Note:
This is a translation of the ESK statement entitled
“Leitlinie zum Sicherheitsmanagement in Endlagerorganisationen”
In case of discrepancies between the English translation and the German original, the original shall prevail.

RECOMMENDATION of the Nuclear Waste Management Commission (ESK)

Guideline on Safety Management in waste management organisations

CONTENTS

1 Background/Initial situation

The management of all radioactive waste by the waste-producing generations must be carried out in such a way that no undue burdens and obligations arise for future generations [1]. For this purpose, safe, practicable and environmentally acceptable solutions must be sought by the present generations and management systems in accordance with [2, § 7c; 5, Ch. 2 (8)] must be installed to achieve these goals, ensuring that all steps and elements of implementation are carried out with the necessary care.

In its final report, the Commission on the Storage of High-Level Radioactive Waste recommended that a guideline on Safety Management be drawn up in the near future [3, Ch. 6.5.1]. It was stated by the Commission that such a Safety Management should not only apply to the applicant, operator or project implementer, but also to all authorities and other organisations involved [3, Ch. 6.5.1].

Safety Management defines strategies and processes that guarantee reliable implementation of the safety requirements and continuous improvement [4, Ch. 3.48] of the safety level of the repository. It also includes the monitoring of the safety level achieved and the initiation of concrete processes for continuous improvement. The Safety Management comprises the entirety of all activities for the proper planning, organisation, management and monitoring of the waste management organisation with regard to safety and resilience [4, Section 3.227]. This concerns the people, work and necessary processes for anticipatory planning and provision of the required human, organisational and financial resources, an appropriate infrastructure [4, Ch. 3.117], and a safety-promoting working environment, as well as regulated cooperation with external organisations.

The Ordinance on Safety Requirements and Preliminary Safety Analyses for the Disposal of High-Level Radioactive Waste [5] contains a large number of requirements whose implementation must also be supported by the Safety Management. At its 76th meeting on 16/17 May 2019, the ESK therefore decided to develop a guideline on Safety Management in waste management organisations (hereinafter: guideline on Safety Management). Its content is essentially based on national [e.g. 5-9] and international regulations [e.g. 1, 10-13] as well as numerous experiences and implementation examples from nuclear technology, mining, and aviation. The guideline supplements existing ESK guidelines, in particular the guideline on safe operation of a repository [14].

The guideline was developed within the framework of an ad hoc working group, revised in the ESK Committee on FINAL DISPOSAL at the 74th, 75th and 76th meetings on 19 June 2020, 31 July 2020 and 17 September 2020, discussed within the ESK at its 83rd and 85th meetings on 1 October 2020 and 10 December 2020 and then voted on within the ESK by circular procedure. The guideline was then discussed at the 88th ESK meeting with the primarily affected organisations BMU, BASE and BGE and revised by the ad hoc working group in cooperation with BASE and BGE. It was adopted on 1 September 2021 at the 91st ESK meeting.

2 Scope, objective and approach

The common goal of all stakeholders is the disposal of radioactive waste with the best-possible safety. Best-possible safety is to be achieved by involving all stakeholders. The aim of the guideline on Safety Management is to instruct the waste management organisations involved (applicant, operator or project implementer) as well as the competent authorities and other organisations involved in achieving the best-possible safety (hereinafter always referred to collectively as "waste management organisations") to introduce a Safety Management in their respective areas and to monitor its implementation/compliance accordingly[1]. The Safety Management has to be continuously reviewed in the sense of a dynamic system and adapted to the current tasks and work as required. To this end, the guideline describes in particular the organisational and content-related aspects for establishing a corresponding Safety Management.

The waste management organisations additionally involved in the realisation of a repository must examine, taking into account their own tasks and legal framework conditions, to what extent the guideline can be applied to their own work. All stakeholders must take into account that their own actions (may) have an impact on the actions of other stakeholders. The extent to which an organisation takes the requirements of this guideline into account must be measured against the overall objective of the safe disposal of radioactive waste.

In order to define this scope of consideration, the requirements formulated in the guideline (starting with Ch. 4) are displayed separately from explanatory texts. The subdivision into individual requirements is intended to allow their implementation to be discussed specifically at the requirement level and to be determined in a binding manner for the respective organisation.

This guideline primarily refers to activities within the framework of the realisation of a repository for high-level radioactive waste. Taking into account that at the site of such a repository, low- and intermediate-level radioactive waste may also have to be emplaced and that the same organisations are partly responsible for the implementation and supervision of existing facilities, application of this guideline to the operators and supervisory authorities of already existing facilities for the disposal of low- and intermediate-level radioactive waste may be wise. The establishment of different Safety Management systems in sub-units of the same organisation is not considered advantageous. The primary objective of a Safety Management is to promote the highest possible level of safety.

The top management [4, Ch. 3.263] of the respective waste management organisation bears comprehensive responsibility for establishing a high level of safety that meets all requirements and for actively implementing it [2, § 7c]. It must ensure that a Safety Management is developed, documented, communicated and implemented in accordance with this guideline, in which the safety-relevant information, processes and activities are presented in a manner that is appropriate to the different levels[2] and comprehensive. Particular care must be taken to ensure that the safety level is not lowered by other requirements (e.g. financial or time

[1] This is to be done within the framework of an integrated management system [15, Ch. 4.3] in which the topic of Safety Management must be explicitly established and which aims, among other things, at establishing a positive safety culture.

[2] Appropriateness to the different levels means the adaptation of measures to the influence of a process, an activity or equipment on the safety level or the protection of the people and the environment.

requirements). To this end, the potential safety risks[3] associated with the exploration and planning, construction, operation and decommissioning of a repository must also be identified with a view to long-term safety. Based on this, measures for their avoidance/control have to be defined and implemented. In view of future developments, a regular review [4, Ch. 3.197] and updating of the guideline must be provided for.

The realisation of a repository is characterised by long exploration, planning, construction and operation periods. During these periods, the legal, non-mandatory and social requirements for the repository may change. The Safety Management of the waste management organisation has to ensure that changing requirements are continuously incorporated and conflicts caused by contradicting requirements are resolved. Special attention is paid to requirements that ensure safety beyond the time of closure (long-term safety) (i.e. for a period of one million years, cf. [5, § 1 (2)]). For this purpose, the question must be asked as to when which decisions have to be made and which technical and scientific bases must be available for each of these decisions. It must be defined when which research and development are to be launched [5], which data are to be recorded for later monitoring as reference values, etc., so that the future, safety-relevant activities can be determined in good time.

The guideline on Safety Management refers to all activities carried out today and foreseeable developments that affect the site selection, exploration and planning, construction, operation and decommissioning of the repository for high-level radioactive waste in Germany. In principle, it also includes the possibility of emplacement of low- and intermediate-level waste at this site.

The term "safety" refers to ensuring the achievement of a solution for the long-term safe isolation of radioactive waste in a stable process. This also includes the safe construction and operation of underground facilities. The requirements include, in particular, safety-relevant aspects as well as other legally justified requirements, e.g. with regard to environmental protection and safety at work. However, in addition to externally imposed requirements, they can also include objectives that are defined by the waste management organisation itself in its own Safety Management. If the term "safety" refers solely to the Safety Management, it is referred to in the following as "safety in relation to Safety Management". In this context, the achievement of the defined goals or the activities agreed upon for this purpose are regularly reviewed for compliance and effectiveness. The aim is to achieve a continuous improvement of the waste management organisation’s performance with regard to the activities covered by the Safety Management.

The guideline on Safety Management begins by defining the terms relevant to the further explanations and describes the essential components of a Safety Management (Ch. 3). The generic structure of a Safety Management of a waste management organisation is presented and its essential elements are explained (Ch. 4). Eventually, the requirements for a Safety Management in the individual phases of the realisation of a repository are described (Ch. 5). A number of terms have been used in this guideline on the basis of ISO Standard 22300 [4]. Corresponding definitions are referenced at the first occurrence of the term.

[3] The term "risk" is used in two ways in the document. On the one hand, it describes the risk of a decline of the safety level (cf. [7, Ch. 4.1.5], in this case referred to as "safety risk"); however, it also describes the risk resulting from an insufficient Safety Management for the waste management organisation itself (consequently referred to as "risk to the waste management organisation", cf. [7, Ch. 3.7]).

3 Fundamentals and definitions of terms

In order to achieve the highest possible safety level, it is important to identify the causes of risks that may impair or reduce safety and to understand the cause-effect relationships. A continuous review of the safety level is necessary to identify deficits/safety risks at an early stage and to initiate measures to (re-)achieve a stable safety status. The safety risk is described by a statement that indicates the probability of occurrence of an event leading to damage for damage events or scenarios and describes the expected extent of the damage (Fig. 1).

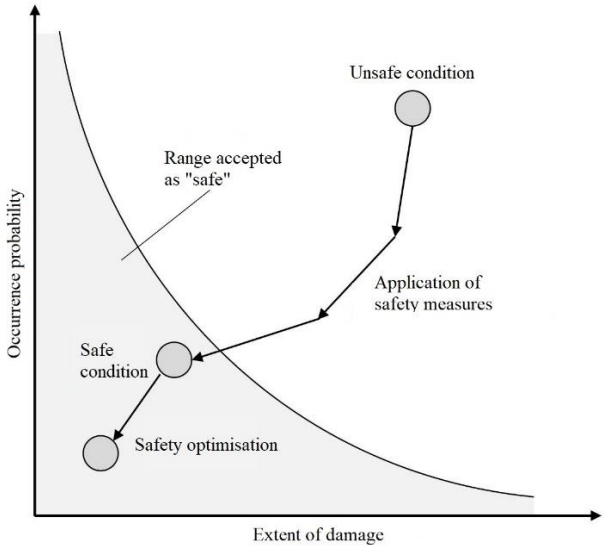

Fig. 1: Schematic representation of the range accepted as "safe".

The safety requirements to be applied in each case define the extent of the range accepted as "safe" (Fig. 1). Within this range defined by the requirements, an even higher or more robust level of safety may be achieved through targeted and continuous improvement measures by further reducing the probability of occurrence or the possible extent of damage or both. If an opposing trend is detected through the use of system indicators (Ch. 4.6), countermeasures can be taken at an early stage. If the safety range is left, a safety deficit exists that can put the integrity of employees, the population and the environment at risk. It should be noted that the range accepted as safe may change, e.g. due to changes in legal regulations, and as a result a previously safe condition may no longer be in the range accepted as safe.

Damage events can have several causes (multi-causality) but can always be attributed to the three factors of man, technology and organisation (MTO). These three factors are the starting points for the Safety Management. In view of the long-time horizon associated with disposal, damage events and MTO factors must be considered in terms of both their short- and long-term effects.

The aim of implementing a Safety Management is to achieve the highest possible safety level and to guarantee it in the long term. In principle, the Safety Management consists at least of the following elements, which may be specific to the waste management organisation and, if necessary, must be supplemented by other elements specific to the repository. These must not contradict each other and must be designed congruently:

- **Safety Management concept:** This defines the safety objectives of a waste management organisation and describes measures to achieve these objectives. It forms the basis for planning and implementing individual safety measures with the aim of achieving the planned safety level and minimising identified safety risks.

- **Safety policy:** In accordance with the mission statement, this describes the objectives, intentions and orientation of the waste management organisation with regard to best-possible safety (cf. [6, § 1]). It is adopted by the top management and exemplified to the employees.

- **Systems analyses**[4]**:** Systems analyses include the analysis of safety in relation to the Safety Management, i.e. the systems, organisational structures or operational processes described therein. It allows the causes of damage to be identified, their probability of occurrence and the extent of damage to be assessed, and the risk to the waste management organisation to be estimated from it.

- **Safety Management report:** This is prepared by the respective waste management organisation and provides information on e.g.
  - the Safety Management and its application,
  - the methodology for identifying hazards and the measures for their prevention,
  - a concept for the prevention of severe damage events,
  - the planning, construction and operation of the structures, systems and components (ASK) and their operational safety,
  - internal and external emergency plans.

- **System indicators**[5]**:** These are derived from systems analyses. They should be easy to gather and are to be monitored regularly. They provide an overview of the safety status of a waste management organisation and indicate a possible change (improvement or deterioration) at an early stage.

- **Safety culture:** It comprises the lived implementation of the common objectives, interests, norms, values and behavioural patterns of a waste management organisation for dealing with safety issues. It requires a continuous learning process of all employees and must permeate all levels of a waste management organisation. At the top of a waste management organisation, the top management has a decisive influence on the safety culture of the entire waste management organisation by making the values of safety and quality clear so that the employees do not get into a conflict between safety and operative objectives in their daily tasks (see also [2]).

[4] The term "safety analysis" in this guideline refers to the Safety Management and is not to be confused with the safety analysis that is prepared for operational or long-term safety.

[5] The term "system indicators" refers to indicators used to assess the Safety Management. The term deliberately differs from the term "safety indicators" otherwise used for management systems in order not to cause confusion with the term otherwise used in the safety analyses for operational and long-term safety.

4 Safety Management of a waste management organisation

Requirement	Explanation
a) Safety must be achieved and maintained through an effective Safety Management.	to a) The Safety Management comprises all measures during the period of site selection, exploration and planning, construction and operation up to the decommissioning of a repository for the systematic avoidance, detection, analysis, assessment and monitoring of safety risks during this period and beyond. If other, subject-specific management systems are introduced in addition to the Safety Management, these must be combined to form an integrated management system [15, Ch. 4.3].
b) In the Safety Management, comparable requirements have to be implemented in a standardised manner, processes have to be aligned and safety-relevant activities have to be planned and realised in a coordinated manner.	to b) In accordance with the premise of "safety first", the Safety Management is to take a leading role in the alignment with requirements. It is based on the premise that there are always safety risks and human errors and that processes are needed to improve regular communication and consultation [4, Ch. 3.41] about these safety risks and the measures to reduce them. The premise of "safety first" is exemplified through the top management as part of the safety culture.
c) In the Safety Management, minimum safety requirements must be defined, applied in accordance with other requirements and, if necessary, further developed.	to c) The minimum requirements are defined on the basis of the legal and non-mandatory requirements and further requirements that the waste management organisation defines for itself.

d) The Safety Management must be established, documented, implemented, evaluated, controlled and continuously improved by: i) compliance with the range accepted as safe, taking into account operational and economic requirements and the claim for further improvement, ii) description and implementation of the planned and systematic actions required to give confidence that all requirements are fulfilled, iii) development of a safety culture that promotes a common commitment to safety and supports a proactive, questioning and learning waste management organisation at all levels.	to d) For the concept of continuous improvement, see [13, DI-14]. The approach follows a PDCA approach common in management systems (cf. [7, Ch. 3.6]). The range accepted as safe is shown in Fig. 1. The safety culture (cf. Ch. 4.1) is an inherent part of the management system, which also systematically and continuously improves cultural aspects, allows regular assessments of the safety level, and ensures learning from experience [1, Ch. 3.12].
e) The Safety Management must be designed not only for normal operation, but also for any anomalous operating conditions and incidents that may occur.	to e) The Safety Management is to remain capable of acting and reacting adequately both in normal operation as well as in any abnormal operating conditions and potential incidents [13, DI-15].
f) The Safety Management has to ensure that the work performed in the individual processes is carried out in compliance with the state-of-the-art in science and technology.	to f) Ensuring the state-of-the-art in science and technology requires continuous quality assurance (cf. [5, §§ 5(4), 6(4), 9(1), 12(4)]).

4.1 Safety culture and policy

Requirement	Explanation
a) The Safety Management has to establish a safety culture within the waste management organisation and implement it via the internal safety policy.	to a) The safety culture comprises a common basic attitude, responsibility and way of acting of all actors for safety, a common understanding of what constitutes safety and how it is achieved - both in relation to the entirety of the waste management organisation and its internal interrelations as well as to all individuals.

b) It has to be ensured that the safety culture is known and practised by all employees and external companies involved.	to b) The safety culture is to promote trust, a learning attitude, cooperation, consultation and communication, as well as constructive handling of non-conformities [4, Ch. 3.149] among the employees of the waste management organisation and employees of external companies involved. This implies that employees can raise safety issues [4, Ch. 3.224], make suggestions and point out non-conformities without fear of punishment, exclusion, intimidation or other personal disadvantages. Furthermore, the safety culture should be oriented towards what is done well, correctly and without problems and should honour the corresponding behaviour [16].

4.2 Safety Management concept

Requirement	Explanation
a) In the Safety Management concept, all relevant framework conditions, the defined safety objectives of the waste management organisation and the measures for achieving the objectives must be described or defined.	to a) The creation and implementation of a Safety Management concept serves to reach the range accepted as safe, to remain within it and to optimise safety by minimising the identified safety risks (cf. Fig. 1). It also serves to ensure safety in relation to the Safety Management itself. As the Safety Management concept forms the basis for the planning and implementation of individual safety measures, it should also deal with issues of uncertainties and situations deviating from normal operation (cf. “requirement” 4.2f).
b) The Safety Management concept has to work towards an organisational structure that implements the safety policy of the waste management organisation through a clear definition of responsibilities, authorities and communication channels, as well as incentives and sanctions, referring to i) functional responsibilities, levels of authority and interactions of those who manage, perform and assess work,	to b) The references mentioned are based on [13, DI-17]. The term interoperability is defined in [4, Ch. 3.128]. For the process of improvement cf. Ch. 4.8, for documentation cf. Ch. 4.7. The individual phases of repository realisation are explained in Ch. 5. The requirement in b (vi) refers to [6, § 38 (2)].

ii) interoperability and resulting interaction of the waste management organisation with contractors, including the supervision of their activities, iii) process descriptions and further information explaining how the work is prepared, carried out, recorded, assessed, reviewed and improved, iv) Man-Technology-Organisation (MTO) interactions that have an impact on safety and safety culture, v) systematic gathering, documentation and evaluation of operating experience, vi) provisions for the documentation of knowledge, information and data on all aspects related to the safety of the repository until its closure, for the transfer of this documentation to the authority or for its permanent safekeeping by the authority, and vii) adequate knowledge transfer during the different phases (Ch. 5) of the project.	
c) The Safety Management has to define processes for dealing with or minimising uncertainties and risks for the waste management organisation.	to c) The minimisation of uncertainties is further elaborated in [11]. The term risk is used in this context according to [4, Ch. 3.215].
d) Within the framework of the above-mentioned processes, it must be shown transparently to what extent uncertainties regarding safety can be reduced even further or may not be reduced any more.	to d) The requirement takes up the requirements mentioned in [5, § 11]. This includes programmes for the collection of available information and internal processes that ensure that irreversible or hardly reversible decisions, in particular, are made as early as necessary or as late as possible, that several alternatives are considered for decision-making wherever possible and that the best-possible approach in terms of safety is chosen. The waste management organisation's research and development projects are to provide the basis for decision-making [5, §§ 11(3), 12].
e) The Safety Management has to ensure that the waste management organisation has an emergency management system in place, that	to e) Emergency management (as per [4, Ch. 3.78]), emergency plans and emergency drills involve the participation of other external

emergency plans are developed and that emergency drills are carried out in the existing facilities at certain intervals.	emergency organisations. The emergency plan should be subject to continuous review and updating in the light of accumulated experience and operating experience of comparable facilities and activities at home and abroad [13, DI-19 and DI-64].
f) The Safety Management has to ensure that procedures and organisational structures are defined in an emergency manual in order to be able to deal with nuclear or conventional events in the best possible way. The extent of the emergency measures is to be adapted to the possible extent of damage. Among other things, the following has to be done: i) designate clear communication and decision-making channels, ii) define clear responsibilities, iii) define material supply and transport routes, iv) make proxy arrangements, v) coordinate the involvement of external organisations, vi) provide for mutual aid agreements; and vii) organise interaction with the public.	to f) Additional requirements for the emergency manual can be found in [17]. In each phase of operation, unforeseen events can occur that require quick and structured action. The term mutual aid is defined in [4, Ch. 3.148].

4.3 Safety objectives

Requirement	Explanation
a) The safety objectives have to be defined in such a way that the safety-relevant and safety-oriented requirements valid at the time are covered.	to a) Safety-relevant requirements (in particular from a mining and nuclear technology perspective and for occupational health and safety) from outside result i.a. from: i) international standards and regulations, ii) national statutory regulations, iii) the non-mandatory regulations drawn up for this purpose,

	iv) the application of accepted rules and regulations from mining and nuclear technology, v) the quantities of waste to be conditioned, stored or disposed of (waste streams according to [18]), their chemical and radiological composition, vi) the current age and condition of the waste, vii) the boundary conditions according to the state-of-the-art in science and technology, viii) the financial framework conditions as well as ix) the expectations of society as a whole. In addition, there may be safety-relevant requirements from the waste management organisation itself due to x) the safety policy in place in the management system, xi) the internal strategies, mission statements, plans set by the top management, xii) the boundary conditions set by the organisational structure (e.g. available human resources), xiii) internal regulations for the evaluation and control of suppliers and the Safety Management or quality management implemented there, or xiv) additional requirements derived for the waste management organisation itself (e.g. with regard to occupational safety or radiation protection).
b) For each safety objective, it has to be stated by what and how it is fulfilled and by which system indicators success is measured.	to b) The documentation of the fulfilment serves for the comprehensibility and transparency of the internal pursuit of the safety objectives [12].
c) The safety objectives have to be documented; in the process, it has to be recorded how the safety-relevant and safety-oriented requirements valid at the time are fulfilled and how the	to c) Documentation includes the source, topicality and relevance of the safety objectives or the safety-relevant and -oriented requirements.

requirements and the derived safety objectives are related (source, topicality, relevance).	
d) The safety objectives have to be adapted to the changing requirements over time.	to d) Changes in the requirements listed under a) have to be taken into account. The system indicators are to be adjusted as necessary and reviewed on an ongoing basis to ensure that the safety-oriented purpose of the indicators used is maintained.

4.4 Systems analyses

Requirement	Explanation
a) It has to be ensured by means of systems analyses that safety is regularly reviewed with regard to the Safety Management for all facilities and activities in the sense of a graded approach.	to a) Systems analyses in relation to the Safety Management (Ch. 3) aim to identify hazards at an early stage, to assess their probability of occurrence and extent of damage (cf. Fig. 1) (if necessary also qualitatively or semi-quantitatively) and from this to estimate the risk to the waste management organisation. These include the systematic analysis of normal operation and its effects, the way in which failures have occurred or may occur, and the consequences of such events [1, Ch. 3.15]. Systems analyses of the waste management organisation include, in particular: i) proof that the safety requirements are fulfilled, ii) proof that the installations comply with the planning principles and requirements, iii) the presentation of operational incidents or accidents, their cause, root cause analysis and corrective measures taken, iv) changes to the waste management organisation, v) the importance of assessing human reliability, vi) the justification and documentation of aspects that lie outside the scope of

	consideration of the safety analyses according to [5].
b) Within the framework of the Safety Management, provision has to be made for the performance of analyses of the safety of the repository system (operational safety analyses and long-term safety analyses).	to b) The safety analyses according to [5, §§ 8, 9] are to include e.g. facility states of the repository (operational safety), scenario and model development (long-term safety) for the assessment of performance and robustness or the presentation of uncertainties in the assessment. Operational safety analyses take into account changes to installations, systems and components, new findings from research and development, as well as monitoring, maintenance, testing, inspection and ageing management programmes. Further, MTO factors and changes in operational procedures are considered.
c) As a result of the systems analyses, it has to be demonstrated that the range accepted as safe has been reached and that the condition can be considered stable.	to c) The verifications are based on the safety objectives (Ch. 4.3) and system indicators (Ch. 4.5) defined in the Safety Management. The accepted range is shown in Fig. 1.

4.5 System indicators

Requirement	Explanation
a) The Safety Management has to define and apply system indicators.	to a) The definition and application is based on the methodology described in [19]. The system indicators are an important tool to assess whether the range accepted as safe (Fig. 1) is reached with the current Safety Management. Periodic or continuous application and monitoring of the system indicators points to possible improvements and/or deteriorations. This makes it possible to initiate corrective measures (according to [4, Ch. 3.54]) at an early stage before an unacceptable risk arises for the waste management organisation, and to assess the effect of the corrective measures. Specific indicator trends recorded over a period of time can provide an early warning for the management to investigate the causes behind the observed changes. System indicators can be derived, among other things, within the framework of systems analyses, on the basis of damage events and regulatory requirements. Furthermore, system indicators can be used in a cross-facility comparison. In addition to comparisons with other repository projects, depending on the indicator, comparisons with underground facilities and/or nuclear installations can also be useful in terms of continuous improvement (cf. Ch. 4.8).
b) Conditions and/or limit values are to be defined for the system indicators, compliance with which can be checked accordingly.	to b) It may be necessary to record reference values or time series of environmental parameters at an early stage (baseline measurement or measurement of natural fluctuations).
c) The system indicators have to be adapted to the changing safety objectives and their effectiveness has to be reviewed continuously.	to c) Antagonistic effects should be avoided when developing indicators and interpreting results. The number of reported accidents as an indicator of safety can e.g. have opposite effects: Accidents may actually be actively avoided or accidents may be declared irrelevant,

	be trivialised or not be reported at all.

4.6 Resources

Requirement	Explanation
a) The Safety Management has to ensure that sufficient human, administrative, financial and technical resources are provided to meet the externally and internally imposed safety requirements.	to a) The Safety Management is to work towards ensuring that employees are regularly motivated to promote resilient action and increase the level of safety through their flexible actions [16].
b) The Safety Management has to work towards ensuring that the manpower and technical equipment are coordinated with each other. The employees have to be trained accordingly on the equipment used.	to b) The term training is defined on the basis of [4, Ch. 3.265].
c) The Safety Management has to work towards planning personnel resources for the long term. Appropriate measures must be taken to maintain competence.	to c) The tasks of a waste management organisation shift over time. Knowledge transfer must be ensured over the period of the work (cf. [18, Ch. 3.1.3]). New ideas and empirical knowledge should be in constant exchange with each other.
d) The Safety Management has to work towards adapting the requirements for the installations, systems and components to the intended work and its duration. Regular functional checks have to be carried out.	to d) Installations are to be understood as part of the infrastructure [4, Ch. 3.117] that continuously adapts to the organisation and its operation. The Safety Management has to ensure that the installations used for exploration and planning, construction, operation and decommissioning are regularly maintained and that measuring instruments are calibrated. The installations for safety-related activities have to be maintained in a condition in which they are ready for use at all times.
e) For safety-relevant activities, the skills of the personnel required for the respective phase of repository realisation are to be kept available redundantly on the basis of the Safety Management, so that expected and unexpected absences can be absorbed.	to e) Safety-relevant activities ensue from their influence on the safety objectives or on the safety indicators describing them.
f) The Safety Management has to ensure that in the case of personnel changes and transitions	to f) The realisation phases and their requirements for the Safety Management are presented in Ch.

from one realisation phase to the next, persons with the appropriate suitability are hired and safety-relevant work is only implemented after sufficient training.	5. Superiors ensure that new employees are informed about the waste management organisation's internal safety policy and have sufficient time to internalise the safety culture that is lived within the organisation.
g) The Safety Management resources have to be proactively adjusted to foreseeable future developments.	to g) The requirement refers to [13, DI 10 and DI-11, 13]. In this context, it should also be ensured that uncertainties in the context of suppliers of materials and labour are identified and addressed at an early stage and that, in view of the long operating periods of repository projects, appropriate solutions for possible safety-relevant failures on the part of suppliers are prepared by the Safety Management in good time so that supply chains [4, Ch. 3.251] are not interrupted and all necessary resources are available at all times.
h) It has to be ensured that detailed descriptions of the requirements exist for safety-relevant materials and services, the validity of which has to be checked periodically.	to h) If required, suppliers have to be assessed periodically with regard to their conformity with the requirements.
i) The Safety-relevant installations must be kept redundant and regularly maintained, and redundant measuring devices must be calibrated regularly.	to i) The safety relevance of an installation results from its influence on the safety objectives or on the system indicators describing them. The use of safety-relevant installations and measuring devices is to be exercised on a regular basis.

4.7 Documentation

Requirement	Explanation
a) The Safety Management and the results achieved therefrom for safety have to be documented.	to a) Documentation is to be carried out in accordance with [20]. The aim of the documentation is the traceability of all information required for safety-oriented disposal and, if necessary, retrieval or salvage [6, § 26 (2)]. This also includes information on which alternatives were not considered in decisions and why. Furthermore, it is important to enable transparency and intergenerational knowledge transfer as well as to fulfil possible requirements for the preservation of evidence.

	The Safety Management is to be documented in a separate document or as a separate part of the overall management system. Security interests and data protection rules are to be taken into account.
b) The Safety Management documentation must be accessible to all persons in the waste management organisation and must be easily and unambiguously comprehensible and user-friendly.	to b) The accessibility and user-friendliness is to follow [20, Section 3.1 (1)].
c) The documentation on the Safety Management of a waste management organisation must include at least the following: i) all relevant legal and regulatory requirements for safety, ii) all internal requirements of the waste management organisation for the handling of radioactive waste, iii) a description of the objectives and principles of the safety policy and the measures taken to achieve them, iv) all descriptions of the processes and activities responsible for safety, including the infrastructures and responsibilities assigned to them, v) all resources and processes used for review as well as the responsibilities defined for it and the means provided for logging, vi) all processes for safety-related improvement and regular revision of the Safety Management, vii) safety-relevant experiences and changes derived from them in the sense of a continuous improvement process and viii) all resources and mechanisms required for documentation, including archiving requirements.	to c) The scope of the documentation and the archiving of the documents are to be determined in accordance with the intended uses within the waste management organisation or with external requirements (e.g. [6, Section 38] and the safety relevance. The scope of the documentation is to be oriented analogously on [20, Section 3.1 (2)].
d) The Safety Management documentation always has to describe the current state of construction	to d) The Safety Management has to ensure that the pertaining documentation cannot be changed

and operation. It has to be kept available at all times and unauthorised persons must not be able to change the documentation.	without authorisation, despite its up-to-dateness and continuous availability.
e) The documents on the current facility have to include at least: i) all details of the radioactive waste present in the facility, ii) the geoscientific data and samples collected for the exploration of the site (and, if necessary, the immediate geological surroundings) and during underground excavation, iii) the results of the data collected during the monitoring and details of any non-conformities that have occurred, iv) in the case of repositories where emplacement has begun, additionally the exact method of emplacement and the geo-referenced position of all radioactive waste in the repository, v) detailed plans of the underground installations, including the drift supports and backfill used, vi) descriptions of the barrier systems to be used or actually used for disposal and the materials provided or used therein (including corresponding samples), vii) the current safety case and the associated safety analyses as well as a description of which programs and data were used to perform these analyses, viii) a complete documentation of decisions and the reasons behind them, ix) a complete documentation of the persons in charge of safety, including their responsibilities and acquired expertise as well as x) regulations and descriptions regarding emergency management.	to e) The documentation on the current facility is not necessarily part of the Safety Management documentation but should be available for safety-related questions at any time and linked to the Safety Management documentation. Requirements for the safety analyses mentioned in (vii) are set out in [5].

f) The documentation of the Safety Management has to be updated during all phases of the realisation of the repository. When the facility is decommissioned, the documentation has to be transferred to permanent safekeeping.	to f) All data and documents (safekeeping data) relevant to disposal have to be made available to the Federal Office for the Safety of Nuclear Waste Management [6, § 38].

4.8 Quality assurance

Requirement	Explanation
a) The Safety Management must be continuously improved in a quality-assured manner.	to a) In terms of a continuous improvement of the company's performance (here in relation to the targeted safety aspects), quality assurance is systematically reviewed and continuously improved using established methods (e.g. PDCA cycle [8]). The aim of quality assurance is to ensure that the Safety Management is carried out reliably at a consistently high level. The establishment of concrete objectives and definitions as well as operational plans allows for the implementation of quality assurance performance reviews and, if necessary, the derivation of corrective actions if deviations are identified.
b) Persons responsible for quality assurance of the improvement process within the Safety Management have to be designated both internally and externally.	to b) Integration of quality assurance into the quality management of the waste management organisation (e.g. as part of the integrated management system) is permissible, provided that the documents important for the Safety Management remain accessible to the latter. There must be no dependencies between controlling and controlled entities and the standards agreed in advance are to be adhered to. The persons carrying out the quality assurance are to be appropriately trained and familiarised with the necessary mechanisms of the Safety Management. If these persons come from the waste management organisation itself, it is to be ensured that they are provided with the necessary time resources, competences and accessibility for this work, which may not be subject to any directives. To ensure knowledge

	maintenance and innovation capacity, teams of internal and external auditors shall be composed of persons of different ages and levels of experience.
c) Data, events and experience from comparable facilities at home and abroad have to be used to verify the effectiveness of the Safety Management.	to c) Events and experiences of a negative as well as positive nature are to be taken into account. The system indicators established for the Safety Management (cf. Ch. 4.5) can also be used.
d) The measures derived from the Safety Management review have to be communicated and implemented internally and, if necessary, externally.	to d) The effectiveness of the measures is to be reviewed in a timely manner.
e) In the event of major organisational changes, the various interfaces and responsibilities must be reviewed and it must be clarified to what extent such changes influence the level of safety.	to e) The safety level is determined on the basis of the system indicators or results from minimising the probability of occurrence and the extent of damage (Fig. 1).

5 Phases of repository realisation

Requirement	Explanation
a) The Safety Management has to establish processes that will shape the individual realisation phases of a repository as a self-learning and constantly optimising procedure.	to a) The realisation phases are site selection, exploration and planning (Ch. 5.1), construction (Ch. 5.2), operation (Ch. 5.3), and decommissioning (Ch. 5.4). The processes should be safe and in accordance with all safety objectives (Ch. 4.3). The transitions between the realisation phases are not clearly defined but can overlap in time. This applies, for example, to the site selection period described in [6] as this includes both the exploration and planning phases on the one hand and the construction phase on the other. Accordingly, the term "phase" in this guideline does not refer to the phases of the site selection procedure [6].
b) The Safety Management has to ensure that during the phases of construction and operation, the Safety Management report is prepared in accordance with defined processes, the data	to b) The Safety Management report of the facility has to be reviewed regularly with regard to content, up-to-dateness concerning work already carried out and, if applicable, changes in the

collections and modelling are incorporated in a quality-checked manner, and the uncertainties are adequately taken into account.	regulatory requirements. The results of such reviews have to be documented and checked at the next review for the implementation of any points of criticism that may have been raised. When reviewing the Safety Management report, it must be checked in particular to what extent assumptions can be replaced by facts that have already been collected.
c) For the phase transitions, the responsibilities for the phases must be defined and regulated in good time.	to c) The Safety Management is to maintain a continuous chain of defined responsibilities in the overall system of the various waste management steps (Ch. 2) throughout all phases of repository realisation (Ch. 4.8). At the interfaces between the different realisation phases, responsibilities may change and it is to be clarified at each of these changes how the safety objectives change.
d) The Safety Management has to establish processes with whose help the system status can be determined at any time.	to d) The facility status comprises i.a. the system indicators as well as all radioactive waste inside the facility and its current location. Determining the facility status ensures that the facility meets the requirements placed on it and the licences issued to the waste management organisation.
e) The Safety Management has to ensure that the respective contractors working on the site know what is expected of the personnel they provide, the equipment, and the implementation of their orders with regard to safety.	to e) The responsibility for safety-relevant processes in the repository or in supervision cannot be delegated externally [2, § 7c(1)]. Nevertheless, the waste management organisations will be dependent on services and supply chains of external companies to a varying extent. To the extent necessary, the management systems of the external companies and their internal mechanisms may have to be subjected to quality control audits. This quality control should ensure that the external work meets the safety standards of the waste management organisation.

5.1 Site selection, exploration and planning

Requirement	Explanation
a) The top management of the waste management organisation has to ensure that a Safety Management is developed, documented, communicated and implemented in accordance with this guideline, in which the safety-relevant processes and activities are presented in a manner that is appropriate to each level and comprehensive.	to a) Already during site selection, exploration and planning, the top management of the respective waste management organisation bears comprehensive responsibility for establishing a high level of safety within the waste management organisation that meets all requirements and for its active implementation towards a safe repository system.
b) In the integrated management system (cf. Ch. 4) of the waste management organisation, measures have to be included that resolve potential conflicting objectives in the sense of the best-possible safety.	to b) The task of the Safety Management is e.g. to compare scheduling with safety concerns and to point out any inconsistencies or contradictions. In case of any conflicting objectives, the principle of "safety first" applies.
c) Assumptions must be made in the planning process and identified as such in the Safety Management.	to c) The assumptions made are to be reviewed regularly and clarification, exploration, development or research work on the assumptions is to be initiated at an early stage in order to successively reduce the scope of assumptions made [5, § 11(3)]. For this purpose, research and development strategies are drawn up and regularly reviewed for their topicality on the basis of the results obtained. These strategies are to identify the remaining safety-relevant knowledge gaps and to schedule the resulting research and development activities that are currently ongoing and planned. For all research and development activities, it is to be ensured that the work is carried out with the necessary care and quality and that the results and quality controls are documented in transparent and comprehensible reports (cf. Ch. 4.7). Depending on the significance of the research and development results for safety, reviews and quality controls are to be carried out by the waste management organisations. Irreversible decisions are only to be taken when research and development results provide a clear basis or when there is no longer any need for continued flexibility.

d) Applying the Safety Management, processes have to be developed or established procedures have to be used with the help of which the repository design can be continuously reviewed and adapted in a safety-oriented manner to the results of the ongoing site characterisation and other changing boundary conditions.	to d) Site selection and site characterisation are dynamic processes that require great flexibility for the repository design, especially at the beginning. The uncertainties arising from geological exploration are to be taken into account and the corresponding flexibility is to be provided in planning and construction, and the necessary margins with regard to safety are to be taken into account in the long-term safety to be achieved with the design of the facility.
e) The Safety Management has to ensure that a method for the preparation of the safety report is developed at an early stage so that the safety level during construction, operation and also in the long-term evolution can be determined.	to e) The content of the safety report is defined in [21, § 3(1)] (cf. also [5, § 2(7)]). The methodology is to clearly separate incoming data (and their origin), models and assumptions, and the effects of uncertainties are to be shown. The aim is that the Safety Management ensures that the safety report is continuously updated on the basis of new findings.

5.2 Construction

Requirement	Explanation
a) The Safety Management shall establish processes or support established processes to ensure that during the ongoing construction of the repository, the execution planning is implemented as accurately as possible so that the safety objectives can be achieved.	to a) The Safety Management is to be adapted to the work relevant to construction in good time before the start of the construction phase.
b) When excavating the repository, new (more detailed) findings have to be checked against the safety report and taken into account accordingly.	to b) For the content of the safety report, see also [21, § 3(1)] and [5, § 2(7)]. The presentation of the geology and the underground structures should be continuously adapted to the conditions actually encountered or arising during construction.
c) Based on the Safety Management, to support the safety report, monitoring measures have to be provided during construction which continuously collect safety-relevant data and allow a detailed target-performance comparison.	to c) The monitoring measures ensure that the status of the facility can be determined at any time during construction and that the facility complies with the requirements and licences

	imposed on it. For the content of the safety report, see [21, § 3(1)] and [5, § 2(7)].
d) The Safety Management shall work towards the continuous optimisation of processes in connection with the excavation of new or the maintenance of existing underground caverns in terms of operational and long-term safety.	to d) The surrounding host rock and its barrier effect should be damaged as little as possible by the excavation of underground cavities [5, § 9 (2)]. To this end, safety standards are drawn up that i) make the safety-relevant aspects clearly recognisable for planners and owner(s) and ii) sensitise the persons involved in the construction to the safety requirements. Planning and actions in the initial phase of construction activities should be carefully reviewed at appropriate stages through quality assurance processes.

5.3 Operation

Requirement	Explanation
a) The Safety Management has to be expanded before the start of the operational phase and has to be applied to all safety-relevant work in this phase.	to a) The safety-related work [14] comprises all activities of the repository with regard to operational and long-term safety, in particular the work on the acceptance and emplacement of the waste. The Safety Management has to ensure that safe handling and control is established for all radioactive materials and waste.
b) The Safety Management has to ensure that all waste emplaced complies with the acceptance criteria and that the individual packages/containers are clearly labelled.	to b) This is to ensure that a clear allocation is possible upon emplacement and in case of retrieval or salvage [6, § 26 (2)].
c) For underground work, the Safety Management has to provide for a clear separation between the work of excavating new cavities and maintenance measures on the one hand and the processes of emplacement on the other.	to c) During the emplacement operation phase, further construction work could take place, which means a coexistence of conventional and non-conventional work. These should be clearly separated in terms of space and/or time. Maintenance measures are activities without a planned radiological hazards.

	Emplacement processes are activities with possible radiological hazards.
d) The Safety Management must work towards ensuring that the processes are automated as far as possible, in particular during conditioning in compliance with the requirements for repositories and during emplacement.	to d) The aim is to achieve the lowest possible risk for the personnel involved through extensive automation [14].
e) In the case of processes with an increased safety risk or the possibility of an increased radiological hazard, the Safety Management has to ensure that the processes are carefully planned and, if necessary, only carried out after prior cold handling.	to e) Cold handling is intended to ensure trial operation [5, § 16]) so that the work steps are known, practised and optimised with regard to radiation protection and safety risks before working with radioactive waste. Even after the transition to active operation, individual processes are to be monitored in accordance with the respective stages, and stopping points are to be provided in order to carry out checks and, if necessary, to be able to make safety-related modifications. In the case of major modifications, renewed cold handling is also to be provided as required so that the modifications will not lead to a reduced safety level.
f) On the basis of the Safety Management, logistical and constructional provisions to ensure retrievability and the possibility of salvage have to be made that do not significantly affect long-term safety.	to f) The requirement to ensure retrievability and the possibility of salvage refers to [6, § 26 (2)]. For the requirement of retrievability, scenarios are to be developed on the basis of which the need for retrieval could arise. The term "scenarios" is defined on the basis of [4, Chapter 3.217].
g) The Safety Management has to ensure that appropriate monitoring measures are used to determine the status of the facility and to fulfil the requirement of retrievability in order to assess the situation in the repository for the safety report and with regard to the necessity of retrieval.	to g) Processes must also be established on how to deal with situations where these measurements show that the facility does not behave as expected. For the content of the safety report, see [21, § 3(1)] and [5, § 2(7)].
h) The Safety Management has to ensure that the installation of the planned technical and geotechnical barriers is quality-assured.	to h) In addition to monitoring the installation, the processes planned also include the provision of the necessary materials.

5.4 Decommissioning

Requirement	Explanation
a) The Safety Management has to be adapted to the safety-relevant work in this phase before the start of decommissioning.	to a) Safety-relevant work [14] includes all decommissioning activities related to long-term safety.
b) The Safety Management has to ensure that the measures for decommissioning the facility are embedded in the management processes at an early stage and that the work is carried out in a quality-assured manner.	to b) Measures for decommissioning the facility have to be carried out in accordance with [5, § 19]. The work may include research and development activities as organisational activities.
c) The Safety Management has to ensure that requirements are formulated in advance for the materials used in decommissioning, that the effect of the elements critical to long-term safety is tested at an early stage during decommissioning, and that their implementation is monitored.	to c) This requirement applies in particular to the materials used in the sealing structures. For testing the effect, see [5, § 16 (2), No. 3].
d) The Safety Management has to ensure that prior to the backfilling of the emplacement areas, all necessary data on the condition of the waste emplaced, the supports, the backfills and the sealing structures are available before they are no longer accessible for a survey.	to d) The requirement results from the necessity of backfilling the emplacement area according to [5, § 19 (2)].
e) The Safety Management has to ensure that a final Safety Management report is prepared after completed decommissioning, taking into account the backfilling and closure work that has effectively been carried out.	to e) The final Safety Management report may be part of the documentation for permanent storage pursuant to [6, § 38]. This report has to include information within the meaning of [5, § 14 (2), No. 2] and all information necessary for a possible salvage of the waste.

6 List of documents

[1] International Atomic Energy Agency
Fundamental Safety Principle
Safety Fundamentals SF-1, Wien, 2006.

[2] AtG
Gesetz über die friedliche Verwendung der Kernenergie und den Schutz gegen ihre Gefahren
Atomgesetz in der Fassung der Bekanntmachung vom 15. Juli 1985 (BGBl. I S. 1565), das zuletzt durch Artikel 6 des Gesetzes vom 27. Juli 2021 (BGBl. I S. 3146) geändert worden ist.

[3] Kommission Lagerung hoch radioaktiver Abfallstoffe
Abschlussbericht
Deutscher Bundestag, Drucksache 18/9100, 19.07.2016, 579 S.

[4] Deutsches Institut für Normung e. V.
Sicherheit und Resilienz – Vokabular (ISO 22300:2018);
Deutsche Fassung EN ISO 22300: 2018-06.

[5] Verordnung über Sicherheitsanforderungen und vorläufige Sicherheitsuntersuchungen für die Endlagerung hochradioaktiver Abfälle vom 6. Oktober 2020 (BGBl. I S. 2094)

[6] StandAG:
Standortauswahlgesetz vom 5. Mai 2017 (BGBl. I S. 1074), das zuletzt durch Artikel 1 des Gesetzes vom 07. Dezember 2020 (BGBl. I S. 2760) geändert worden ist.

[7] Kerntechnischer Ausschuss
Integriertes Managementsystem zum sicheren Betrieb von Kernkraftwerken
Regel KTA 1402, Fassung 2017-11.

[8] Kerntechnischer Ausschuss
Alterungsmanagement in Kernkraftwerken
Regel KTA 1403, Fassung 2017-11.

[9] Bundesministerium für Umwelt, Natur und Reaktorschutz (BMU)
Grundlagen für Sicherheitsmanagementsysteme in Kernkraftwerken
Bonn, 29. Juni 2004 (BAnz 2004, Nr. 138).

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Disposal of radioactive waste
Safety Standard SSR-5, Wien, 2011.

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Leadership, Management and Culture for Safety in Radioactive Waste Management
Draft Safety Guide DS 477, 07.04.2020.

[12] International Nuclear Safety Advisory Group
Management of Operational Safety in Nuclear Power Plants
INSAG-13, Wien, 1999.

[13] WENRA
Radioactive Waste Disposal Facilities Safety Reference Levels
Report der Western European Nuclear Regulators' Association, 22.12.2014.

[14] ESK
Leitlinie zum sicheren Betrieb eines Endlagers für insbesondere Wärme entwickelnde radioaktive Abfälle, Empfehlung der Entsorgungskommission vom 10.12.2015.

[15] IAEA
Report of the integrated Regulatory Review Service (IRRS) Mission to Germany
IAEA-NS-IRRS-2019/02, 1.- 12. April 2019.

[16] Eurocontrol 2013
From Safety-I to Safety-II: A White Paper
Technical Report, DOI: 10.13140/RG.2.1.1626.6961, September 2013.

[17] Kerntechnischer Ausschuss
Anforderungen an das Notfallhandbuch
Regel KTA 1203, Fassung 2009-11.

[18] Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit
Programm für eine verantwortungsvolle und sichere Entsorgung bestrahlter Brennelemente und radioaktiver Abfälle (Nationales Entsorgungsprogramm)
August 2015.

[19] International Atomic Energy Agency
Operational Safety Performance Indicators for NPPs
IAEA-TECDOC-1141, Vienna, 2000.

[20] Kerntechnischer Ausschuss
Dokumentation beim Bau und Betrieb von Kernkraftwerken
Regel KTA 1404, Fassung 2013-11.

[21] AtVfV
Verordnung über das Verfahren bei der Genehmigung von Anlagen nach § 7 des Atomgesetzes vom 01. Mai 1982 (BGBI. I S. 411), das zuletzt durch Artikel 3 vom 11.11.2020 (BGBI. I S. 2428) geändert worden ist.