L04.- Safety Assessment GSR Part 4 (II)

International Atomic Energy Agency

OBJECTIVE

- ✓ Basis for requiring a safety assessment, derived from the Fundamental Safety Principles .
- ✓ Graded approach
- ✓ Assessment of the features relevant to safety.
- ✓ Defence in depth.
- ✓ Safety Analysis.
- ✓ Documentation and Independent verification
- ✓ Management, use and maintenance of the safety assessment.

General requirements

Requirement 2: Scope of the safety assessment.

A safety assessment shall be carried out for **all applications of technology** that give rise to radiation risks; that is, for all types of facilities and activities.

General requirements

Requirement 3: Responsibility for the safety assessment.

The responsibility for carrying out the safety assessment shall rest with **the responsible legal person**; that is, the person or organization responsible for the facility or activity.

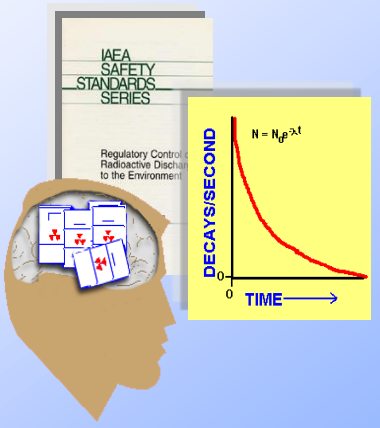
The responsibility of the safety assessment

- The operating organization is responsible for the way in which the safety assessment is carried out and for the quality of the results.
- If the operating organization changes, the responsibility for the safety assessment has to be transferred to the new operating organization.
- The safety assessment has to be carried out by a team of suitably qualified and experienced people.

Purpose of the safety assessment

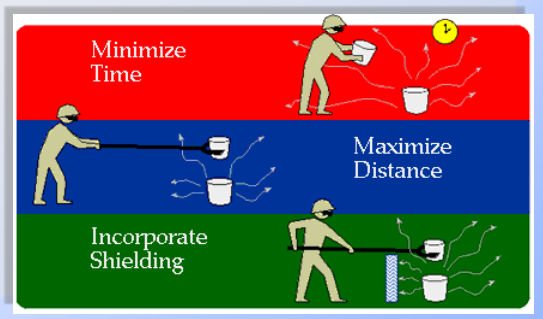
Requirement 4: Purpose of the safety assessment.

The primary purposes of the safety assessment shall be to determine whether an **adequate level of safety has been achieved** for a facility or activity and whether the basic safety objectives and safety criteria established by the designer, the operating organization and the regulatory body, in compliance with the requirements for protection and safety as established in GSR Part 3, have been fulfilled

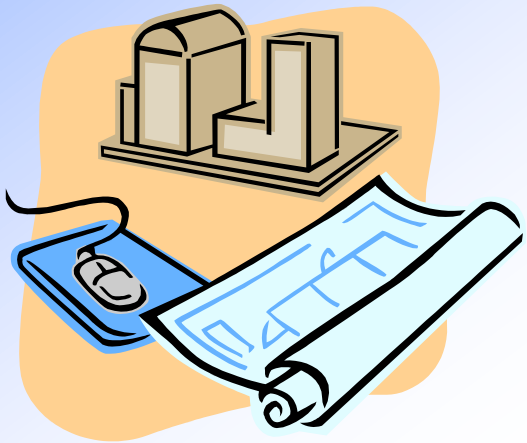


Purpose of the safety assessment

- To determine whether radiation risks are being controlled within specified limits and constraints, and
- Whether they have been reduced to a level that is as low as reasonably achievable.
- To address all radiation risks that arise from normal operation and from anticipated operational occurrences and accident conditions;
- To address failures that might occur and the consequences of any failures.

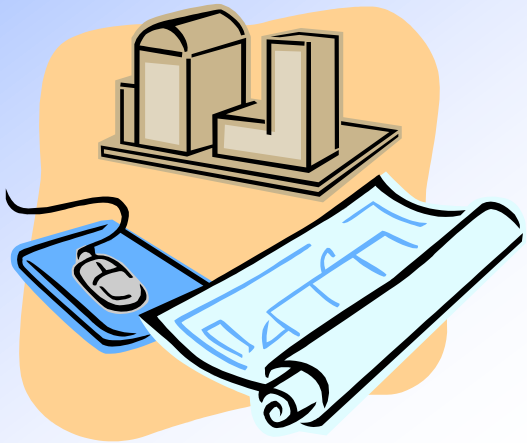


Purpose of the safety assessment



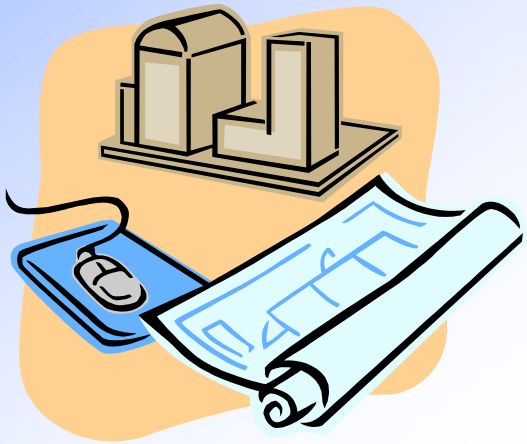
- To determine whether adequate measures have been taken to prevent anticipated operational occurrences and accident conditions,
- whether any radiological consequence can be mitigated if accidents do occur.
- to address all the radiation risks to individuals and population groups.

Purpose of the safety assessment



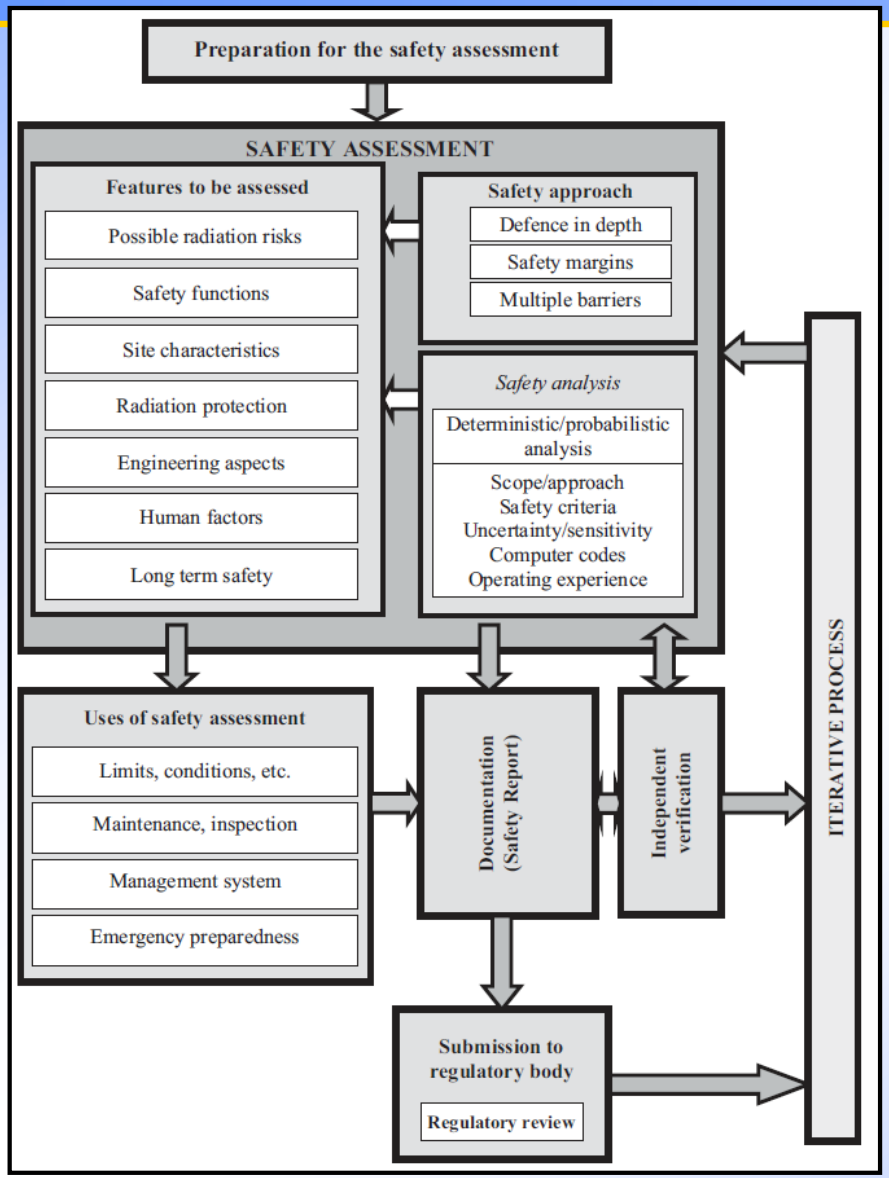
- Address radiation risks in the present and in the long term;
- To determine whether adequate defence in depth has been provided, as appropriate, through a combination of several layers of protection

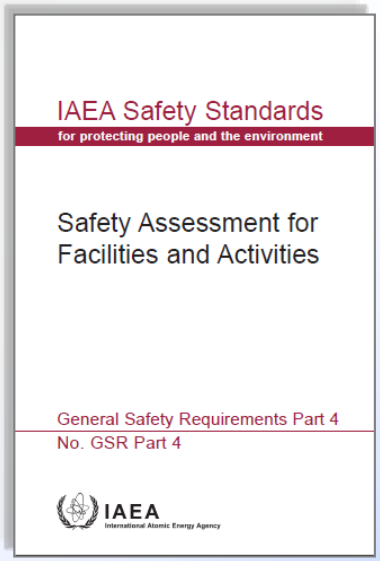
Purpose of the safety assessment



- Has to include a **safety analysis**, which consists of a set of different quantitative analyses for evaluating and assessing challenges to safety in various operational states, anticipated operational occurrences and accident conditions.
- The scope and level of detail of the safety analysis are determined using a graded approach.

Overview of the Safety Assessment Process





The figure shows the main elements of the process for safety assessment and verification.

Specific requirements

Requirement 5: Preparation for the safety assessment.

The first stage of carrying out the safety assessment shall be to ensure that the necessary resources, information, data, analytical tools as well as safety criteria are identified and are available.

Specific requirements

Requirement 6: Assessment of the possible radiation risks.

The possible radiation risks associated with the facility or activity shall be identified and assessed.

The term 'possible radiation risks' relates to the maximum possible radiological consequences that could occur when radioactive material is released from the facility or in the activity, with no credit being taken for the safety systems or protective measures in place to prevent this.

Specific requirements

Requirement 7: Assessment of safety functions.

All safety functions associated with a facility or activity shall be specified and assessed.

Safety functions are functions that are necessary to be performed for the facility or activity to prevent or mitigate radiological consequences of normal operation, anticipated operational occurrences and accident conditions. These functions can include control of reactivity, removal of heat from radioactive material, confinement of radioactive material and shielding, depending on the nature of the facility or activity.

Assessment of safety functions

- All safety functions associated with a facility or activity shall be specified and assessed.
- This includes the safety functions associated with :
  - *the engineered structures, systems and components,*
  - *any physical or natural barriers and*
  - *inherent safety features as applicable, and*
  - *any human actions necessary to ensure the safety of the facility or activity*
- An assessment is undertaken to determine whether the safety functions can be fulfilled for:
  - *all normal operational modes,*
  - *all anticipated operational occurrences and*
  - *the accident conditions to be taken into account; these include design basis accidents and beyond design basis accidents*

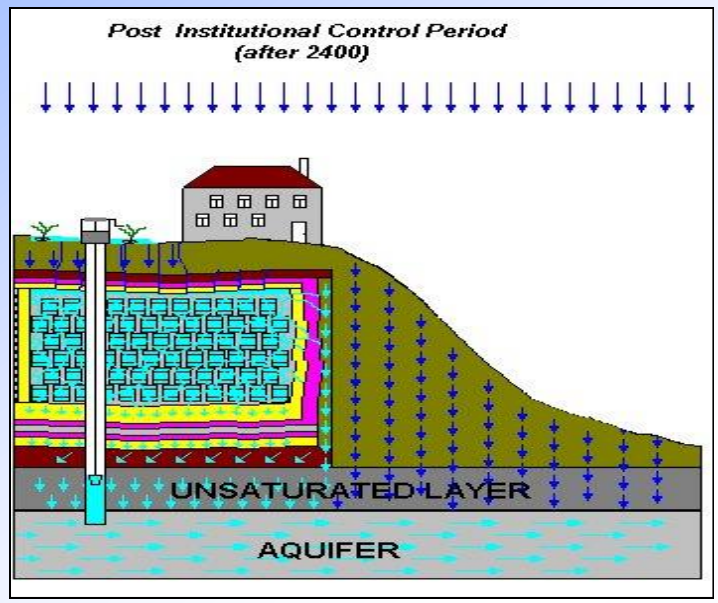
Assessment of safety functions

It has to be determined whether the structures, systems, components and barriers that are provided to perform the safety functions **have an adequate**:

- *level of reliability,*
- *redundancy,*
- *diversity,*
- *separation,*
- *segregation,*
- *independence and*
- *equipment qualification,*

as appropriate, and whether potential vulnerabilities have been identified and eliminated.

Specific requirements



Requirement 8: Assessment of site characteristics.

An assessment of the site characteristics relating to the safety of the facility or activity shall be carried out.

Assessment of site characteristics

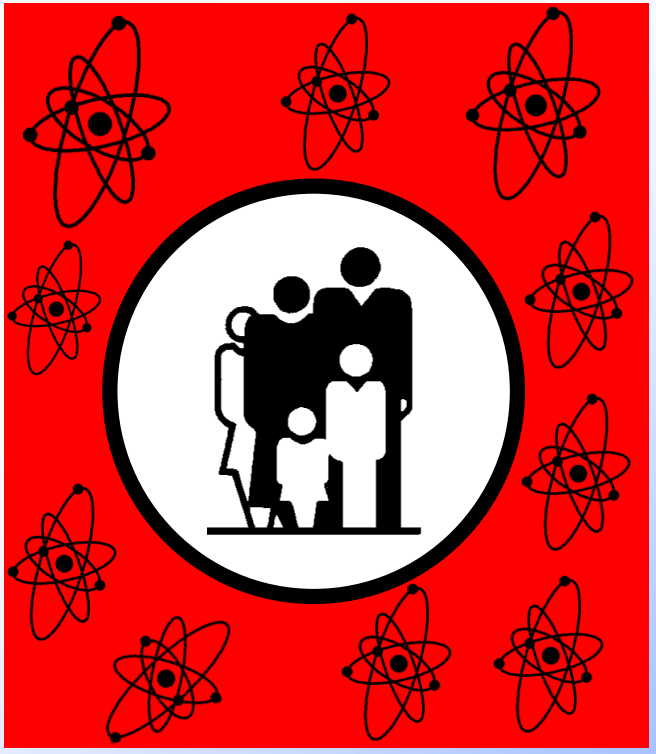
An assessment of the site characteristics relating to the safety of the facility or activity has to cover:

- The physical, chemical and radiological characteristics that will affect the dispersion or migration of radioactive material.
- Identification of natural and human induced external events in the region that have the potential to affect the safety of facilities and activities.
- The distribution of the population around the site and its characteristics with regard to any siting policy of the State,
- the potential for neighboring States to be affected and the requirement to develop an emergency plan.

Specific requirements

Requirement 9: Assessment of the provisions for radiation protection.

It shall be determined in the safety assessment for a facility or activity whether adequate measures are in place to protect people and the environment from harmful effects of ionizing radiation.



Assessment of the provisions for radiation protection

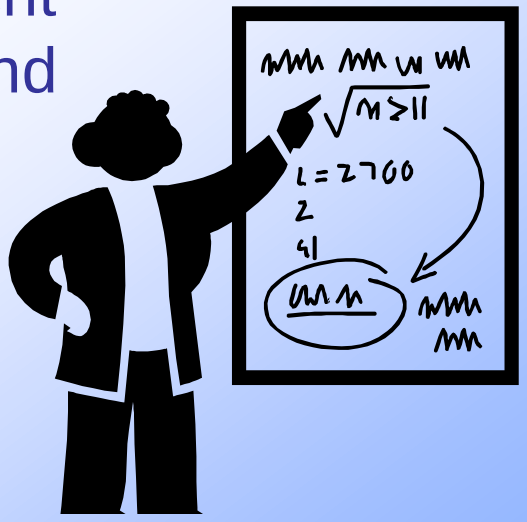
It has to be determined

- whether adequate measures are in place to control the radiation exposure of workers and members of the public within relevant dose limits, and
- whether protection is optimized so that the magnitude of individual doses, the number of people exposed and the likelihood of exposures being incurred have all been kept as low as reasonably achievable, economic and social factors having been taken into account

Specific requirements

Requirement 10: Assessment of engineering aspects.

It shall be determined in the safety assessment whether a facility or activity uses, to the extent practicable, structures, systems and components of robust and proven design



Assessment of engineering aspects

- ✓ The design principles that have been applied for the facility are identified in the safety assessment, and it has to be determined whether these principles have been met.
- ✓ The external events that could arise for a facility or activity have to be addressed in the safety assessment, and it has to be determined whether an adequate level of protection against their consequences is provided.
- ✓ The internal events that could arise for a facility have to be addressed in the safety assessment,
- ✓ It has to be demonstrated whether the structures, systems and components are able to perform their safety functions under the loads induced by normal operation and the anticipated operational occurrences and accident conditions that were taken into account explicitly in the design of the facility.

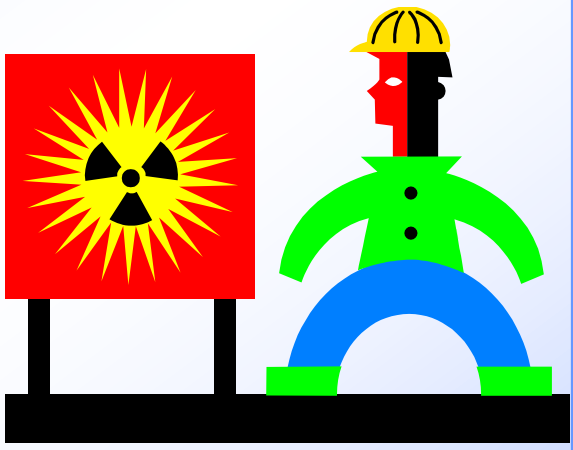
Assessment of engineering aspects

- It has to be determined in the safety assessment **whether the materials used are suitable** for their purpose with regard to the standards specified in the design,
- It has to be determined in the safety assessment **whether equipment essential to safety has been qualified to a sufficiently high level** that it will be able to perform its safety function in the conditions that would be encountered in normal operation, and following anticipated operational occurrences and accidents.
- The provisions made for the decommissioning and dismantling of the facility have to be specified.

Specific requirements

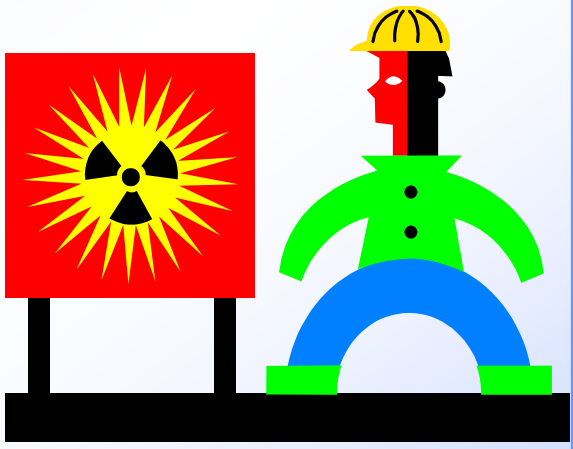
Requirement 11: Assessment of human factors.

Human interactions with the facility or activity shall be **addressed** in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required in response to anticipated operational occurrences and accidents, **ensure an adequate level of safety**.



Assessment of human factors

- It has to be evaluated whether personnel competences, the associated training programmes and the specified minimum staffing levels for maintaining safety are adequate.
- It has to be determined whether requirements relating to human factors were addressed in the design and operation of a facility;
- For existing facilities and activities, aspects of safety culture are to be included, as appropriate.



Specific requirements

Requirement 12: Assessment of safety over the lifetime of a facility or activity.

The safety assessment shall cover all the stages in the lifetime of a facility or activity in which there are possible radiation risks.

OBJECTIVE

- ✓ Basis for requiring a safety assessment, derived from the Fundamental Safety Principles .
- ✓ Graded approach
- ✓ Assessment of the features relevant to safety.
- ✓ Defence in depth.
- ✓ Safety Analysis.
- ✓ Documentation and Independent verification
- ✓ Management, use and maintenance of the safety assessment.

Definition of defence in depth

Defense in depth, is a hierarchical deployment of different levels of diverse equipment and procedures to prevent the escalation of anticipated operational occurrences and to maintain the effectiveness of physical barriers placed between a radiation source or radioactive material and workers, members of the public or the environment, in operational states and, for some barriers, in accident conditions.

The objectives of defence in depth are:

(a) To compensate for human induced events and component failures;

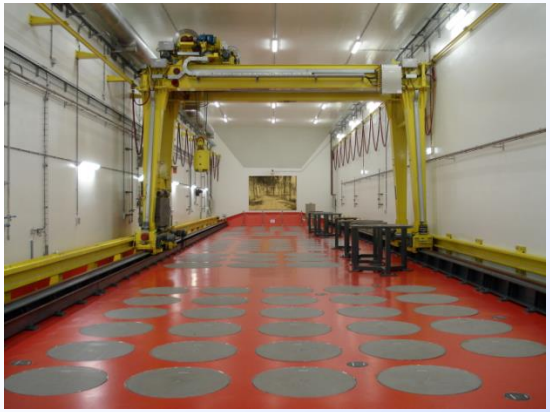
(b) To maintain the effectiveness of the barriers by averting damage to the facility and to the barriers themselves;

(c) To protect workers, members of the public and the environment from harm in accident conditions in the event that these barriers are not fully effective.

Defence in depth and safety margins

Requirement 13: Assessment of defence in depth.

It shall be determined in the assessment of defence in depth whether adequate provisions have been made at each of the levels of defence in depth.



Assessment of defence in depth

The assessment should ensure that the legal person responsible for the facility can:

a) *Address deviations from normal operation;*
b) *Detect and terminate safety related deviations from normal operation;*
c) *Control accidents within the limits established for the design;*
d) *Specify measures to mitigate the consequences of accidents that exceed design limits;*
e) *Mitigate radiation risks associated with possible releases of radioactive material.*

Assessment of defence in depth

The necessary layers of protection, including physical barriers to confine radioactive material at specific locations, and the necessary supporting administrative controls for achieving defence in depth have to be identified in the safety assessment. This includes identification of:

- ✓ *Safety functions that must be fulfilled;*
- ✓ *Potential challenges to these safety functions;*
- ✓ *Mechanisms that give rise to these challenges, and the necessary responses to them;*
- ✓ *Provisions made to prevent these mechanisms from occurring;*
- ✓ *Provisions made to identify or monitor deterioration caused by these mechanisms, if practicable;*
- ✓ *Provisions for mitigating the consequences if the safety functions fail.*

Assessment of defence in depth

It has to be determined whether:

a) *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 barrier when challenged; preventing the failure of one barrier leading to the failure of another barrier; and preventing significant releases of radioactive material if failure of a barrier does occur;*

b) *The layers of protection and physical barriers are independent of each other as far as practicable;*

c) *Special attention has been paid to internal and external events that have the potential to adversely affect more than one barrier at once or to cause simultaneous failures of safety systems;*

d) *Specific measures have been implemented to ensure reliability and effectiveness of the required levels of defence.*

Assessment of defence in depth

It has to be determined

- Whether there are adequate safety margins in the design and operation of the facility,
- Whether acceptance criteria for each aspect of the safety analysis are such that an adequate safety margin is ensured.

Safety margins are typically specified in codes and standards as well as by the regulatory body.

OBJECTIVE

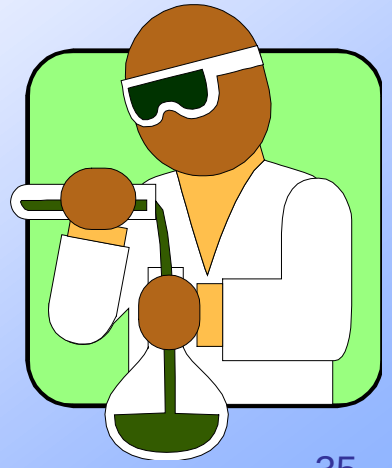
- ✓ Basis for requiring a safety assessment, derived from the Fundamental Safety Principles .
- ✓ Graded approach
- ✓ Assessment of the features relevant to safety.
- ✓ Defence in depth.
- ✓ **Safety Analysis.**
- ✓ Documentation and Independent verification
- ✓ Management, use and maintenance of the safety assessment.

Safety analysis

Requirement 14: Scope of the safety analysis.

The performance of a facility or activity in all operational states and, as necessary, in the post-operational phase shall be assessed in the safety analysis.

- *It has to be determined whether the facility or activity is in compliance with the relevant safety requirements and regulatory requirements.*



Scope of the safety analysis

To be addressed in the safety analysis:

- ✓ The consequences arising from all normal operational conditions;
- ✓ The frequencies and consequences associated with all anticipated operational occurrences and accident conditions:
  - *design basis accidents*
  - *severe accidents*

to a scope and level of detail that is consistent to a graded approach and the uncertainties inherent in the processes that are included in the analysis.

Scope of the safety analysis

- ✓ Anticipated operational occurrences and accident conditions that challenge safety are to be identified; partial failures of components or barriers as well as complete failures have to be considered.
- ✓ Relevant operating experience has to be taken into account in the safety analysis. This includes operating experience from the actual facility or activity, where available, and operating experience from similar facilities and activities.
- ✓ The cause of the anticipated operational occurrences or accident conditions, their possible effects, their significance and the effectiveness of the proposed corrective actions have to be determined

Safety analysis

Requirement 15: Deterministic and probabilistic approaches.

Both deterministic and probabilistic approaches shall be included in the safety analysis.

- Deterministic and probabilistic approaches have been shown to complement one another and can be used together to provide input into an integrated decision making process.
- The extent of the deterministic and probabilistic analyses carried out for a facility or activity has to be consistent with the graded approach.

Deterministic and probabilistic approaches

- The aim of the **deterministic approach** is to specify and apply a set of conservative deterministic rules and requirements for the design and operation of facilities or for the planning and conduct of activities.
- When these rules and requirements are met, they are expected to **provide a high degree of confidence** that the level of radiation risks to workers and members of the public arising from the facility or activity will be acceptably low.
- This conservative approach **provides** a way of compensating for uncertainties in the performance of equipment and the performance of personnel, by providing **a large safety margin**.

Deterministic and probabilistic approaches

- The objectives of a **probabilistic safety analysis** are to determine all significant contributing factors to the radiation risks arising from a facility or activity, and to evaluate the extent to which the overall design is well balanced and meets probabilistic safety criteria where these have been defined.
- It constitutes a conceptual and mathematical tool for deriving numerical estimates of risk.
- The probabilistic approach uses realistic assumptions whenever possible and provides a framework for addressing many of the uncertainties explicitly.

Safety analysis

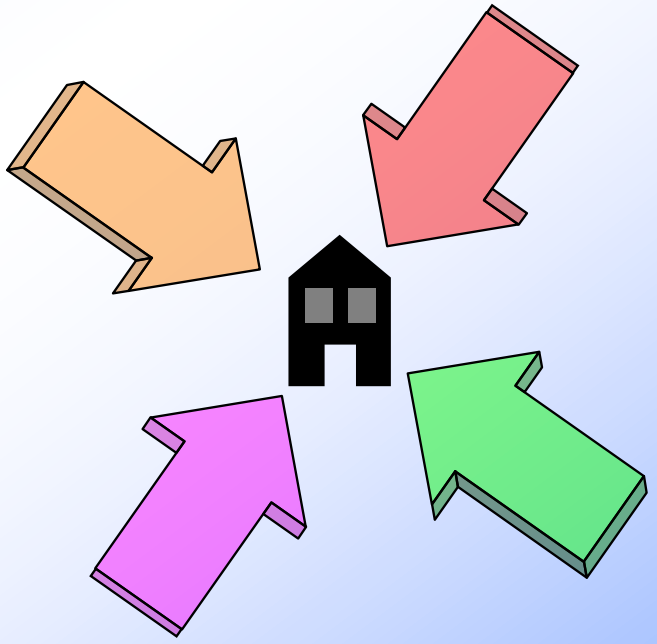
Requirement 16: Criteria for judging safety.

Criteria for judging safety shall be defined for the safety analysis.

Safety analysis

Requirement 17: Uncertainty and sensitivity analysis.

Uncertainty and sensitivity analysis shall be performed and taken into account in the results of the safety analysis and the conclusions drawn from it.



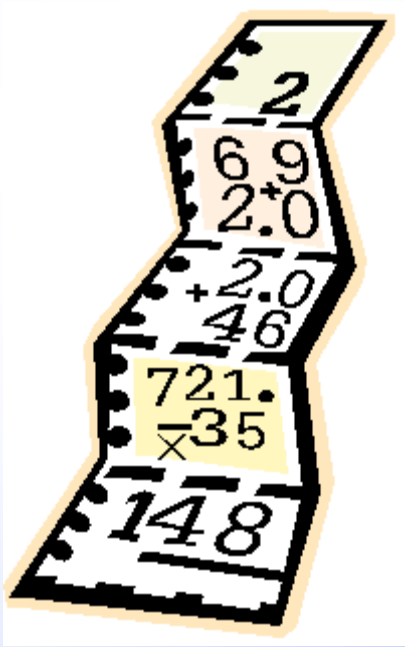
Uncertainty and sensitivity analysis

- ✓ There will always be uncertainties associated with such predictions that will depend on the nature of the facility or activity.
- ✓ These uncertainties have to be taken into account in the results of the safety analysis and the conclusions drawn from it.
- ✓ Uncertainties in the safety analysis have to be characterized with respect to their source, nature and degree, using quantitative methods, professional judgement or both.
- ✓ Uncertainties that may have implications for the outcome of the safety analysis and for decisions made on that basis are to be addressed in uncertainty and sensitivity analyses.

Safety analysis

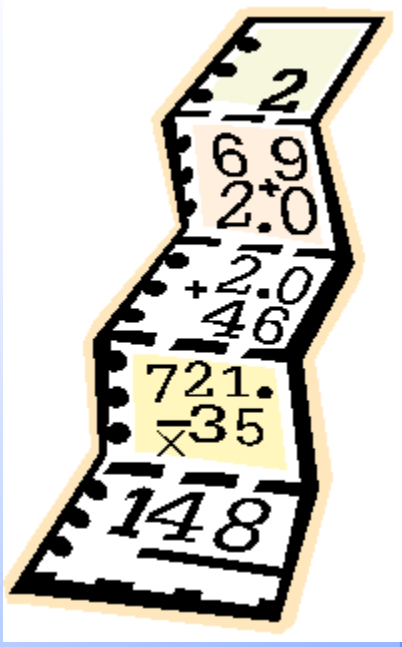
Requirement 18: Use of computer codes.

Any calculational methods and computer codes used in the safety analysis shall undergo verification and validation.



Use of computer codes

- ✓ Model verification. - Process of determining that a computational model correctly implements the intended conceptual model or mathematical model;
- ✓ Model validation. - process of determining whether a 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 with experimental data.
- ✓ The uncertainties, approximations made in the models, and shortcomings in the models and the underlying basis of data, and how these are to be taken into account in the safety analysis, all have to be identified and specified in the validation process.
- ✓ It has to be ensured that users of the code have sufficient experience in the application of the code to the type of facility or activity to be analysed



The safety analysis

Requirement 19: Use of operating experience data.

Data on operational safety performance shall be collected and assessed.

OBJECTIVE

- ✓ Basis for requiring a safety assessment, derived from the Fundamental Safety Principles .
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- ✓ Management, use and maintenance of the safety assessment.

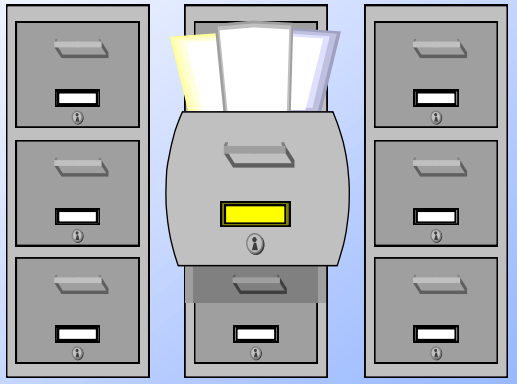
Documentation

Requirement 20: Documentation of the safety assessment.

The results and findings of the safety assessment shall be documented.

Documentation of the safety assessment

- ✓ The results and findings of the safety assessment are to be documented in the form of a safety report.
- ✓ The outcomes of the safety assessment are supplemented by:
  - *supporting evidence, and*
  - *reasoning about the robustness and reliability of the safety assessment, and*
  - *its assumptions, including information on the performance of individual components of systems.*



Documentation of the safety assessment

The safety report includes:

a) A justification for the selection of the anticipated operational occurrences and accidents considered in the analysis;

b) An overview and necessary details of:
   - *the collection of data,*
   - *the modelling,*
   - *the computer codes, and*
   - *the assumptions made;*

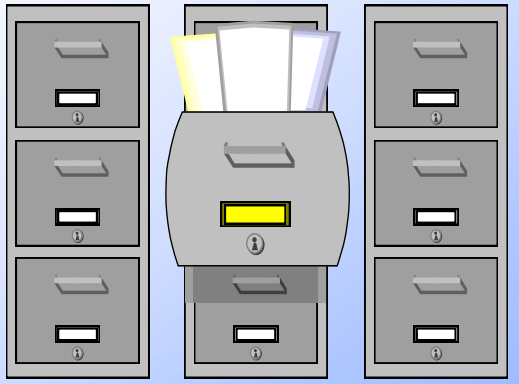
c) Criteria used for the evaluation of the modelling results;

d) Results of the analysis;

e) Conclusions on the acceptability of the level of safety achieved and the identification of necessary improvements and additional measures.

Documentation of the safety assessment

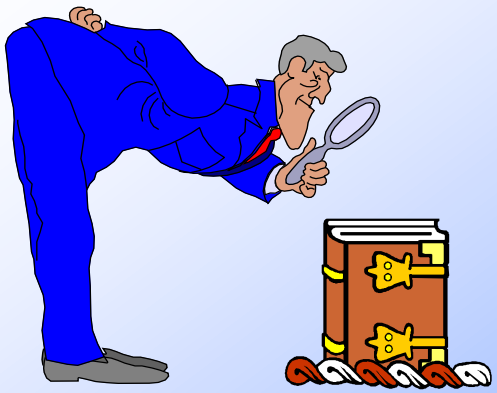
- ✓ The safety report is to be updated as necessary.
- ✓ The safety report has to be retained until the facility has been fully decommissioned and dismantled or the activity has been terminated and released from regulatory control.



Independent verification

Requirement 21: Independent verification.

The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body.



Independent verification

- ✓ is performed by suitably qualified and experienced individuals or a group different from those who carried out the safety assessment.
- ✓ The aim of independent verification is to determine whether the safety assessment has been carried out in an acceptable way.
- ✓ The decisions made on the scope and level of detail of the independent verification have to be reviewed in the independent verification itself, to ensure that:
  - *are consistent with the graded approach,*
  - *reflect the possible radiation risks associated with the facility or activity,*
  - *its maturity and complexity*

Independent verification

- The independent verification has to determine whether the safety assessment carried out is comprehensive, with spot checks in which a much more detailed review is carried out.
- It also has to be considered in the independent verification whether there are any contributions to the radiation risks that have not been taken into account.
- It has to be determined whether the models and data used are accurate representations of the design and operation of the facility or the planning and conduct of the activity.

Independent verification

- The regulatory body has to carry out a separate independent verification to satisfy itself that the safety assessment is acceptable and to determine whether it provides an adequate demonstration of whether the legal and regulatory requirements are met.
- The verification by the regulatory body is not part of the operating organization's process and is not to be used or claimed by the operating organization as part of its independent verification.

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Management, use and maintenance of the safety assessment

Requirement 22: Management of the safety assessment.

The processes by which the safety assessment is produced shall be planned, organized, applied, audited and reviewed.

Management, use and maintenance of the safety assessment

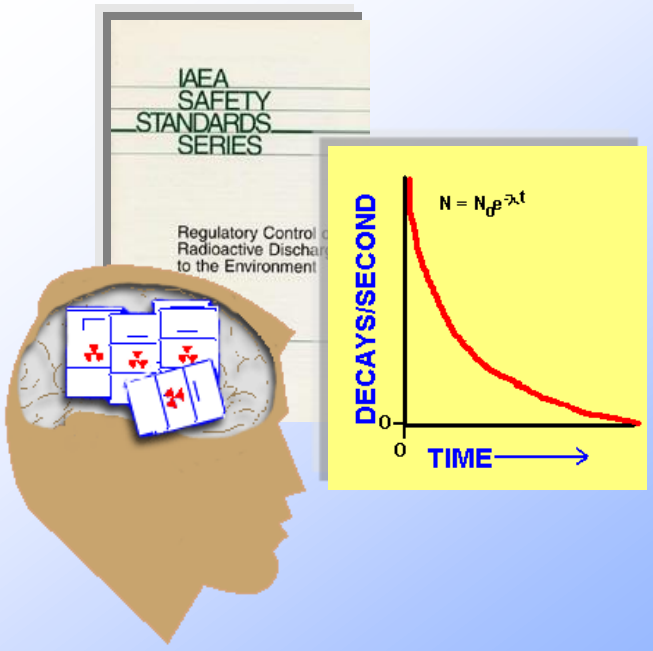
Requirement 23: Use of the safety assessment.

The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity and to make decisions in an integrated, risk informed approach.

Management, use and maintenance of the safety assessment

Requirement 24: Maintenance of the safety assessment.

The safety assessment shall be periodically reviewed and updated.



Management, use and maintenance of the safety assessment

- ✓ The safety assessment in itself cannot achieve safety.
- ✓ Facilities and activities change and evolve over their lifetimes.
- ✓ Knowledge and understanding also advance with time and experience.
- ✓ The safety assessment has to be updated to reflect such changes and to remain valid.

Management, use and maintenance of the safety assessment

- The safety assessment has to be reviewed to identify the input assumptions for which compliance is to be ensured by means of appropriate controls for safety management.
- The safety assessment provides one of the inputs into defining the limits and conditions that are to be implemented by means of suitable procedures and controls.
- The results of the safety assessment have to be used to specify the programme for maintenance, surveillance and inspection to be established to ensure that:
  - *All necessary conditions are maintained;*
  - *All structures, systems and components maintain their integrity and functional capability over their required lifetime.*

Management, use and maintenance of the safety assessment

- The results of the safety assessment have to be used to specify the procedures to be put in place for all operational activities significant to safety and for responding to anticipated operational occurrences and to accidents.
- Also to be used as an input into planning for on-site and off-site emergency response and accident management.
- The results of the safety assessment are to be used to specify the necessary competences for the staff involved in the facility or activity, which are used to inform their training, control and supervision.

Management, use and maintenance of the safety assessment

- ✓ The results of the safety assessment have to be used to make decisions in an integrated, risk informed approach.
- ✓ The processes by which the safety assessment is produced have to be planned, organized, applied, audited and reviewed in a way that is in accordance with the graded approach.
- ✓ Consideration to be given to ways in which results and insights from the safety assessment may best be communicated to a wide range of interested parties, including the designers, the operating organization, the regulatory body and other professionals.
- ✓ Communication of the results from the safety assessment to interested parties has to be commensurate with the possible radiation risks arising from the facility or activity.

Management, use and maintenance of the safety assessment

- The safety assessment has to be periodically reviewed and updated at predefined intervals in accordance with regulatory requirements to take into account:
  - a) *Any changes that may significantly affect the safety of the facility or activity;*
  - b) *Significant developments in knowledge*
  - c) *Emerging safety issues;*
  - d) *Safety significant modifications to the computer codes, or changes in the input data used in the safety analysis*