activity, which are applied to ensure compliance with safety principles and requirements); b. controls (processes, procedures or other instruments that are put in place to ensure compliance with safety principles and requirements); and c. conditions (prerequisites, requirements for functions, facilities or organizations that must exist to ensure safety) for the retrieval operations.
Assessment end points	1. Assessment of the retrieval operations, possible end points include: a. Radionuclide releases caused by the retrieval and upgrading operations; b. Radionuclide concentrations in environmental materials; c. Doses and risks to workers during waste retrieval and upgrading of the facility; d. Doses to public (potential exposure group member); e. Doses to non-human biota.
Assessment philosophy	1. Use of cautious assumptions, but in view of the intervention situation these should be as realistic as possible (see Table 1). 2. Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site-specific data are not available (see Table 1).
Assessment timeframes	1. Duration of retrieval activities.
Remarks	1. The assessment of the fate of retrieved wastes is not part of this safety assessment. This will be covered by other relevant safety assessments addressing the management steps for these wastes such as clearance, discharge, processing, storage, transport and disposal.

Table 4: Assessment context of SA-CLEAR

Derivation of clearance and discharge levels and procedures	SA-CLEAR
Purpose of assessment	Clearance: 1. Establish generic clearance levels for wastes in general or for certain waste types, possibly also including certain restrictions on clearance (e.g. clearance levels for metal scrap subject to smelting). or 2. Determination whether unconditional or conditional clearance of certain wastes is possible (i.e. whether clearance of these particular wastes complies with criteria such as the de minimis principle). Discharges: 3. Establish general or facility specific discharge limits. Clearance and Discharges: 4. Development of clearance and discharge procedures (in particular type and extent of required measurements and monitoring).
Assessment end points	1. Assessment of exposure from wastes after clearance or discharge, possible end points include: a. Doses to public (potential exposure group member). Note: For clearance, scenarios to be determined based on type of material and possible (for unconditional clearance) or restricted (for conditional clearance) options for disposal and recycling of materials.
Assessment philosophy	1. In general, cautious assumptions are being used. However, in particular when applying the low dose levels of the de minimis principle for clearance, overly conservative assumptions should be avoided (see IAEA Safety Guide RS-G-1.7). 2. For generic clearance levels and discharge limits as well as for addressing the unconditional clearance of certain wastes, necessarily generic data have to be used. The use of site-specific data will only possible for certain cases of conditional clearance (i.e. when the recycling or disposal routes are known and will be ensured by regulatory provisions) and for facility specific discharge limits.
Assessment timeframes	1. Dose assessments for clearance, in principle, have to be carried out for unlimited time frames. However, in practice limitations of timeframes to be considered arise from the half-life of radionuclides involved and from the fact that within scenarios usually considered the highest exposures arise immediately or shortly after clearance (exception: water pathways). 2. For discharges, exposures usually occur within short time frames with the exception of exposures resulting from the accumulation of radionuclides in the environment (e.g. through adsorption by river sediments or ground deposition of aerosols). The latter case has to be treated in analogy to clearance
Remarks	1. As shown in Figure 1, clearance and discharges are a waste management options at all stages of the overall process. Therefore, the derivation of general clearance levels and discharge limits is often easier and more effective than addressing clearance at each individual process stage. 2. Since scenarios and dose assessments used for the derivation of clearance levels are usually very general, it appears to be adequate for most cases to use generic clearance levels derived on an international basis (e.g. RS-G-1.7). Specific assessments can then be limited to particular waste types or to establishing levels for

	conditional clearance. 3. The development of clearance procedures in general will have to consider material types and radionuclides of interest in order to determine adequate sampling and measurement procedures.

Table 5: Assessment context of SA-REQUIRE

Derive requirements (storage, transport, disposal)	**SA-REQUIRE**
Purpose of assessment	1. Derivation of requirements for different waste management steps: a. storage; b. transport; and c. disposal. to define waste processing requirements.
Assessment end points	1. End points depend on specific activity considered (see remarks).
Assessment philosophy	1. In general, cautious assumptions are being used. 2. Data are either generic (for waste management activities not addressing a specific facility) or site-specific (when deriving requirements for a particular facility).
Assessment timeframes	1. Timeframes depend on specific activity considered (see remarks).
Remarks	1. The derivation of requirements will part of the safety assessments conducted for the different waste management activities (see SA-STORE, SA-TRANSPORT, ISAM/ASAM). End points and timeframes considered will be determined within these assessments. 2. The derived requirements are either of generic nature (such as normally in the case of transport) or they are based on safety assessments for specific storage or disposal facilities and, therefore, are only valid for certain waste management routes. 3. The derived requirements have to be sufficiently specific to determine the type and extent of waste processing required.

Table 6: Assessment context of SA-PROCESS

Assessment of processing of wastes	**SA-PROCESS**
Purpose of assessment	1. Siting guidelines and/or site selection for the waste processing facility. 2. Assessment of the safety of the waste processing operations, allowing for their detailed planning. 3. Establishment of a. limits; b. controls; and c. conditions for the waste processing operation.
Assessment end points	1. Assessment of the waste processing operations, possible end points include: a. Radionuclide releases caused by the waste processing operations; b. Radionuclide concentrations in environmental materials; c. Doses and risks to workers during waste processing; d. Doses to public (potential exposure group member); e. Doses to non-human biota.
Assessment philosophy	1. In general, cautious assumptions are being used. 2. Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site-specific data are not available (e.g. data concerning the impact of potential events and processes) or to cases in which the collection of data

	concerning the wastes to be processed are not warranted by the importance of the data for the assessment results.
Assessment timeframes	1. Duration of the waste processing activities.
Remarks	1. The necessary type and extent of waste processing depend on the requirements derived for subsequent waste management steps (see Table 5).

Table 7: Assessment context of SA-STORE

Assessment of storage of wastes	SA-STORE
Purpose of assessment	1. Siting guidelines and/or site selection for the storage facility. 2. Assessment of the safety of the waste storage, allowing for detailed planning. 3. Establishment of a. limits; b. controls; and c. conditions for the waste storage.
Assessment end points	1. Assessment of the storage facility, possible end points include: a. Radionuclide releases caused by the storage operation and the stored wastes; b. Radionuclide concentrations in environmental materials; c. Doses and risks to workers during storing the wastes and for activities such as maintenance, surveillance etc.; d. Doses to public (potential exposure group member) during the storage operation and during the storage period; e. Doses to non-human biota; f. Level of security of facility.
Assessment philosophy	1. In general, cautious assumptions are being used. 2. Use of actual data to the extent possible and warranted; i.e. the use of generic data is restricted to cases in which site-specific data are not available (e.g. data concerning the impact of potential events and processes) or to cases in which the collection of data concerning the wastes to be stored are not warranted by the importance of the data for the assessment results.
Assessment timeframes	1. Anticipated timeframe for establishing a disposal facility (including contingency allowance, see Table 1).
Remarks	1. Controls and conditions for the safety of waste storage will require regular reviews. These are addressed in SA-REVIEW (Table 8).

Table 8: Assessment context of SA-REVIEW

Assessment of regular safety reviews of storage facility	SA-REVIEW
Purpose of assessment	1. Determine the frequency and scope of required regular reviews of the safety of a waste storage facility.
Assessment end points	1. Assessment end points are identical to those addressed in SA-STORE (Table 7) concerning the waste storage period.
Assessment philosophy	1. Identical to SA-STORE.
Assessment timeframes	1. Identical to SA-STORE.
Remarks	1. This safety assessment addresses the same events and processes as already considered in SA-STORE Therefore, it will usually will be conducted in combination with or even as part of SA-STORE. 2. During the regular reviews, assumptions made in the underlying safety assessments (SA-STORE, SA-REVIEW) may turn out as inadequate (e.g. neglecting of certain events or processes, overly conservative assumptions). This may require updates of these safety assessments and additional measures to maintain safety.