# IAEA SAFETY STANDARDS

## FOR SAFETY ASSESSMENT

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International Atomic Energy Agency

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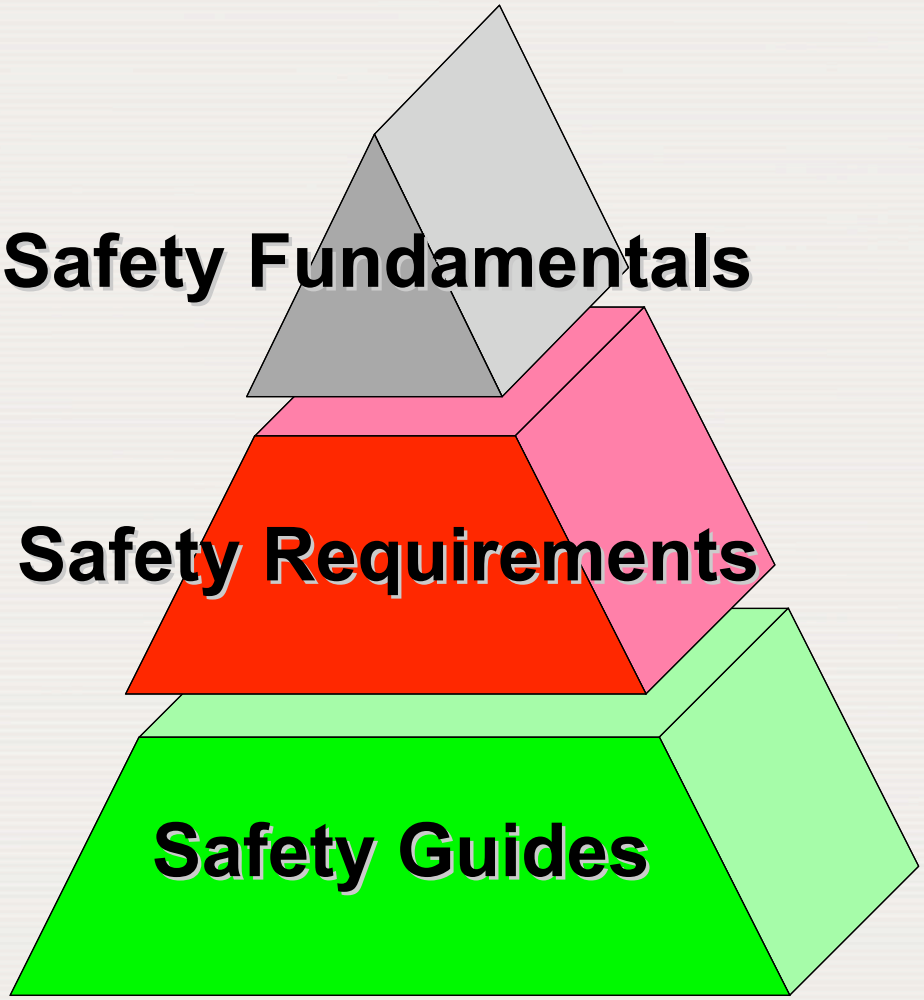
# IAEA Statute (Article III.A.6)

- "To establish or adopt… [in consultation with…] standards of safety for the protection of health and minimization of danger to life and property"

- "…and to provide for the application of these standards"

# Safety Standards Hierarchy




International References for a High Level of Nuclear Safety

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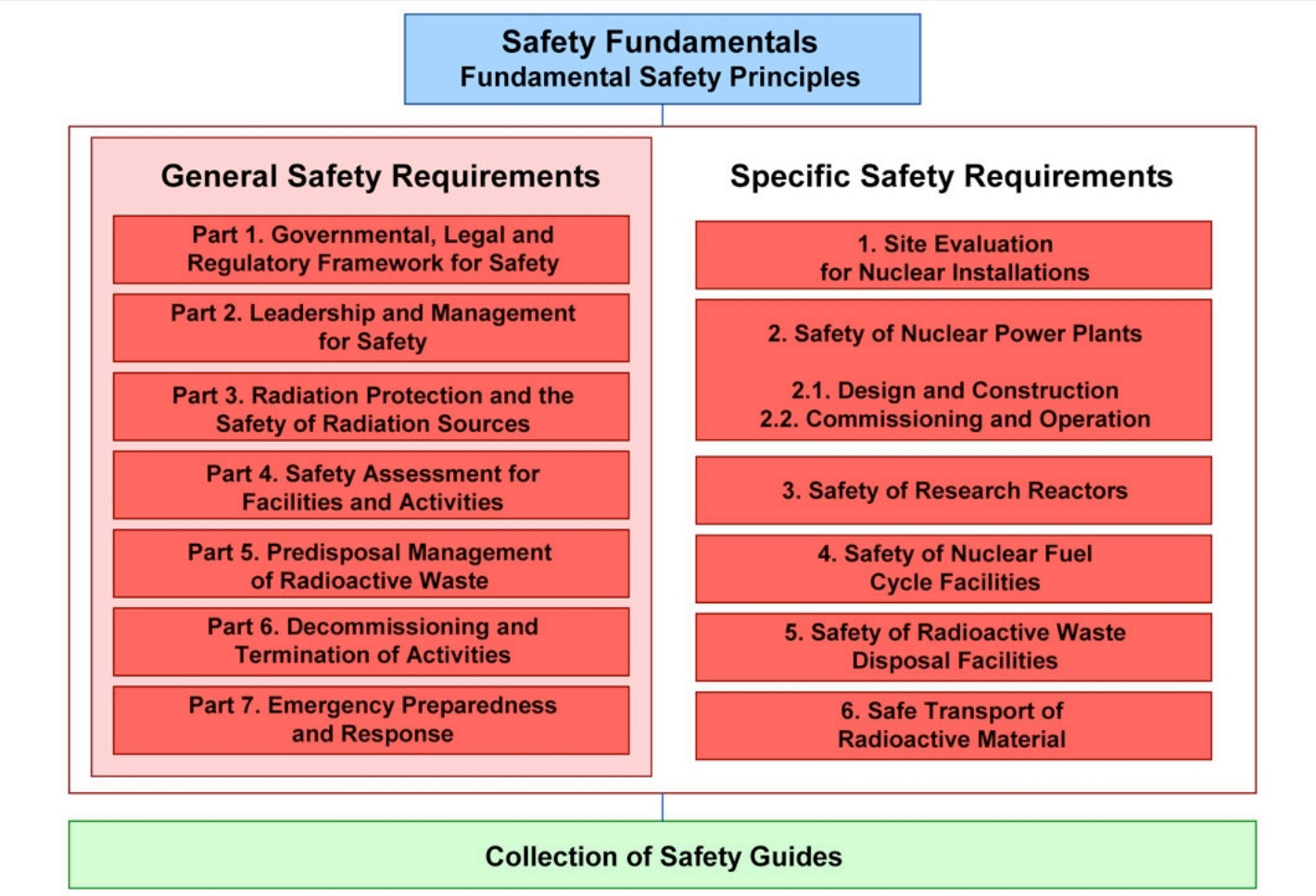
# Future structure of the IAEA Safety Standards

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# Development of Safety Standards

- Development process involving:
  - International Commission
  - International Technical Committees
  - Consultation of IAEA Member States
  - Recognized experts

- Member States approve standards through the Board of Governors or the Director General of the IAEA

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# Status of Safety Standards

Safety Standards represent international consensus on best international practices to achieve a high level of safety

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# Utilization by Member States

- Formally adopted (i.e. China, Netherlands)
- Direct use of standards to establish regulation (i.e. Canada, Czech Republic, Germany, India, Korea, Russian Federation)
- Used as reference for review of national standards and situations (by all States, also by Industry)
- Used by International Organizations (European Safety Directive, WENRA)

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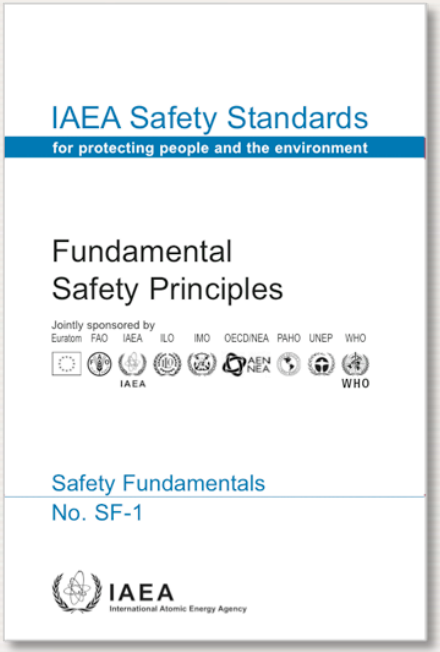
# SF-1 Fundamentals Safety Principles




Principle 5: Optimisation of protection

Principle 6: limitation of risk to individual

Principle 8: Prevention of accidents

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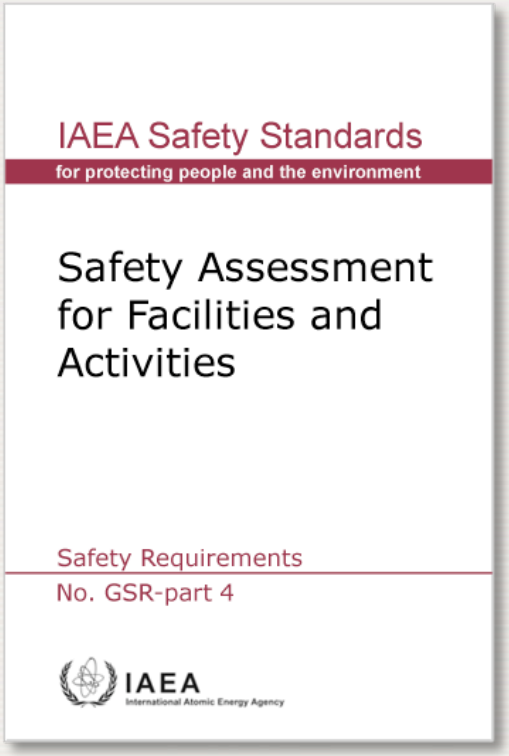
# Safety Assessment Requirements

To be implemented by the designer to fulfill the fundamental safety functions with the appropriate level of defence in depth




To be used by the reviewer of the design (e.g. Utility and Safety Authority) to assess the safety of the design

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# IAEA Safety Standards for Safety Assessment

***Fundamentals***

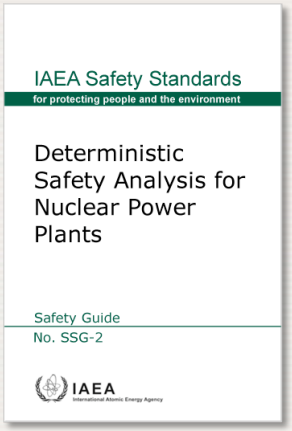
**Safety Principles**

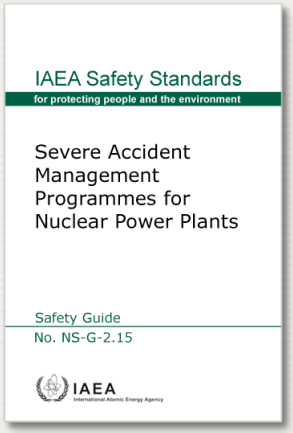
***Requirements***

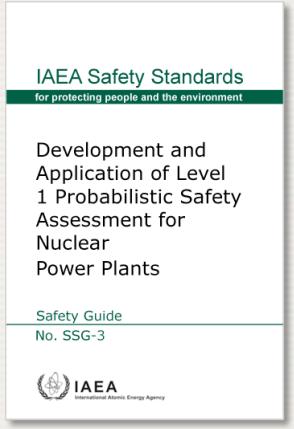
**Safety Assessment GS-R4**

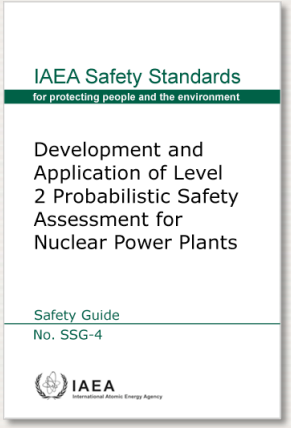
**Other Standards**

**Safety Guides (SGs)**

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# Safety Assessment Background

## Safety Fundamentals, Principles of Nuclear Safety and Radiation Protection. Safety Standards Series

- "*the fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation*".
- The Safety Fundamentals also defines ten principles that collectively state the conditions for achieving this fundamental safety objective.
- Safety assessments are to be undertaken as a means of evaluating compliance with these safety requirements for **all nuclear facilities and activities** and to determine the measures that need to be taken to achieve safety.
- Safety assessment need to be performed by the organization responsible for operating the facility or carrying out the activity, independently verified and submitted to the regulatory authority as part of the licensing process.

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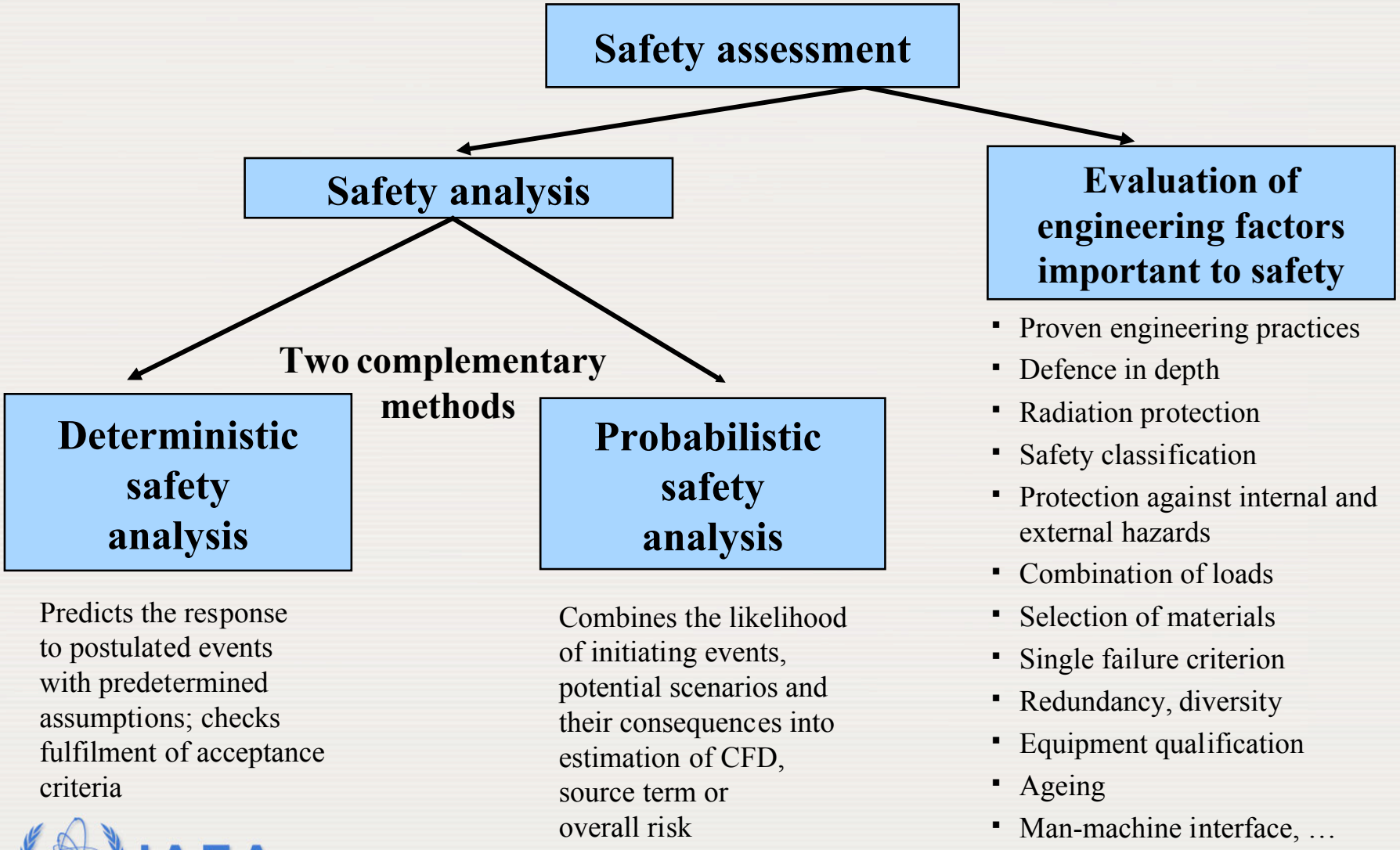
# Safety Assessment and Safety Analysis

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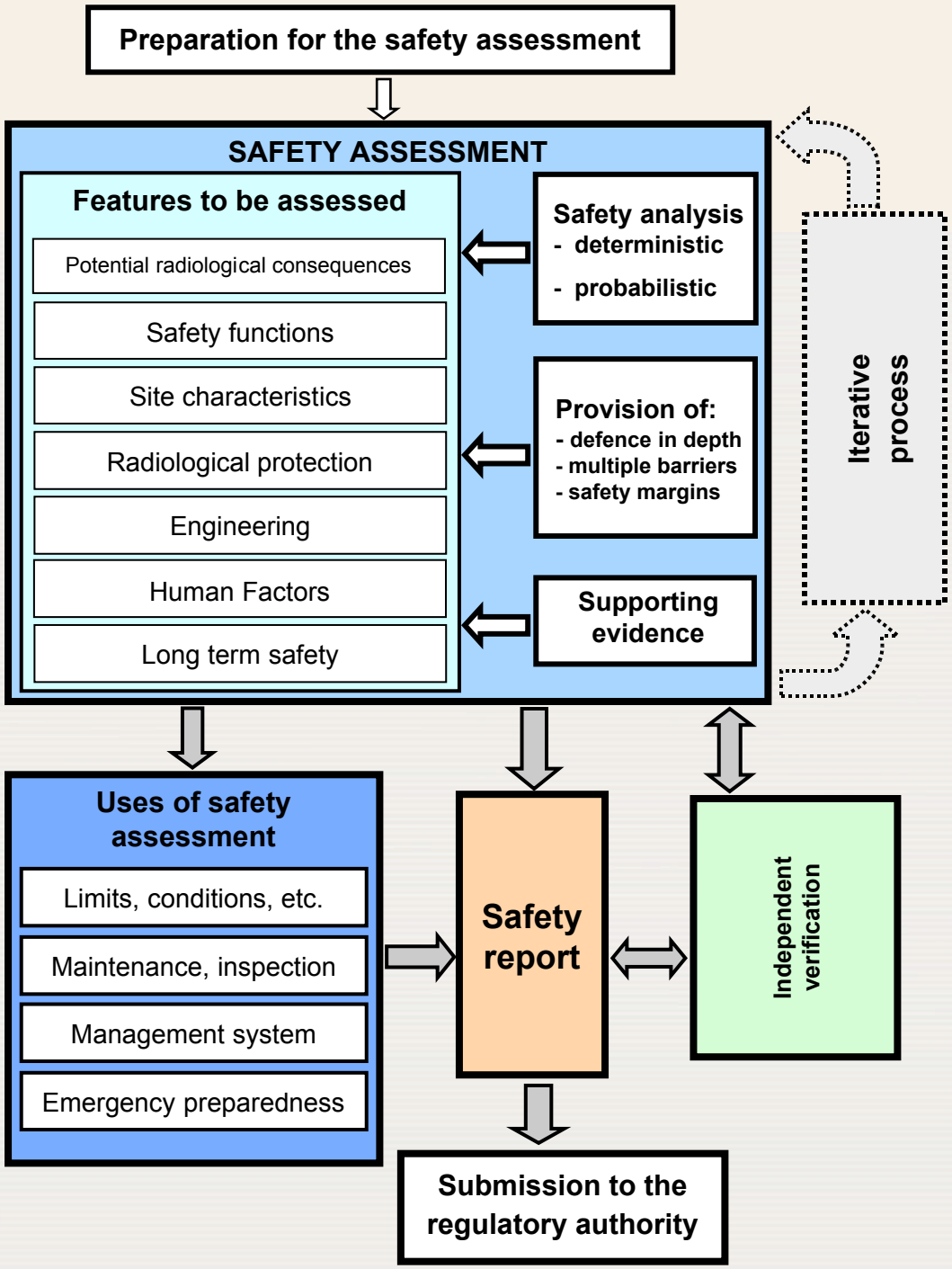
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Submission to the regulatory authority

# Requirements for a Safety Assessment

(1 of 12)

## OVERALL REQUIREMENTS

- Safety assessment shall be carried out for all applications of technology that give rise to radiation risks (facilities and activities).
- The responsibility for carrying out the safety assessment shall be with the person or organization authorized (licensed) to operate the facility or carry out the activity.
- The safety assessment shall have the primary purpose of determining 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 designers, the operator and the regulatory authority have been complied with.
- The safety assessment shall include an assessment of the radiological protection provisions to determine whether the radiological risks are being controlled within specified limits and whether they have been reduced to a level that is as low as reasonably achievable.
- The safety assessment shall address all the radiation risks that arise from normal operation and from abnormal and accident conditions.
- The safety assessment shall be carried out as early as possible in the lifetime of the facility or activity and shall be updated as necessary as the facility or activity passes through the stages of its lifetime.

# Requirements for a Safety Assessment

(2 of 12)

- The updating of the safety assessment shall also take account of operating experience including data relating to abnormal and accident conditions and accident precursors both from the facility or activity itself and from other similar facilities or activities.
- For facilities and activities that continue over long periods of time, the safety assessment shall be reviewed and repeated as necessary.
- The safety assessment shall identify all the safety measures necessary to control the potential radiological consequences. It shall determine whether the design and engineered safety features fulfill the safety functions required of them. It shall also determine whether appropriate measures have been taken to prevent abnormal or and accident conditions and whether the radiological consequences would be mitigated should they occur.
- The safety assessment shall address the radiation risks to all individuals and population groups.
- The safety assessment shall address the radiation risks now and in the future (i.e. waste).
- The safety assessment shall determine whether adequate defence in depth has been provided through a combination of several layers of protection, physical barriers, systems to protect the barriers and administrative procedures, which would have to be breached before harm could be caused to people or the environment.

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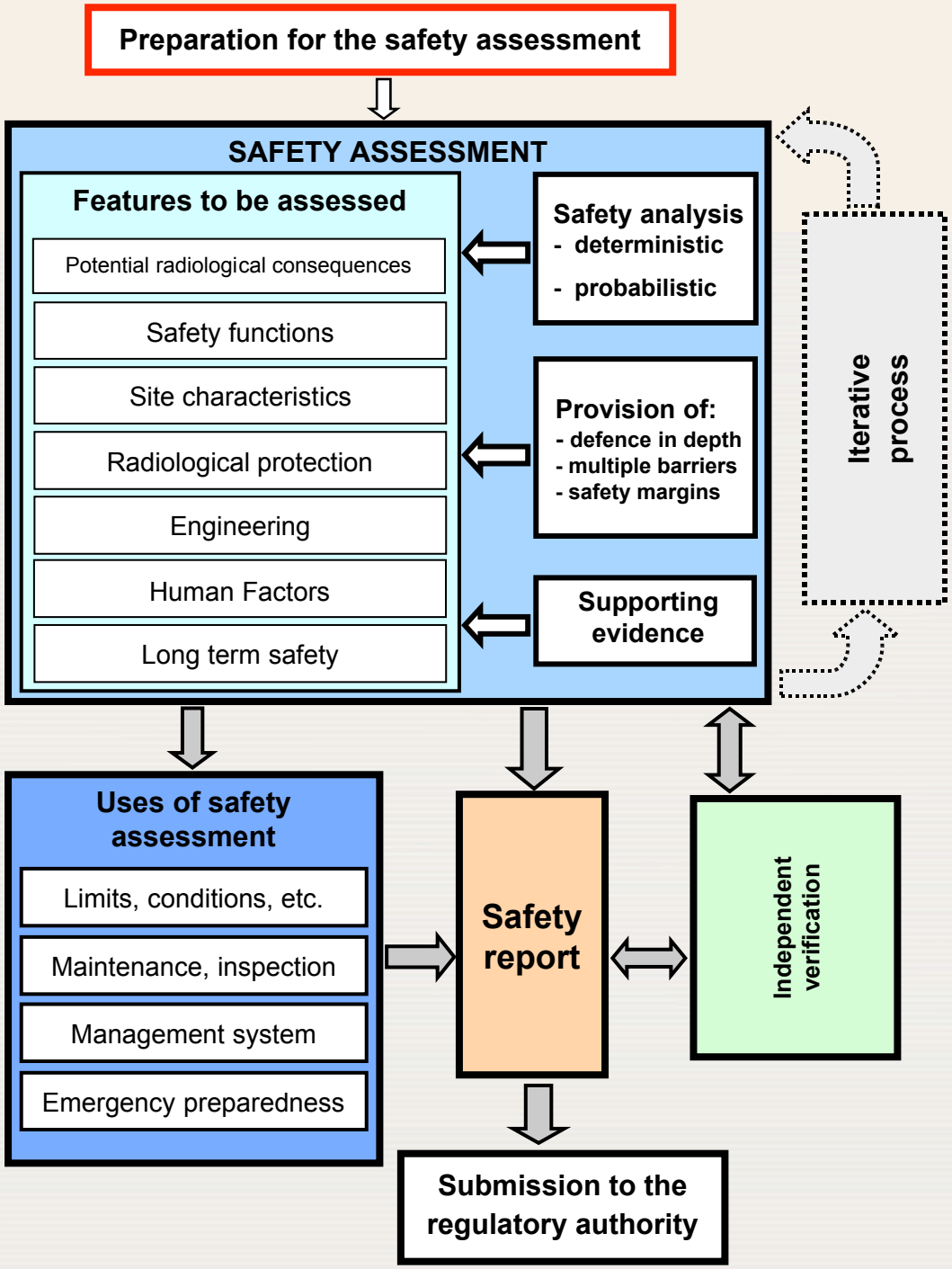
# Requirements for a Safety Assessment

(3 of 12)

- In most cases, the safety assessment includes a safety analysis, which consists of a set of different analyses that quantitatively evaluates and assesses challenges to safety under various operational, abnormal and accident conditions, using deterministic and probabilistic methods as appropriate.
- The computer codes that have been used to carry out the safety analysis shall be verified and validated and this will form part of the supporting evidence presented in the safety report. In the management system, the operator and the regulatory authority shall seek improvements to the tools and data that are used.
- The results of the safety assessment shall be used to identify appropriate safety related improvements to the design and operation of the facility or activity. They allow the assessment of the safety significance of unresolved shortcomings or of planned modifications and to determine their priority. They are used to provide the basis for continued operation.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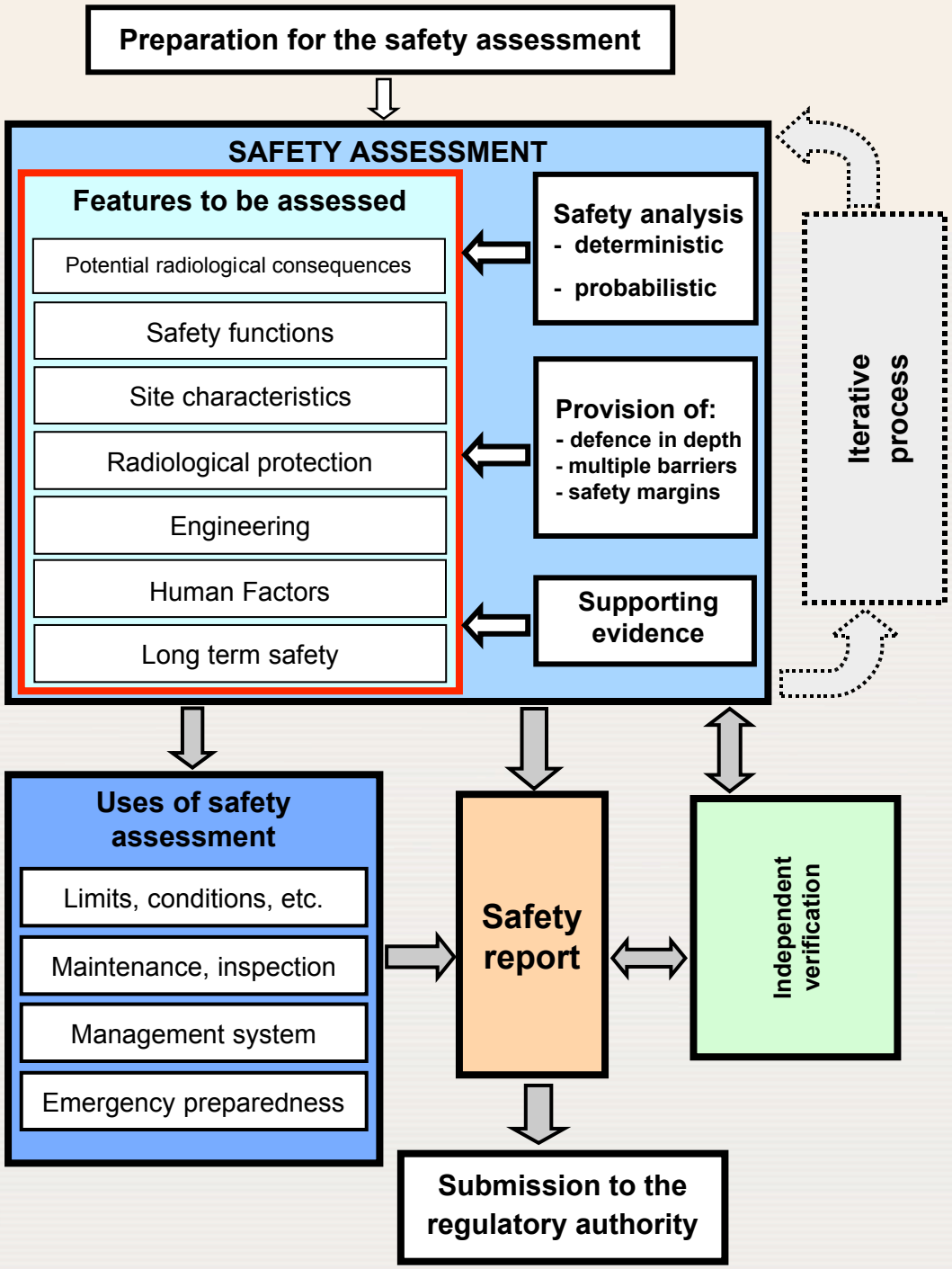
# Requirements for a Safety Assessment
(4 of 12)

***Preparation for the Safety Assessment***

- The first stage in carrying out the safety assessment is to make the necessary preparations. This shall include ensuring that:
  - There are sufficient skilled and expert people available to carry out the work;
  - The required background material is available. This includes all the information relating to the design and operation of the facility or activity;
  - The necessary tools for carrying out the safety assessment are available. This includes the computer codes required for carrying out the safety analysis; and
  - The criteria to be used for judging whether the safety of the facility or activity is adequate have been defined.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# Requirements for a Safety Assessment

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### *Identification of the Potential Radiological Consequences*

- The potential radiological consequences from the facility or activity shall be identified and assessed. This includes the radiation exposure to people and the release of radioactive material to the environment following the occurrence of abnormal or accident conditions that lead to a loss of control.

### *Assessment of Safety Functions*

- All the safety functions associated with a facility or activity shall be identified and assessed. This shall include the safety functions associated with the engineered structures, systems and components, any natural barriers as applicable, and any human actions required to ensure the safety of the facility or activity.
- The assessment of the safety functions shall determine whether they will be carried out with an adequate level of reliability, there is no vulnerability to a single failure or to a common cause failure for engineered equipment, and any structure, system, component or barrier provided to carry out a safety function has an adequate level of redundancy, diversity, separation, segregation, equipment qualification, etc. as appropriate.

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# Requirements for a Safety Assessment
(6 of 12)

## *Assessment of Site Characteristics*

- An assessment of the site characteristics related to the safety of the facility or activity shall be carried out and include:
  - The physical and chemical characteristics that will affect the dispersion or migration of radioactive materials released in normal operation or due to an incident or accident;
  - The identification of the natural and man-made hazards of the area that have the potential to affect the safety of any facility or activity; and
  - The site demographic characteristics in regard to any siting policy of the Member State and the need to determine an emergency plan.
- The scope and level of detail of the site assessment shall be consistent with the potential radiological consequences from the facility or activity, the type of facility or activity to be carried out and the purpose of the assessment (i.e. whether it is to determine whether a new site is suitable for a facility or activity, the safety evaluation of an existing site, the long term assessment of a site for waste disposal, etc.) and will be reviewed periodically during the lifetime of the facility or activity.

# Requirements for a Safety Assessment
(7 of 12)

***Assessment of the Radiological Protection Provisions***

- The safety assessment shall determine whether adequate measures are in place for a facility or activity to control the occupational radiation exposure of people – as required by the Fundamental Safety Objective.
- The safety assessment shall determine whether adequate measures are in place to control the occupational radiation exposure within any relevant dose limit and that the protection is optimized such that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures have all been kept as low as reasonably achievable, economic and social factors being taken into account.
- The safety assessment of the radiological protection provisions shall address normal operation of the facility or activity, and abnormal and accident conditions.

# Requirements for a Safety Assessment
(8 of 12)

## *Assessment of the Engineering*

The safety assessment shall:

- determine whether, to the extent possible, a facility or activity uses structures, systems, components and procedures of robust and proven design with previous successful application. Relevant operational experience, including results of root cause analysis of abnormal and accident conditions where appropriate, shall be taken into account;
- identify the design principles that have been applied to the facility and determine whether these requirements have been met;
- determine whether, where appropriate, a suitable safety classification scheme has been formulated and applied to the structures, systems and components
  - Importance to safety, the severity of the consequences of their failure
  - Identification of the appropriate industry codes and standards and the regulatory requirements that need to be applied in the design, manufacturing, construction and inspection of the engineered features or to the development of procedures and in their management system.

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# Requirements for a Safety Assessment
(9 of 12)

*Assessment of the Engineering (continued)*

The safety assessment shall:

- address the external hazards that could arise for a facility or activity, and determine whether an adequate level of protection is provided (natural external events and man-made events);
- address the internal hazards that could arise for a facility and determine whether the structures, systems and components are able to perform their function under the loads induced by the accidents that have been taken into account explicitly in the design of the facility;
- determine whether the materials used are suitable for their purpose with regard to the standards specified in the design and the operational conditions which arise during normal operation and following abnormal or accident conditions that have been taken into account explicitly in the design of the facility or activity.
- address whether preference has been given to a fail-safe design, or, if this is not possible, whether a means of detecting the failures that have occurred has been incorporated wherever possible.

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# Requirements for a Safety Assessment
(10 of 12)

***Assessment of the Engineering (continued)***

The safety assessment shall:

- determine whether any time related aspects such as ageing, wear-out or life limiting factors, such as cumulative fatigue, embrittlement, corrosion, chemical decomposition and radiation-induced damage, have been adequately addressed;
- determine whether the equipment important to safety has been qualified so that it is able to perform its safety function in the conditions that it would experience during normal operation and following the abnormal and accident conditions that have been taken into account in the design;
- identify the provisions made and the procedures defined for the decommissioning the nuclear facility and the closure of a repository for the disposal of radioactive waste, and determine whether they are adequate from a safety point of view;
- determine whether compliance with the safety requirements has been demonstrated by an appropriate programme of research, analysis and testing complemented by a programme of monitoring during operation to account for operating experience feedback, and the results of safety analysis and safety research.

# Requirements for a Safety Assessment
(11 of 12)

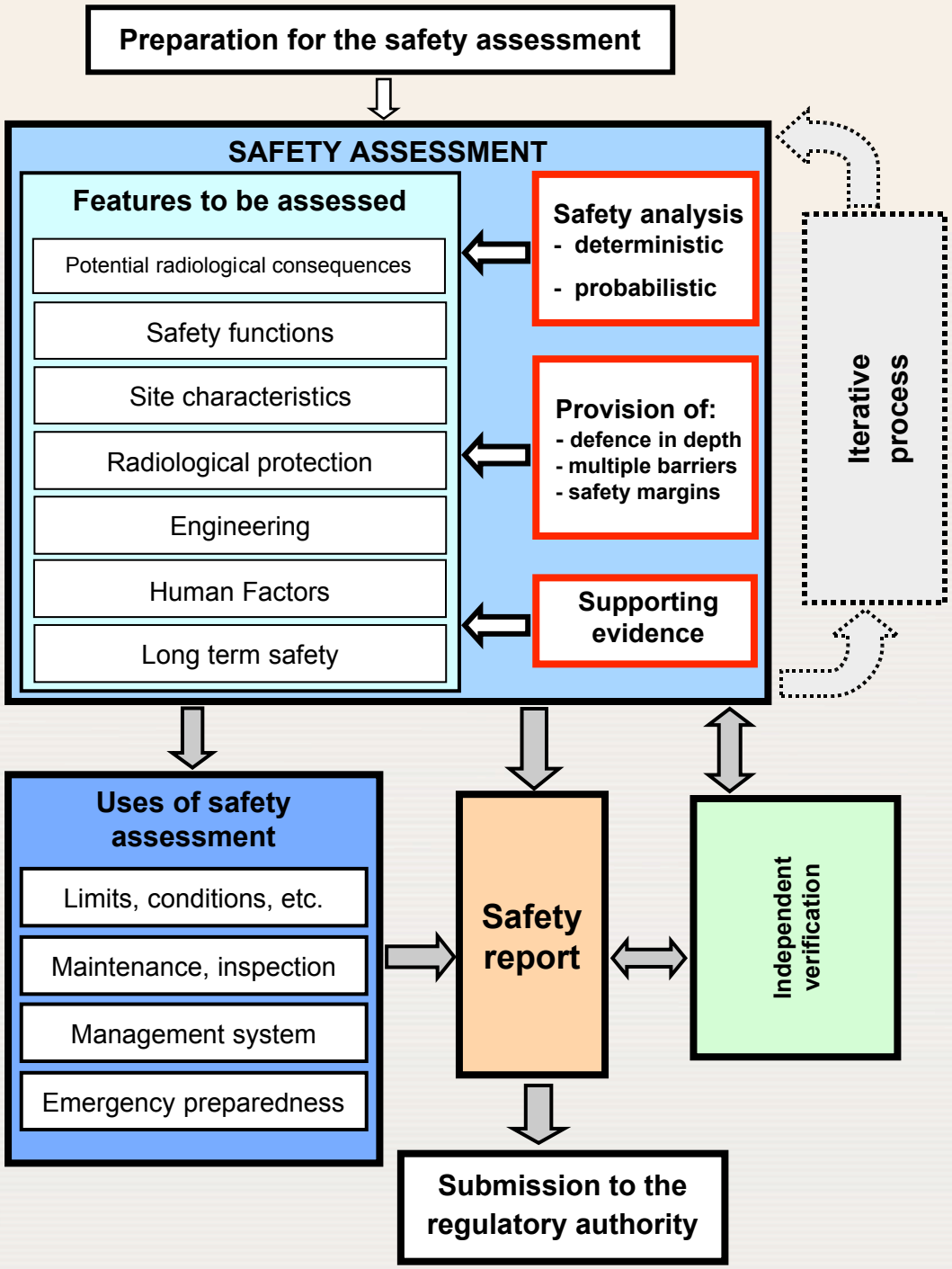
## *Assessment of Human Factors*

- To the extent that safety cannot be achieved by inherently safe design and engineered provisions, the safety assessment shall identify the procedures and measures that are necessary for all normal operational activities, in particular those required to implement the identified operational limits and conditions, and those required in response to abnormal and accident conditions.
- The safety assessment shall determine whether the requirements specified for personnel competences, associated training and minimum staffing levels for maintaining safety are adequate.
- The safety assessment shall determine whether the design and operation of any facility and the procedures for any activities have addressed the requirements to comply with human factors, including those related to the ergonomic design of all the areas, man-machine interfaces where human activities are carried out, and future decommissioning and closure activities.
- For facilities and activities already in existence, the safety assessments shall include aspects of safety culture where appropriate.

# Requirements for a Safety Assessment
(12 of 12)

***Assessment of Long Term Safety***
*(post-closure phase of a repository for the disposal of significant quantities of radioactive material)*

- In the case of a repository for the disposal of significant quantities of radioactive waste, the anticipated and potential radiological effects on human health and the environment shall be considered for the post-closure phase. Potential radiological impacts following closure of the repository may arise from gradual processes, such as the degradation of barriers, and from discrete events that could affect waste isolation such as inadvertent human intrusion. The safety assessment shall address all aspects relevant for long term safety in order to provide a basis for giving reasonable assurance that the repository will meet the design objectives and safety requirements.
- In view of the uncertainties inherent in predicting future events, according to the Safety Standard for the geological disposal of radioactive waste, reasonable assurance of compliance with the safety requirements related to long term hazards is most likely to be achieved by the use of multiple lines of reasoning. This is achieved by supplementing the quantitative estimates of repository performance with other qualitative evidence that the repository will provide isolation of the wastes as designed.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# Defence in Depth and Safety Margins
(1 of 2)

- The assessment of defence in depth shall determine whether adequate provisions have been made at each of the levels of defence in order to:
  - Prevent deviations from normal operation and, in the case of a repository, its desirable long-term evolution;
  - Detect and intercept deviations from normal operation and the desirable long-term evolution should they occur;
  - Control accidents within the limits inherent in the design;
  - Identify accident management measures to control severe accident (beyond design basis) conditions; and
  - Mitigate the radiological consequences of potential releases.
- The safety assessment shall identify the necessary layers of protection including physical barriers to confine the radioactive material at specific locations and the need for supporting administrative controls.

# Defence in Depth and Safety Margins

(2 of 2)

- In order to determine whether defence in depth has been adequately implemented the safety assessment shall determine whether:
  - The highest priority has been given to: reducing the number of challenges to the integrity of layers of protection and physical barriers; preventing the failure or bypass of a barriers; preventing failure of one barrier leading to the failure of another one; and preventing significant releases if failure of the barriers should occur;
  - The layers of protection and physical barriers are independent of each other as much as possible;
  - Special attention has been given to internal and external hazards that have the potential to adversely affect more than one barrier at once or to cause simultaneous failures of safety systems; and
  - Specific measures have been implemented to ensure the effectiveness of the required levels of defence.
- The safety assessment shall determine whether there are adequate safety margins in the design and operation of the facility or activity so that there is a wide margin to failure of any structures, systems or components for any of the abnormal or accident conditions that could occur.

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# Safety Analysis
(1 of 4)

## *Scope of Safety Analysis*

The safety analysis shall:

- assess the performance of a facility or activity in all operational states and, as necessary, in the post-operational phase and shall determine whether there is compliance with the safety requirements;
- address both the consequences arising from all normal operational conditions as well as the probabilities and consequences associated with all identified abnormal or accident conditions;
- identify the abnormal and accident conditions that challenge nuclear safety (all internal and external events and processes that may impact on physical barriers to confine the radioactive material or otherwise give rise to radiological risks;
- address the abnormal and accident conditions that arise during operation of the facility or activity. The aim shall be to determine the cause of the abnormal or accident conditions, its significance and determine the effectiveness of the proposed corrective action.

# Safety Analysis
(2 of 4)

## *Approaches to Safety Analysis*

- The safety analysis shall incorporate deterministic and probabilistic approaches, as appropriate. Both can provide input into an integrated decision making process.
- The aim of the deterministic approach is to define and apply a set of conservative rules and requirements for the design and operation of a facility or activity. If these rules and requirements are met, they are expected to provide a high degree of confidence that the level of risk to workers and members of the public from the facility or activity will be acceptably low.
- Probabilistic safety analysis determine all significant contributors to the radiological risk from a facility or activity and to evaluate the extent to which the overall design is well balanced and meets probabilistic safety criteria if been defined. The probabilistic approach uses realistic assumptions whenever possible and is able to quantify uncertainties explicitly.
- With increasing quality of models and data it is possible to develop more realistic deterministic analysis and to make use of probabilistic information in selecting accident scenarios. Increasing emphasis is also being given to probabilistically specifying how compliance with the deterministic safety criteria is demonstrated, e.g. by specifying confidence intervals, and how safety margins are defined.

# Safety Analysis
(3 of 4)

## *Criteria for Judging Safety*

- Criteria for judging safety shall be defined for the safety analysis that are sufficient to meet the fundamental safety objective and the fundamental principles given in and the requirements of the designers, operator and the regulatory authority.
- In addition, detailed criteria may be developed to assist in assessing compliance with these higher level objectives, including risk criteria which relate to the likelihood of abnormal or accident conditions occurring with significant radiological consequences.

## *Uncertainty and Sensitivity Analysis*

- There will always be uncertainties associated with safety analysis (predictions) which depend on the exact nature of the facility or activity and the complexity of the safety analysis. To the extent practicable the results of a safety analysis shall be robust, i.e. tolerant to uncertainties.
- Uncertainties in the safety analysis shall be characterized with respect to their source, nature and degree, using quantitative methods, professional judgment or both. 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.

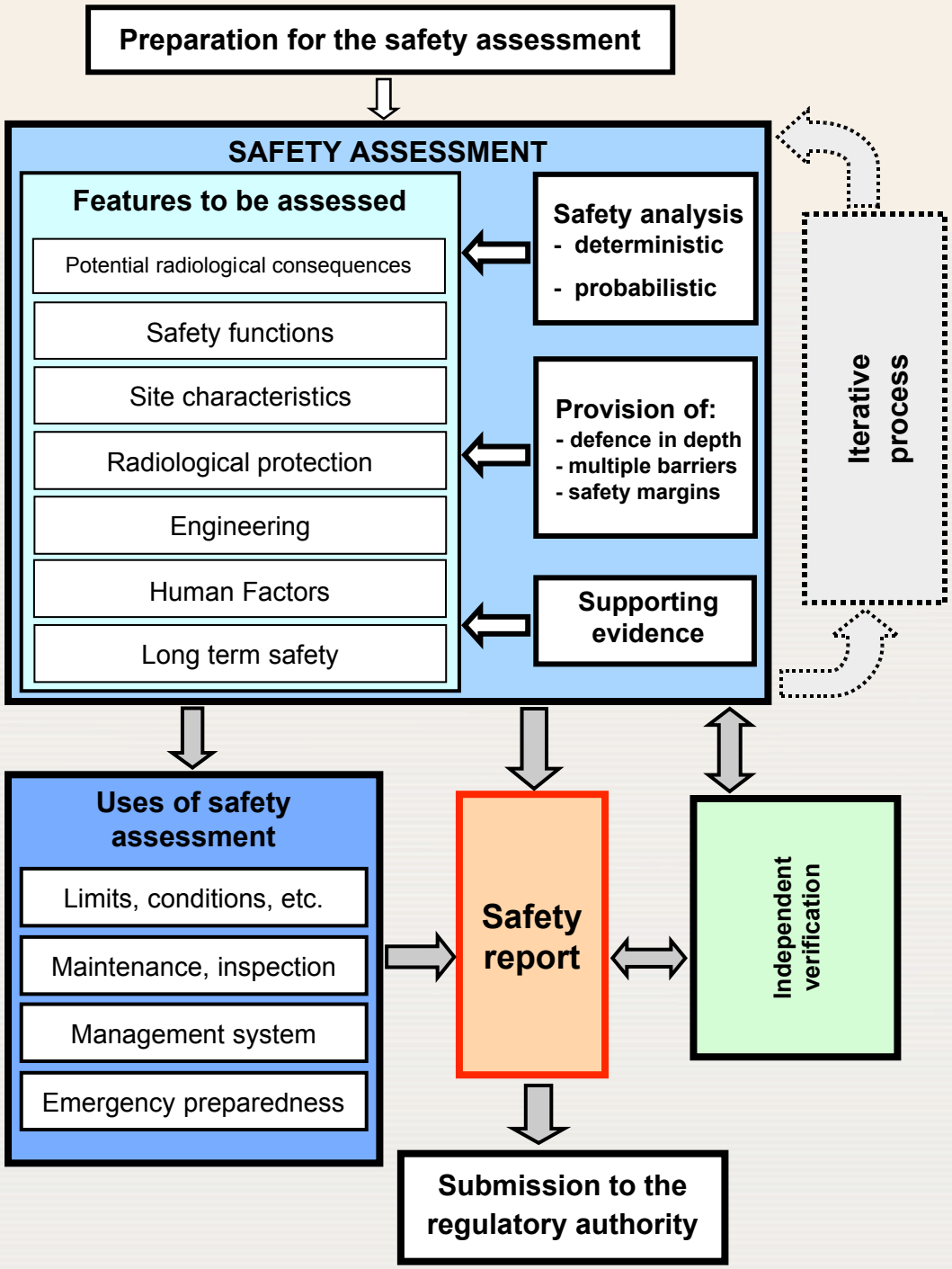
# Safety Analysis
(4 of 4)

## *Use of Computer Codes*

- The computer codes used in the safety analysis shall undergo a sufficient level of verification and validation.
  - Verification determines whether the controlling physical equations and data have been correctly translated into the computer code.
  - Validation determines whether the mathematical model is an adequate representation of the real system being modelled by comparing the predictions of the model with observations of the real system or experimental data. The validation process shall identify the uncertainties and shortcomings in the models and the underlying data basis and how these are to be taken into account in the safety analysis.

## *Use of Data from Operating Experience*

- Operational safety performance data shall be collected and assessed, including records of incidents such as human errors, performance of safety systems, radiation doses, generation of radioactive waste and effluents. For complex facilities, the collection of data may be based on a set of safety performance indicators that have been established for the facility. Operational safety experience shall be used, as appropriate, to update the safety assessment and review management systems.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# Safety Assessment Documetation

- The results and findings of the safety assessment shall be documented in the form of a safety report to present the assessment and the analysis that determine whether the nuclear facility or activity is in compliance with the fundamental safety principles and any other safety requirements set out in national laws and regulations.
- The quantitative and qualitative outcome of the safety assessment forms the basis of the safety report. It is supplemented by supporting evidence and reasoning for the robustness and reliability of the safety assessment and its assumptions.
- The safety analysis shall be documented with sufficient scope and detail and provide in particular:
  - A justification for the selection of events and processes addressed and for the definition of scenarios;
  - An overview and necessary details of the collection of data, the modeling and the assumptions;
  - Criteria used for the evaluation of the modeling results;
  - Results of the analysis addressing the performance of the facility or activity, incurred risks and prevailing uncertainties; and
  - Conclusions on the acceptability of the level of safety achieved and the identification of necessary improvements and additional measures.
- Safety report shall be retained until the nuclear facility has been fully decommissioned or the repository for nuclear waste has been closed.

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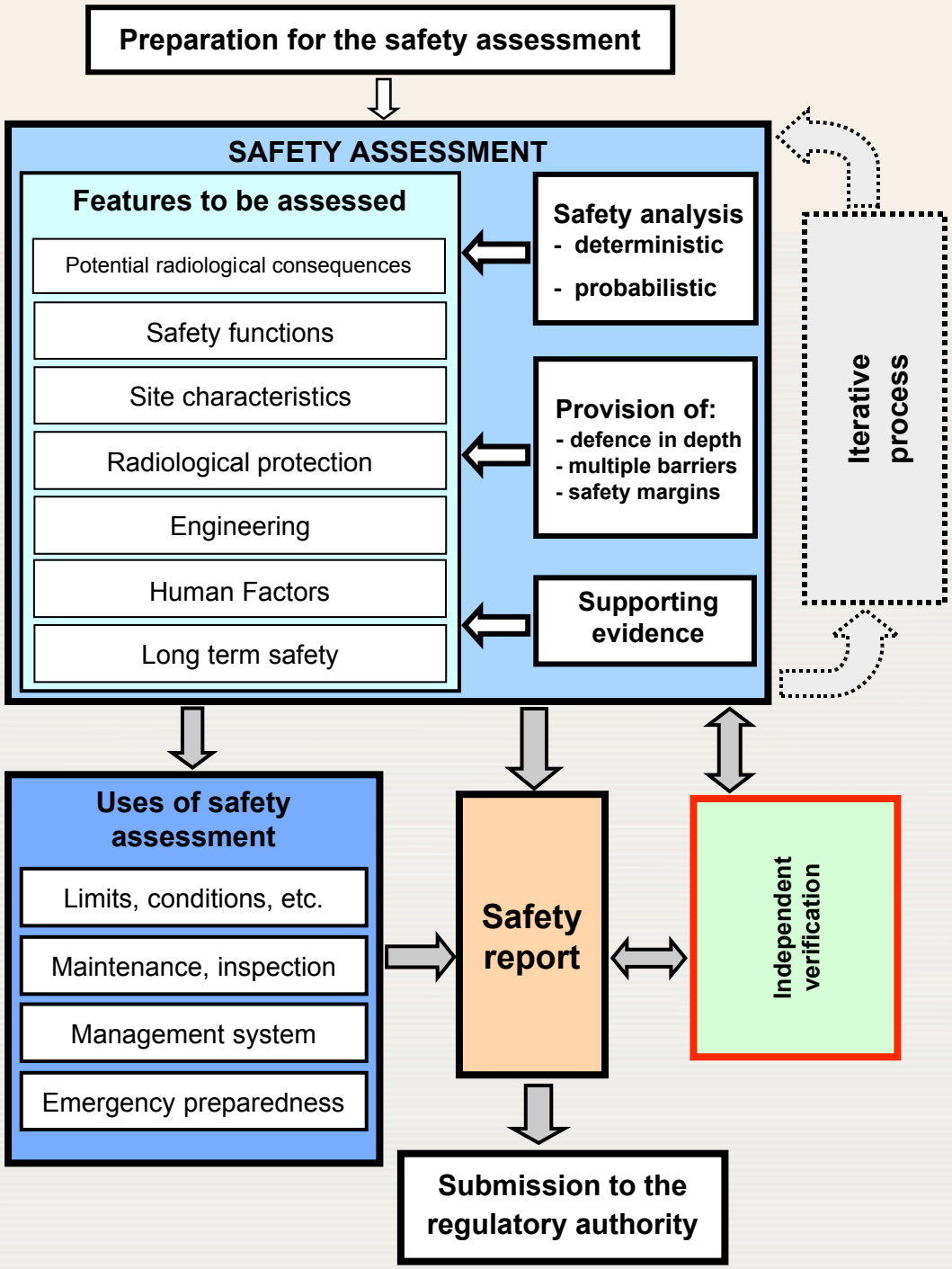
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# Independent Verification

- The operating organisation shall carry out an independent verification to increase the level of confidence in the safety assessment before it is used by the operator or submitted to the regulatory authority.
- The independent verification shall be performed by individuals or a group of people that is separate from those carrying out the safety assessment. The aim shall be to determine whether the safety assessment has been carried out in a way that is consistent with the current state of the art for that type of facility or activity.
- Decisions about the scope and level of detail of the independent verification are subject to a graded approach and should reflect the level of risk, complexity and novelty of the facility or activity.
- The independent verification shall combine an overall review to determine whether the safety assessment carried out is comprehensive along with spot checks where a much more detailed review is carried out that focuses on those aspects of the safety assessment that have the highest impact on the risk from the facility or activity.
- The independent verification shall ensure that the models and data used are accurate representations of the design and operation.
- A separate independent verification shall also be carried out by the regulatory authority to determine whether the safety assessment meets their requirements.

# Graded Approach for Safety Assessment
(1 of 2)

- Resources devoted to safety have to be commensurate with the magnitude of the radiation risks - graded approach needs to be applied in carrying out the safety assessments for the wide range of facilities and activities due to the very different levels of risk that they pose. This allows flexibility in the way that the radiation risks are assessed and controlled without unduly limiting the operation of facilities or the conduct of activities.
- A graded approach shall be used to determining the scope, extent, level of detail and the effort that needs to be devoted to the safety assessment carried out for any particular facility or activity.
- The main factor in the application of the graded approach to the safety assessment shall be the magnitude of the radiation risks to workers, members of the public and the environment arising from the facility or activity (releases during normal operation, the potential consequences for abnormal and accident conditions, and the possibility of very low probability events with potentially high consequences). A judgement then needs to be made on the scope, extent, level of detail and the effort that needs to be applied to any particular facility or activity.

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# Graded Approach for Safety Assessment
(2 of 2)

- The graded approach to safety assessment shall also take into account other relevant factors such as the maturity or complexity of the facility or activity.
  - The maturity relates to 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 availability of experienced manufacturers and constructors.
  - The complexity relates to the extent and difficulty of the effort required to construct a facility or implement a practice, of the number of the related processes requiring control, the extent to which radioactive materials have to be handled, the longevity of the radioactive materials, the reliability and complexity of systems and components and their accessibility for maintenance inspection, testing and repair.
- The application of the graded approach shall be reviewed as the safety assessment progresses and a better understanding is obtained of the level of risk arising from the facility or activity, and the scope, extent, level of detail and the effort applied adjusted accordingly. For example, as the safety assessment progresses, it may emerge that the likelihood of significant consequences is greater than originally considered and more effort and/or detail may be required to demonstrate compliance with the safety requirements, or vice versa.
- The graded approach shall also be applied to the requirements for updating the safety assessment.

# The Management, Use and Maintenance of the Safety Assessment

(1 of 3)

- The safety assessment is one of the key requirements to enable the operator to manage facilities and activities safely. It is also a vital input to the safety report required to demonstrate compliance with regulatory requirements.
- The safety assessment in itself cannot achieve safety.
- Safety is only achieved if the input assumptions are valid, the derived limits and conditions are implemented and maintained and the assessment reflects the installation or activity as it actually is at any point in time.
- Safety assessments require to be updated to reflect such changes as knowledge, experience and understanding that also develop with time.
- The updating of safety assessments is also important in order to provide a baseline for the future evaluation of monitoring data and performance indicators and for radioactive waste facilities to provide an appropriate record for future site use. of safety assessments have been set out.
- The safety assessment shall be reviewed to identify the input assumptions that need to be complied with by appropriate safety management controls.

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# The Management, Use and Maintenance of the Safety Assessment
(2 of 3)

- The safety assessment shall be used to identify the limits and conditions that need to be implemented through suitable procedures and controls. These shall include means for monitoring to ensure that the limits and conditions are complied with at all times.
- The safety assessment shall be used to identify the maintenance and inspection programme that needs to be established using procedures and controls that are auditable in order to ensure that
  - Any necessary conditions are maintained; and
  - Any structures, systems and components maintain their integrity and functional capability over their required lifetime.
- The safety assessment shall be used to identify the procedures that need to be put in place for all operational activities significant to safety and for responding to abnormal and accident conditions. The safety assessment shall also be used to plan for on- and off-site accident management and emergency response.
- The safety assessment shall be used to identify the necessary competences for the staff involved with the facility or activity and this shall be used to inform their training, control and supervision.

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# The Management, Use and Maintenance of the Safety Assessment
(3 of 3)

- The safety assessment shall be used as a basis for management decisions in an integrated risk informed approach.
- The processes by which safety assessment are produced shall be planned, organized, applied, audited and reviewed in a way that is commensurate with the importance to be placed upon the claims made in the resulting safety report.
- Results and insights from the safety assessment need be communicated to a wide range of interested parties including the designers, the operator, the regulatory authority, other safety professionals and the public.
- Safety assessments and the management systems that implement them shall be periodically reviewed in accordance with regulatory requirements. In addition, they shall be reviewed and updated:
  - When there is any significant change to the installation or activity;
  - When significant changes in knowledge and understanding occur;
  - When there is an emerging safety issue due to a regulatory concerns or an incident.
  - Periodically at a predefined period as specified by the regulatory authority but typically not less than one in ten years.

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