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Regional Workshop on the Development of National Strategies and Regulatory Requirements for Spent Fuel Management

IAEA Concept of the Safety Case and Safety Assessment

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- ✓ The objective of this Safety Requirements publication is to establish the generally applicable requirements to be fulfilled in safety assessment for facilities and activities, with special attention paid to defence in depth, quantitative analyses and the application of a graded approach to the ranges of facilities and of activities that are addressed.
- ✓ The publication also addresses the independent verification of the safety assessment that needs to be carried out by the originators and users of the safety assessment.

IAEA Safety Standards

for protecting people and the environment

Safety Assessment for Facilities and Activities

General Safety Requirements

No. GSR Part 4 (Rev. 1)

- | | | |
|---|--|---|
| 1. Introduction |  | 1. Graded approach |
| 2. Basis for Requiring a Safety | | 2. Scope of the <u>safety assessment</u> |
| 3. Graded Approach to Safety | | 3. Responsibility for the <u>safety assessment</u> |
| | | 4. Purpose of the <u>safety assessment</u> |
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| | | 8. <u>Assessment</u> of site characteristics |
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| | | 15. Deterministic and probabilistic approaches |
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| | | 18. Use of computer codes |
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Safety Assessment for
Facilities and Activities

General Safety Requirements
No. GSR Part 4 (Rev. 1)

Safety Assessment

1. *Assessment* of all aspects of a practice that are relevant to *protection and safety*; for an *authorized facility*, this includes *siting*, *design* and *operation* of the facility.
2. *Analysis* to predict the performance of an overall *system* and its impact, where the performance measure is the radiological impact or some other global measure of the impact on *safety*.
3. The systematic process that is carried out throughout the design process (and throughout the *lifetime* of the *facility* or the *activity*) to ensure that all the relevant *safety requirements* are met by the proposed (or actual) design.

Safety Case

- A collection of arguments and evidence in support of the *safety* of a *facility* or *activity*. This will normally include the findings of a safety assessment and a statement of confidence in these findings.
For a disposal facility, the safety case may relate to a given stage of development. In such cases, the safety case should acknowledge the existence of any unresolved issues and should provide guidance for work to resolve these issues in future development stages.

The Safety Case

What is a safety case?

- From the general perspective
 - *It is a demonstration that the hazards that have the potential to occur from the activities being carried out are adequately controlled and managed*
- From the assessment perspective
 - *It is the totality of the documentation that demonstrates that an installation will remain safe during all phases of its life*
- From GSR Part 5
 - *A collection of arguments and evidence in support of the safety of a facility or activity. This will normally include the findings of a safety assessment and a statement of confidence in these findings*

The Safety Case

is the collection of scientific and technical arguments and evidence in support of the safety of the waste management facility or activity, covering:

- The suitability of the site and location
- The design
- Construction and operation of the facility
- The assessment of radiation risks
- Assurance of the quality of all the safety related work associated with facility or activity

Purpose of Safety Case

- **Demonstrate** that all planned activities can be carried out in a safe manner
- **Provide guidance** for the design, engineering and planning of operations to ensure safety
- **Input to regulatory process**, including evidence of compliance and arguments for confidence building

Safety Standards on Safety Assessment

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Safety Assessment for Facilities and Activities

General Safety Requirements

No. GSR Part 4 (Rev. 1)



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Predisposal Management of Radioactive Waste

General Safety Requirements Part 5
No. GSR Part 5

IAEA Safety Standards

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The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste

General Safety Guide
No. GSG-3



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Disposal of Radioactive Waste

Specific Safety Requirements
No. SSR-5

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The Safety Case and Safety Assessment for the Disposal of Radioactive Waste

Specific Safety Guide
No. SSG-23



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Decommissioning of Facilities

General Safety Requirements Part 6
No. GSR Part 6

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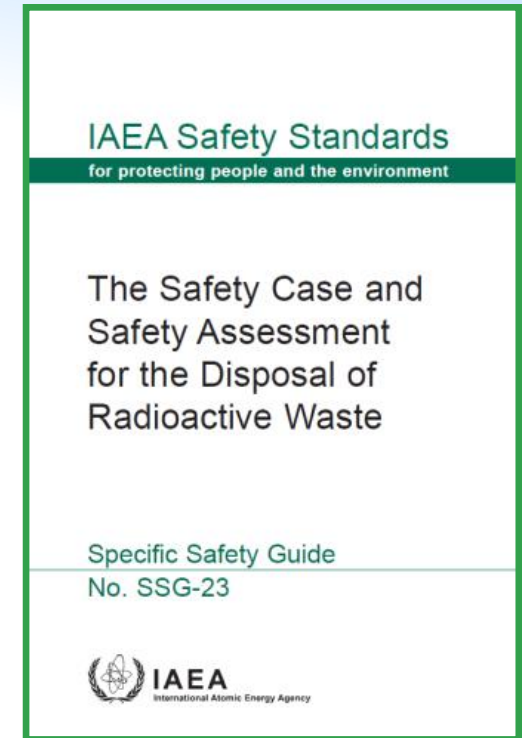
Safety Assessment for the Decommissioning of Facilities Using Radioactive Material

Safety Guide
No. WS-G-5.2



SSG- 23: The SC &SA for the Disposal of **RAW**^{ars}

1. Introduction
2. Demonstrating safety
3. Safety principles & requirements
4. The safety case
 - I. Role and development
 - II. Components
5. Post-closure radiological assessment
 - I. Assessment context
 - II. Disposal system description
 - III. Development of scenarios
 - IV. Formulation of models
 - V. Calculations and analysis of results
 - VI. Refinement of models
 - VII. Comparison of results with criteria



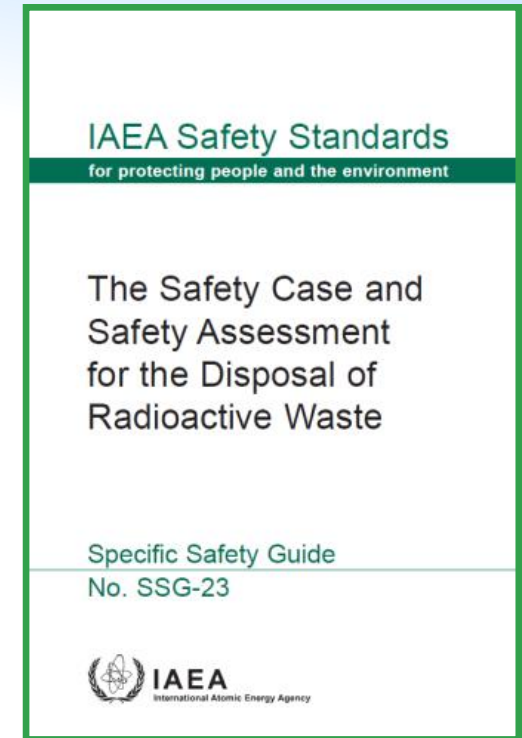
SSG- 23: The SC &SA for the Disposal of ^{RAW}ars

6. Specific issues

- I. Evolution of the safety case
- II. Graded approach
- III. Defence in depth
- IV. Robustness
- V. Assessment timeframe
- VI. Human intrusion
- VII. Institutional control
- VIII. Retrievability of waste
- IX. Appraisal of options

7. Documentation & uses of the safety case

8. Regulatory review process



SSG- 23: The SC &SA for the Disposal of ^{RAW}ars

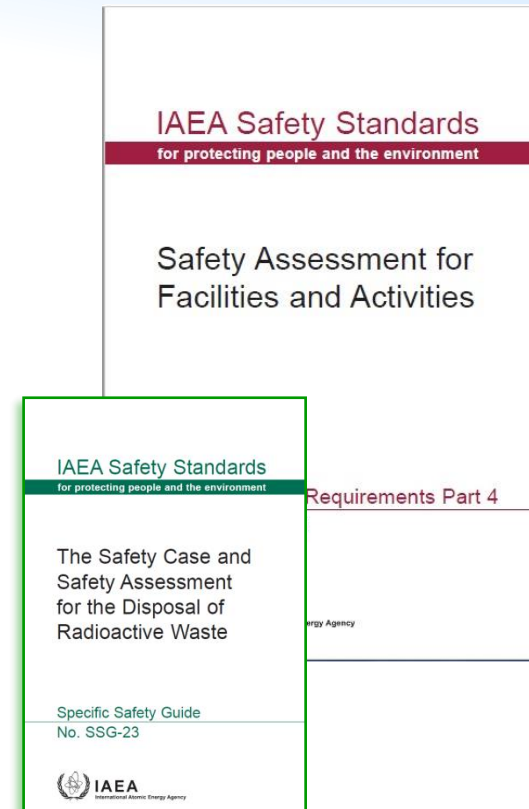
The safety case is the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a disposal facility, covering the suitability of the site and the design, construction and operation of the facility, the assessment of radiation risks and assurance of the adequacy and quality of all of the safety related work associated with the disposal facility.



SSG- 23: The SC &SA for the Disposal of ^{RAW}ars

The safety case and supporting safety assessment provide the *basis* for demonstration of safety and for licensing. They will *evolve* with the development of the disposal facility, and will assist and guide decisions on siting, design and operations.

The safety case will also be the main basis on which *dialogue* with interested parties will be conducted and on which confidence in the safety of the disposal facility will be developed.



Safety Case Components

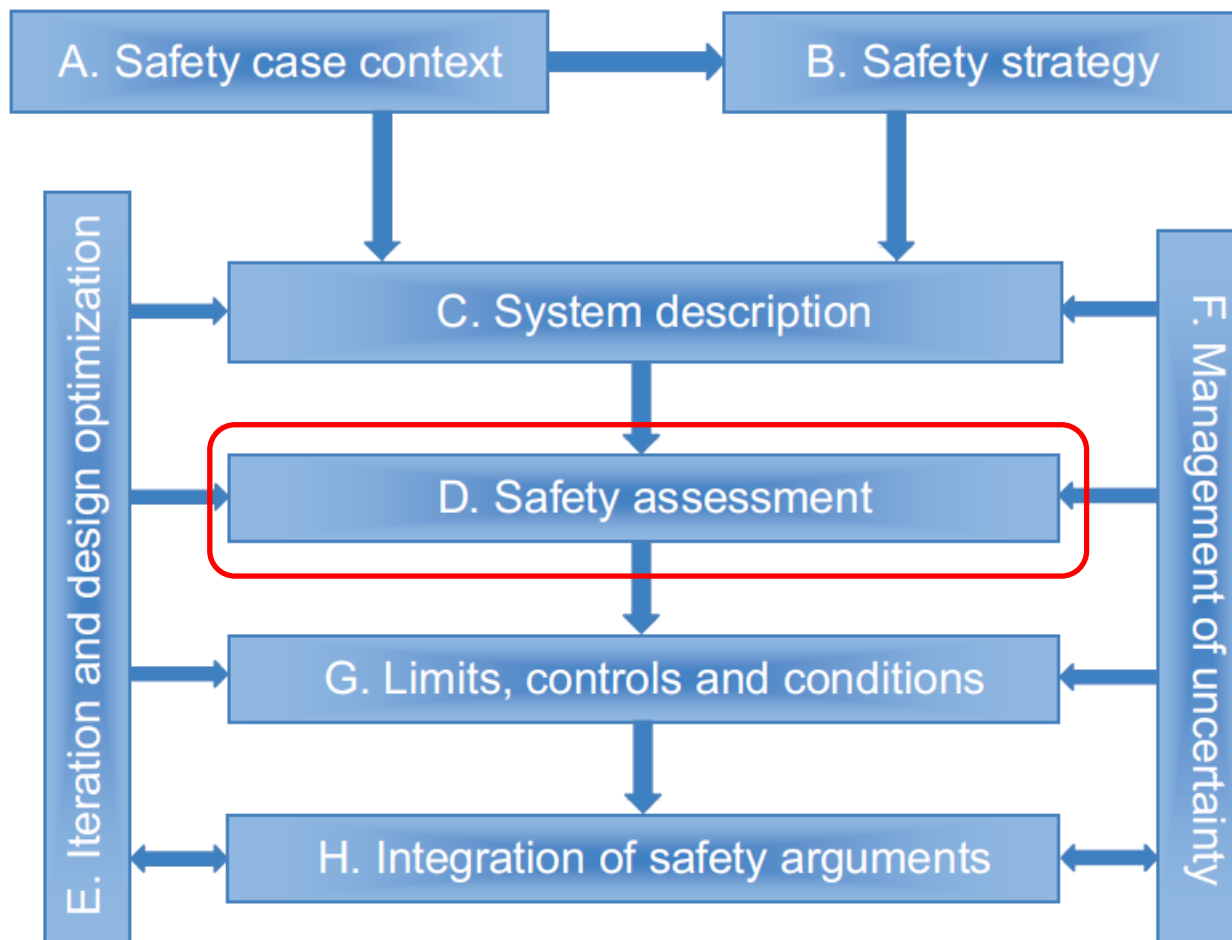
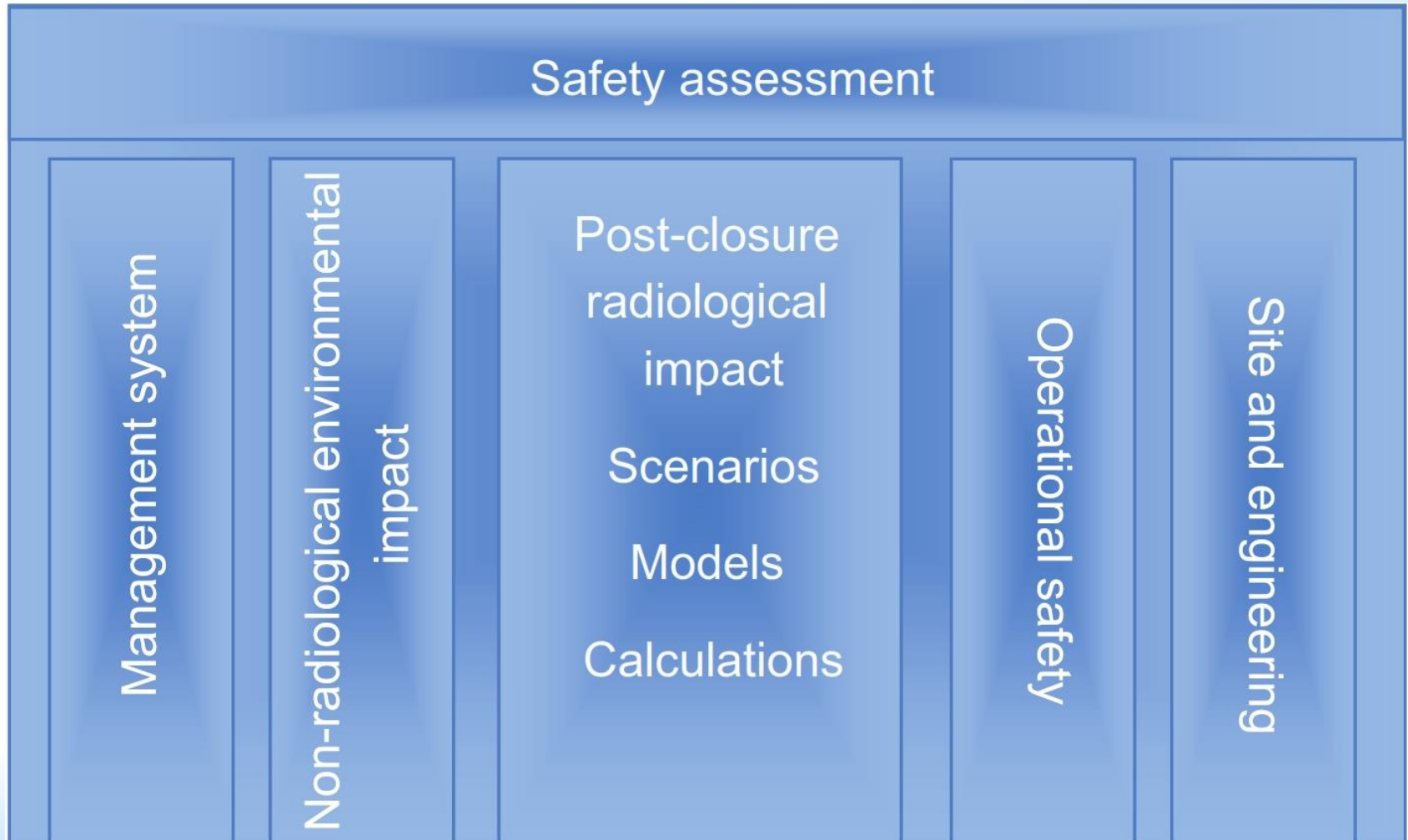


FIG. 2. Components of the safety case.

Aspects included in Safety Assessment



Aspects included in Safety Assessment

The fundamental element of the safety assessment is the assessment of the radiological impact on humans and the environment in terms of both radiation dose and radiation risks.

The other important aspects subject to safety assessment are site and engineering aspects, operational safety, non-radiological impacts and the management system.

The term ‘safety assessment’ is used in SSG-23 to refer to all assessments performed as part of the safety case.

This encompasses all aspects that are relevant for the safety of the *development, operation and closure of the disposal facility*. Thus, the safety assessment also addresses qualitative aspects, non-radiological issues, and organizational and managerial aspects.

Safety Case Context

- Safety objectives
- Safety principles
- Regulations

Safety Strategy

- Isolation, Containment
- Passive systems, robustness
- Defence in depth, demonstrability

System Description

Site and waste characteristics, Safety Functions, Design Options

Safety Assessment

Post Closure

Radiological Impact

Scenarios

Models

Calculations

Management
System

Non-radiological
Environmental Impact

Operational
Safety

Site / Engineering

Iteration & Design Optimization

Limits, controls and conditions

Integration of Safety Arguments

Demonstration of robustness, defense in depth
system understanding, monitoring, etc.

Management of Uncertainties

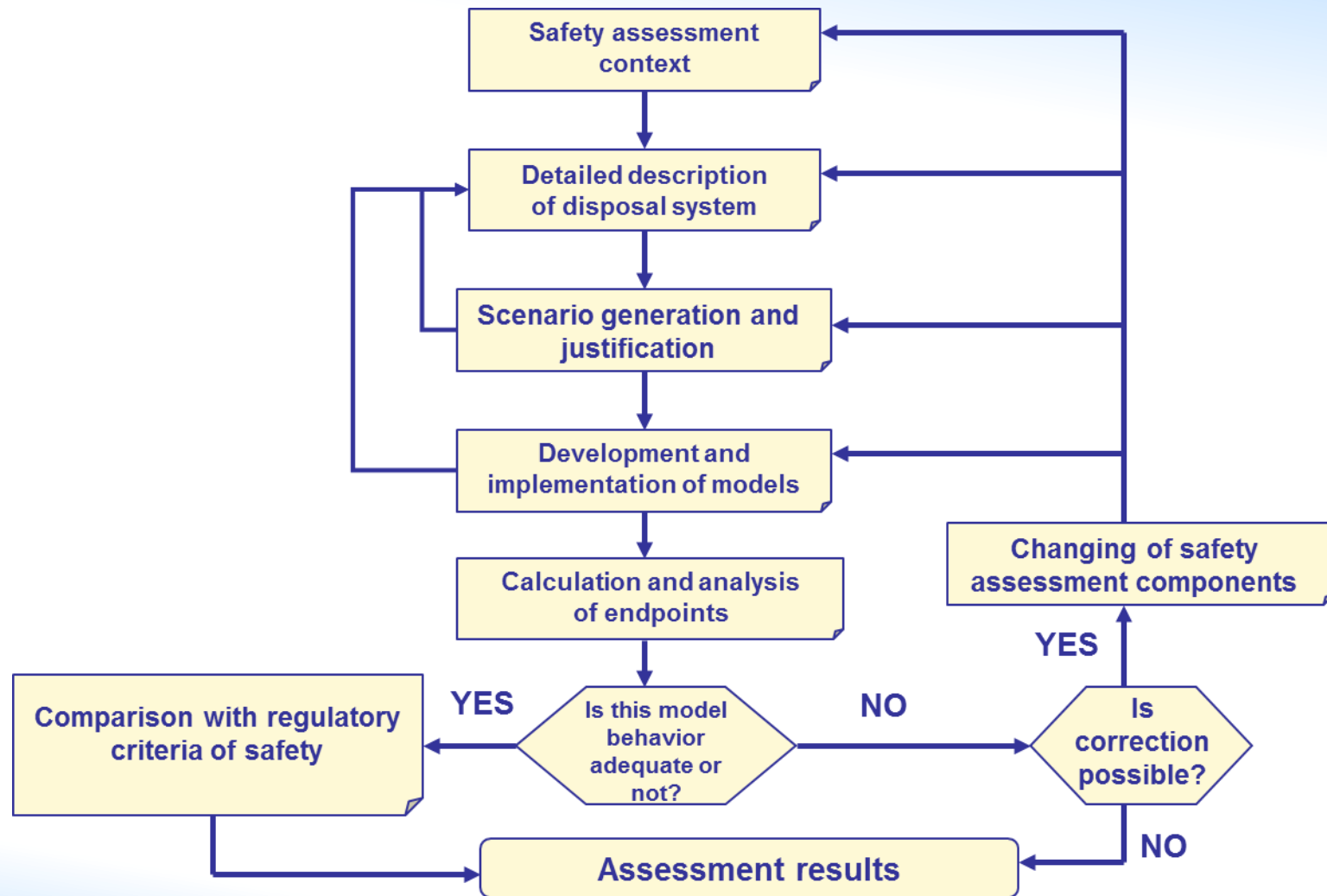
Management System



Stakeholder & Regulatory Involvement

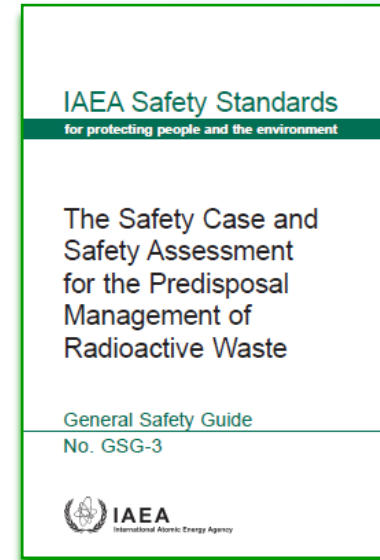


Post-closure Safety Assessment



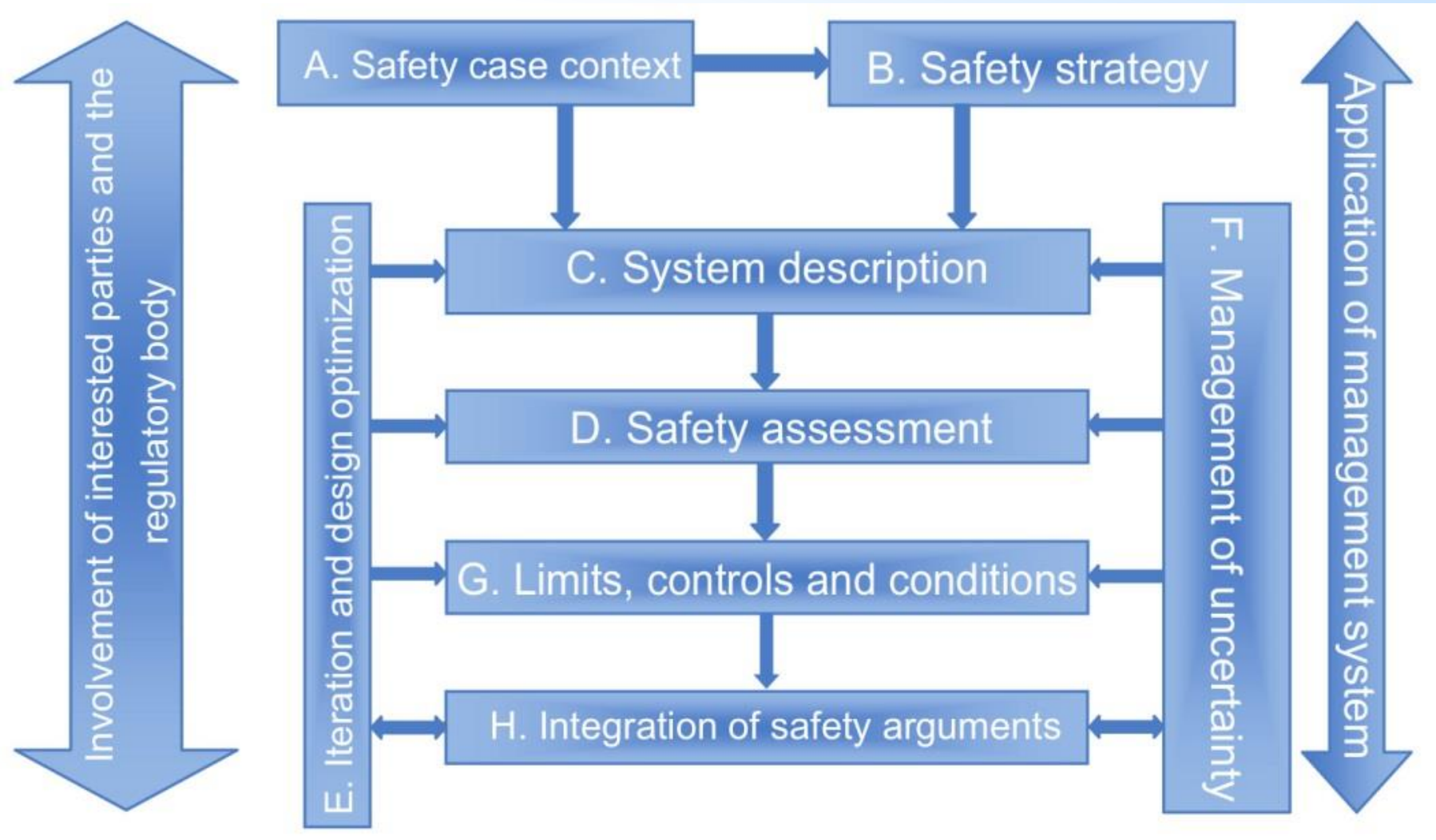
GSG-3: Safety Guide for SC and SA

1. Introduction
2. Demonstrating the Safety of the Predisposal Management of Radioactive Waste
3. Safety Principles and Safety Requirements
4. The Safety Case for Predisposal Management of Radioactive Waste
5. Safety Assessment
6. Specific Issues
7. Documenting and Use of the Safety Case
8. Regulatory Review Process



ANNEX I	Examples Of Hazards And Initiating Events
ANNEX II	Topical Issues for Review of the SC by the RB
ANNEX III	Sample Template Of Regulatory Review Report
ANNEX IV	SADRWMS: Framework for the Overall Process

GSG-3: Safety Case Components and MS



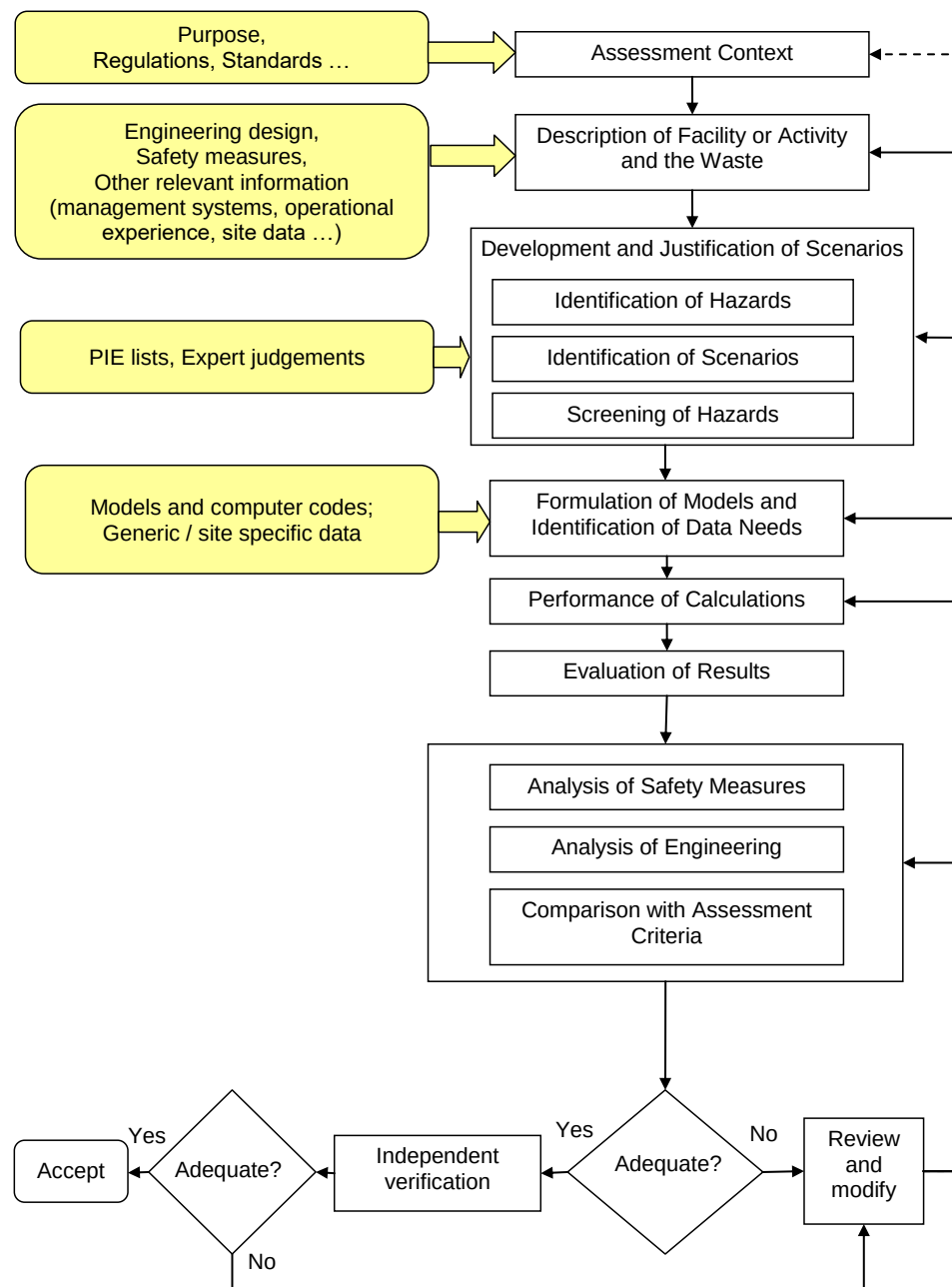
SADRWMS Methodology

IAEA TECDOC SERIES

IAEA-TECDOC-1777

Methodology for Safety Assessment Applied to Predisposal Waste Management

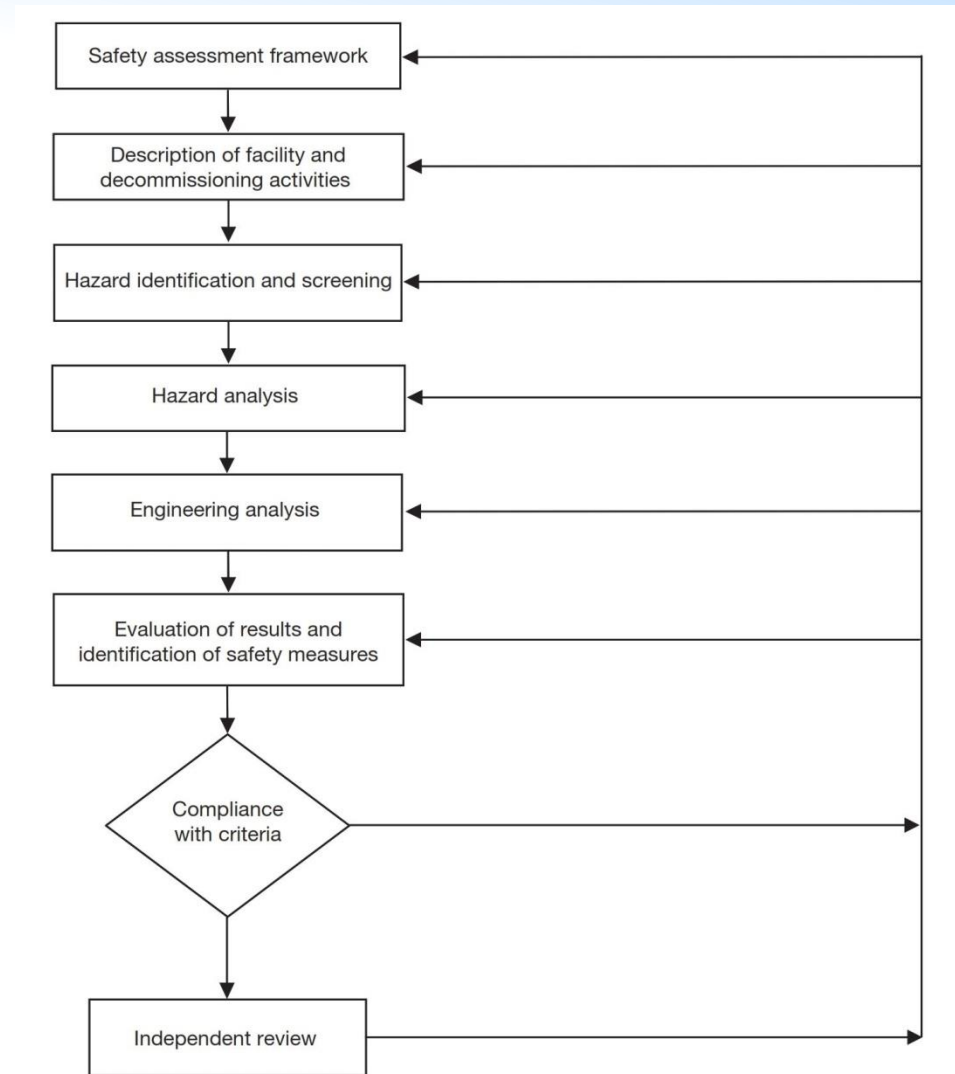
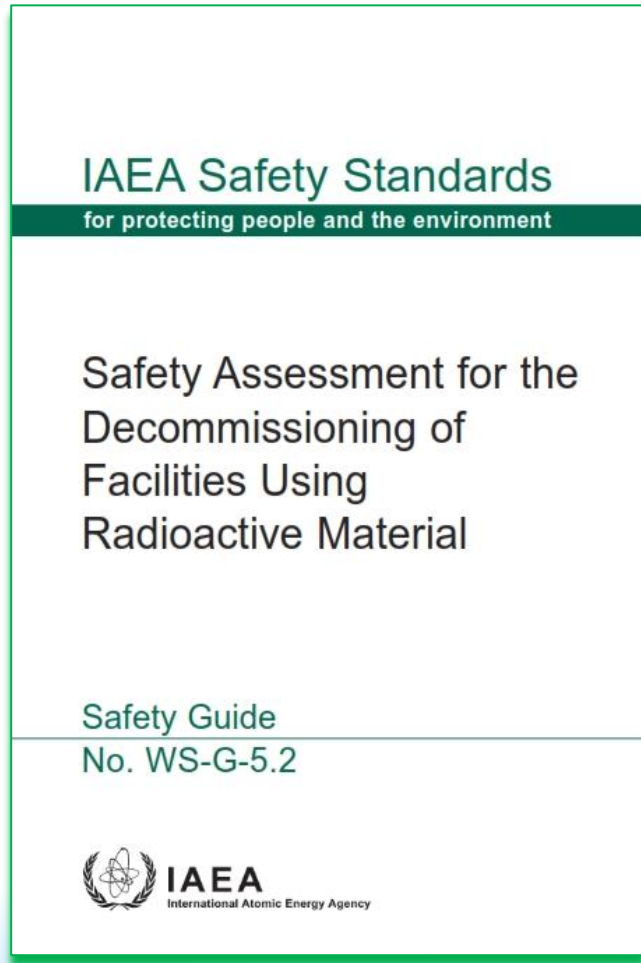
Report of the Results of the International Project on Safety Assessment Driving Radioactive Waste Management Solutions (SADRWMS) (2004–2010)



Differences (Predisposal vs. Disposal)

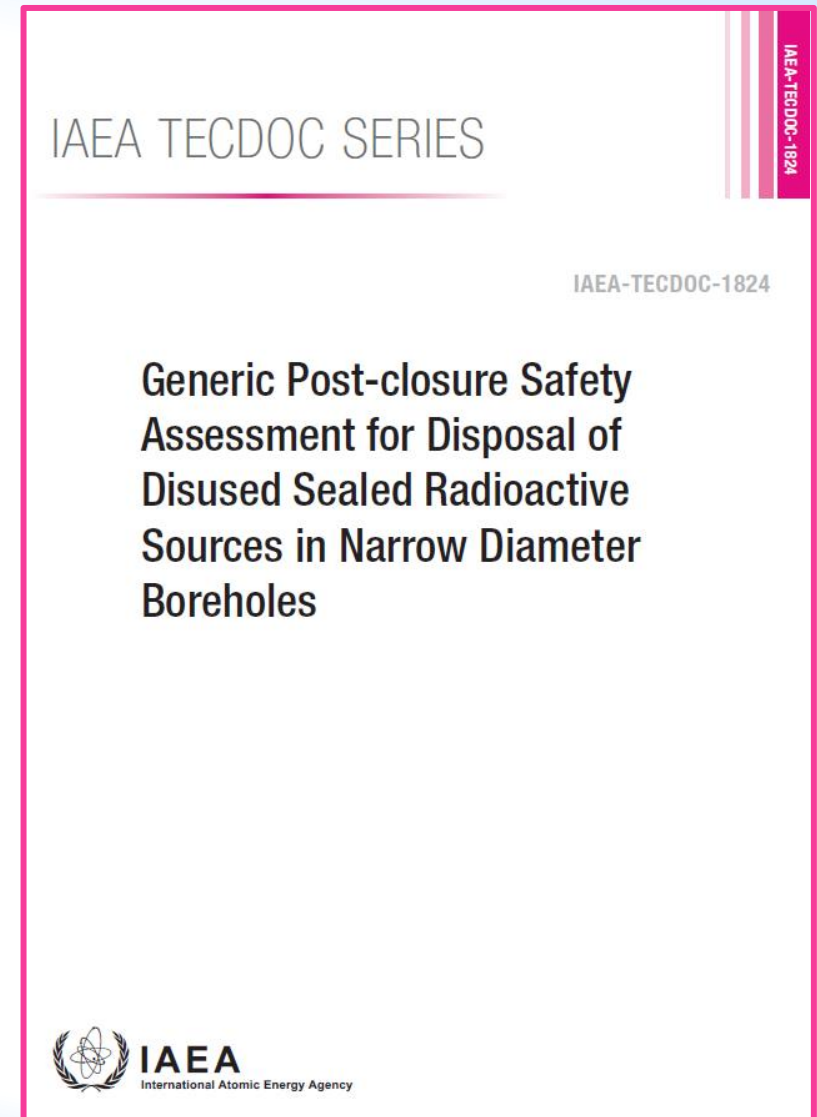
Predisposal	Post-Closure Disposal
Workers and existing residents	Postulated future residents
Relatively well defined active operational conditions and receptors; PIE for scenario generation	Predicted potential migration through geologic environment and assumed activities of future residents; FEPs
Well known engineered system	Variated geology, evolving hydro-geology and other elements of disposal system
Routinely conducted and reviewed for a multitude of facilities	Less common, focused on cases of radioactive waste disposal or leaving waste in place
Independent reviews may be used for complex or unusual facilities	Independent international peer reviews often used to complement regulatory review

WS-G-5.2: SA for Decommissioning



Safety assessment for borehole disposal

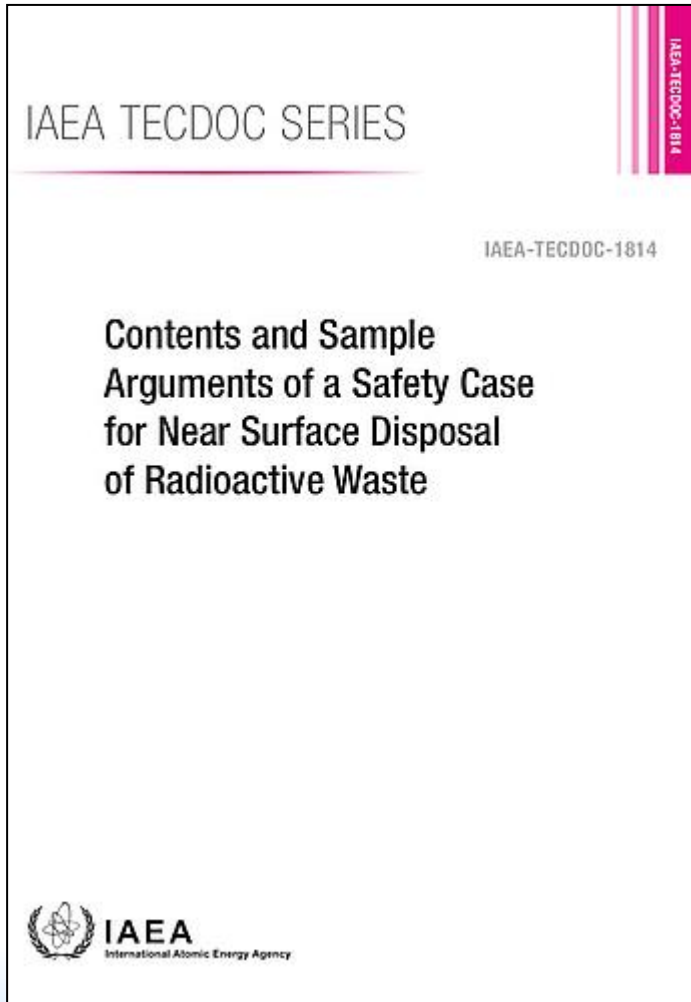
- There have been ~20 years of safety assessment studies for borehole disposal of DSRS
- In 2017, IAEA published a Generic Safety Assessment (GSA)
 - Developed over many years and iterations
 - Considered the disposal of 31 radionuclides in saturated or unsaturated geosphere conditions.



Safety assessment for borehole disposal

- The Generic Safety Assessment (GSA):
 - Was based on a thorough FEPs analysis and scenario development process
 - Included simple, conservative calculations as well as more complex calculations using the Amber code
 - Supported by various more detailed research and process modelling
 - Showed that, **with a suitable combination of inventory, near-field design and geological environment, the BDC is capable of providing a safe solution** for the disposal of both long lived and short-lived radionuclides
 - However, the inventory that can be safely disposed of at a particular site would need to be assessed in a site-specific safety assessment

PRISM - Outcomes

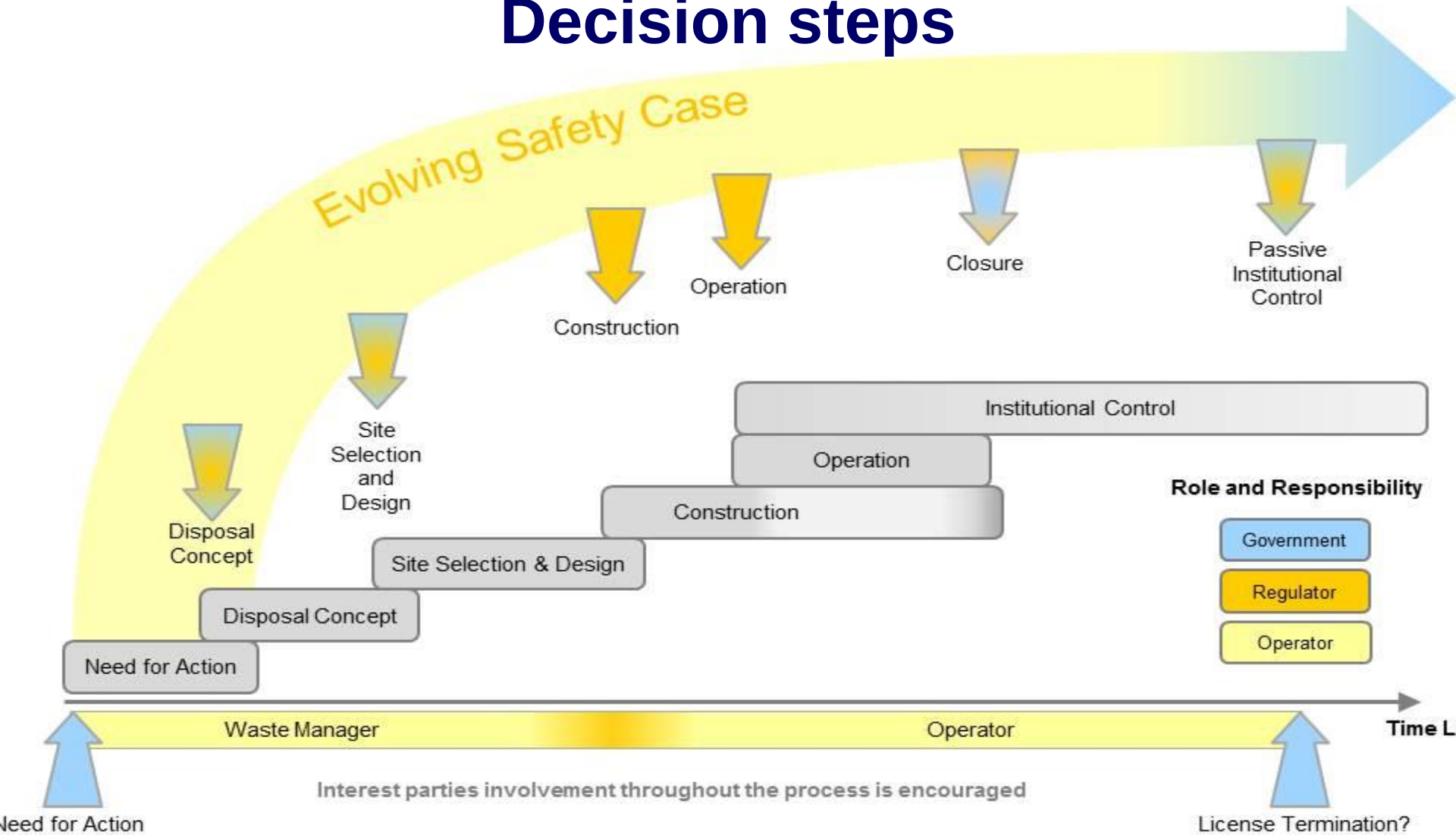


FOREWORD

1. Introduction
2. Key Aspects and Uses of the Safety Case
3. Safety Case and Disposal Facility Evolution
4. Detailed Description of the Key Decision Steps in the Development of a Disposal Facility for Radioactive Waste
5. Components of the Safety Case
6. The MASC Matrix
7. Sample Arguments of a Safety Case for Two Hypothetical Radioactive Waste Facilities
8. References

Evolution of a safety case

Decision steps





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Thank you!





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Overview of Safety Case for Predisposal

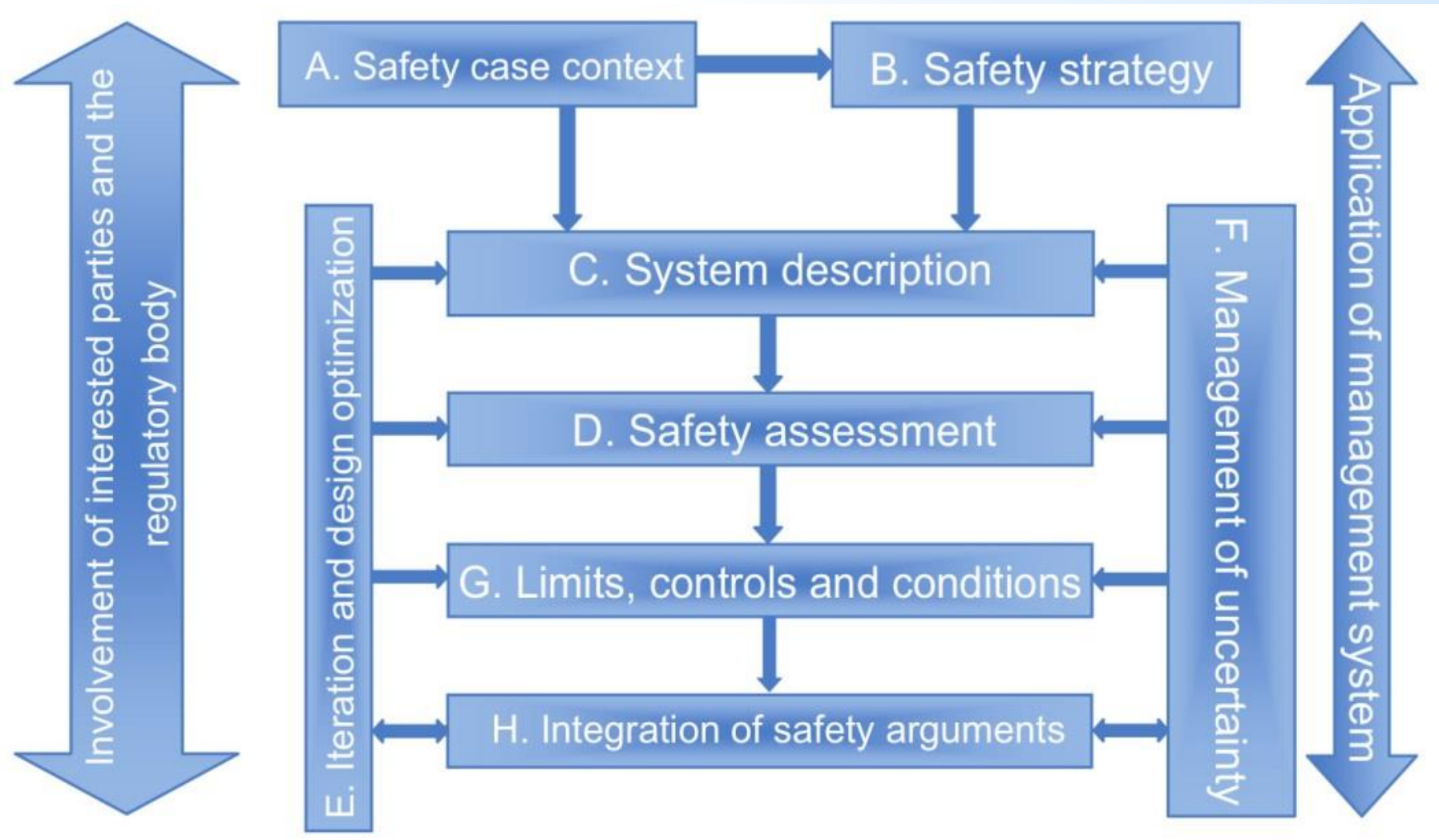
The Safety Case for Predisposal Management of Radioactive Waste

- GSG-3, 4.2. The components of the safety case are indicated in the next slide and should include the following:
 - the context
 - the safety strategy
 - the facility description
 - safety assessment
 - limits, controls and conditions
 - iteration and design optimization
 - uncertainty management
 - and integration of safety arguments
- For smaller scale facilities, such as storage facilities for disused sealed sources, the components of the safety case listed above are still relevant; however, the level of detail and the complexity and depth of the safety assessment are required to be commensurate with the potential hazard (Requirement 1, GSR Part 4).

Components of the Safety Case



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Safety Case Development Process

- Safety case is developed from the conceptualization of the facility and is maintained throughout its lifetime up to decommissioning and license termination;
- Development of a safety case is an iterative process that evolves with the development of the facility;
- The formality and level of technical detail of the safety case depends on the stage of development of facility, the required decisions and specific national requirements.

Safety Case Development Process

- The safety case concept is of particular importance and benefit for large predisposal waste management facilities
- For smaller scale facilities the elements of the safety case process are still relevant, however
 - The level of complexity and detail should be commensurate with the potential hazard;
 - Some aspects will be proportionally less demanding or less relevant (e.g. development in stages)

Safety Case Development Process

- The safety case may be developed in various ways and its content and structure will be greatly influenced by the State specific legislative and regulatory requirements and local concerns
- Although some States do not use the term “safety case” in a formal way, the approaches and processes they use to demonstrate safety are compatible with and, in essence, similar to the safety case concept

COMPONENTS OF SAFETY CASE



Context of the safety case

- Purpose
 - ✓ Depends on facility development stage (testing of initial ideas for safety concepts, site or location selection, demonstration of safety, periodic re-assessment, application to modify the facility or activity etc.)
- Scope
 - ✓ Entire/single facility/activity, boundaries, interfaces.
- Approach
 - ✓ Safety objectives, principles, criteria and regulatory requirements, application of graded approach.

Context of the safety case (cont.)

- It is important that the context for a particular stage (revision) of the safety case is clearly presented and is modified as necessary for subsequent stages (revisions);
- It should be clearly defined:
 - ✓ the lifecycle stage of the facility being considered;
 - ✓ how the safety case has changed from previous safety cases;
 - ✓ how this safety case will support future revisions of the safety case.

Context of the safety case (cont.)

Purpose of the safety case

- The safety case will be developed as the project progresses and will be used as a basis for decision making, for both regulatory decisions and other decisions relating to, for example, the design, supporting research work or site characterization activities. The context for each revision of the safety case should be set out clearly and should be updated as necessary and appropriate for subsequent revisions of the safety case.

Context of the safety case (cont.)

Purpose of the safety case

- The purpose of *each revision of the safety case* will depend on a number of factors, such as the programmatic framework, the stage of development of the facility, and whether the safety case is being submitted to the regulatory body as part of a formal licensing procedure or to obtain directions from the regulatory body. For each revision of the safety case, the operator should provide a clear description of its purpose, which, depending on the stage of development of the facility, could include:

Context of the safety case (cont.)

Purpose of the safety case could include:

- Testing of initial ideas for safety concepts
- Site or location selection
- Demonstration of the safety of the facility or activity
- Optimization of the facility design or activity arrangements
- Evaluation of clearance and discharge activities
- Determination and justification of the expected lifetime of the facility
- Assessment of the maximum inventory of waste that can be accepted (the 'radiological capacity' of the facility)
- Definition or revision of limits, controls and conditions
- Input to monitoring and data acquisition programmes
- Periodic reassessment as required by law or regulation
- Application to modify the facility or activity or to collocate new facilities
- Shutdown and decommissioning of the facility, either at the planned end of the life of the facility or as a consequence of non-compliance with regulations
- Determination of whether remedial action is necessary
- Demonstration of compatibility with a disposal option

Context of the safety case (cont.)

Scope of the safety case

- The scope of the safety case should be clearly defined. It should identify whether the safety case considers an entire facility or a single activity within a larger facility. It should also consider site boundaries and interfaces with neighbouring activities and facilities.
- In the case of step by step development of the facility, the scope of the safety case should provide a clear definition of the relevant stage in the facility's lifetime, how the safety case has changed from previous versions, and how it will support future revisions. For example, it should be explained how the safety case for the commissioning stage has progressed from the safety case for the construction stage, and how this will justify the operation of the facility once commissioning is complete.

Context of the safety case (cont.)

Demonstration of safety

- The approach to demonstration of safety refers to the safety objectives and safety principles that must be applied and the regulatory requirements that must be met. The safety objectives and safety principles may be established by the regulatory body. The regulatory framework that governs how the safety case is to be developed should be documented as part of the context for the safety case, and the safety case should be developed in a manner consistent with that framework. The safety criteria may vary in different countries and are required to be specified in the context for the safety case.

Context of the safety case (cont.)

Demonstration of safety

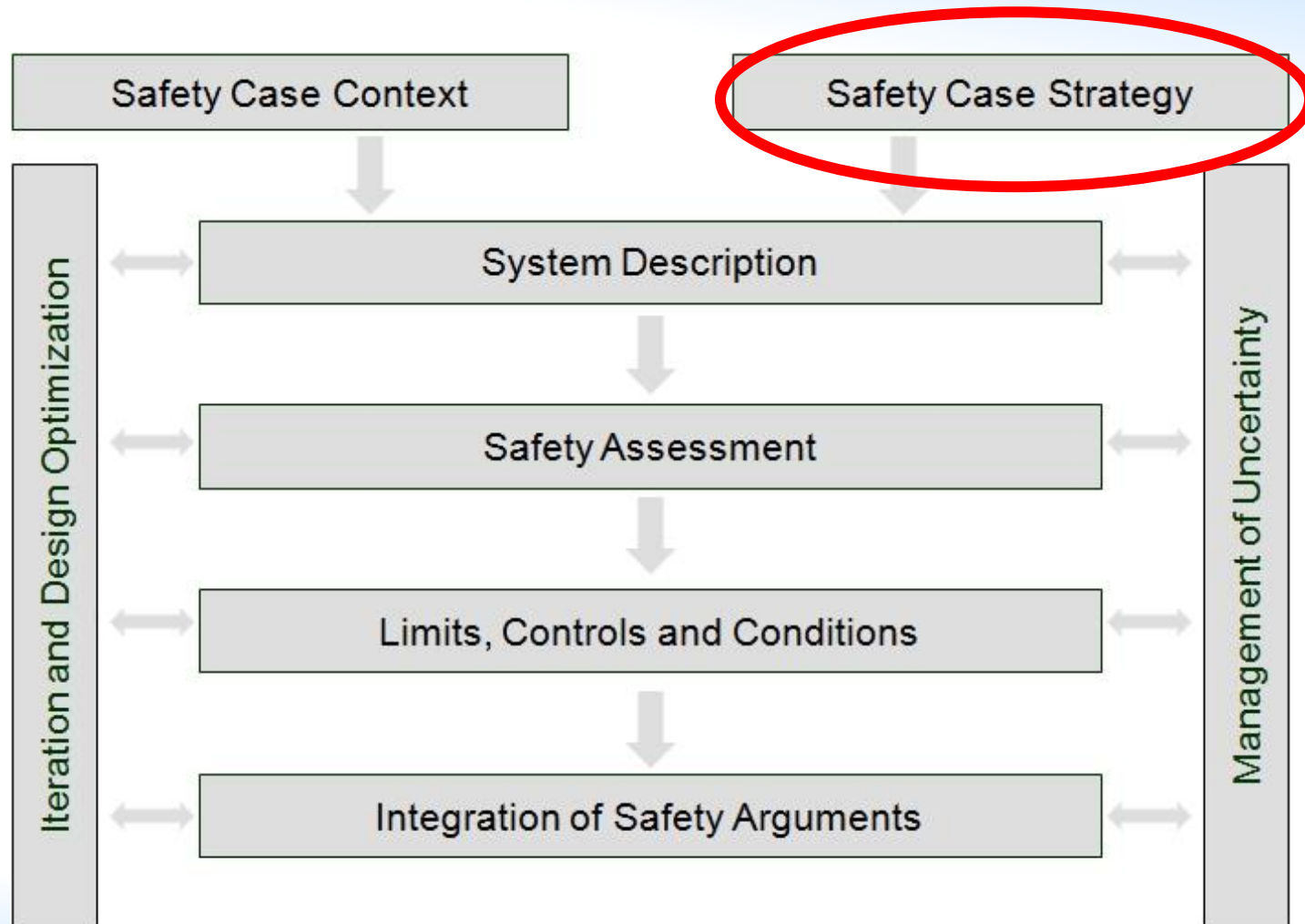
- Safety requirements other than safety criteria, as well as other requirements relating to the safety case, should be specified in the context for the safety case (e.g. industrial safety criteria, environmental criteria, clearance criteria and criteria for release of the site from regulatory control).
- The approach to demonstration of safety should also set out explicitly how the management of uncertainties will be addressed in the safety case. This should cover, as a minimum, how uncertainties will be identified, how they will be characterized and what the approach will be to their management.

Context of the safety case (cont.)

Graded approach

- A graded approach is required to be taken in determining the scope, extent and level of detail of the safety case and supporting safety assessment to be carried out. The graded approach adopted should be explained and justified and should be such that the scope, extent and level of detail of the safety case and supporting safety assessment are commensurate with the hazards, the complexity of the facility or activity and the characteristics of the waste to be managed. The safety case should provide a justification for the extent and depth of the safety arguments and supporting safety assessment. For example, in the case of a step by step approach, the safety assessment for generic storage concepts being considered prior to site selection might be conducted in less detail than the safety assessment for facility commissioning. Factors relevant to the graded approach for a safety assessment are given in GSR Part 4.

COMPONENTS OF SAFETY CASE



Safety case strategy

- Defines the approach that is taken in site selection, facility location, facility design and operation:
 - ✓ to comply with the safety objectives, principles and criteria;
 - ✓ to comply with regulatory requirements;
 - ✓ to ensure that good engineering practice has been adopted and that safety and protection are optimized.
- Should be established at the early stage of facility conceptualization.

Safety case strategy (cont.)

- As the project develops, the safety strategy should be continually validated and any changes should be justified in the safety case;
- It is also important that any evolution of the safety strategy be carefully recorded and the records preserved for use in the future when staff may have changed.

Safety case strategy (cont.)

The safety strategy should address a number of key elements:

- ✓ Provision of multiple safety functions;
- ✓ Concept for defense in depth;
- ✓ Concept for shielding and containment;
- ✓ Selection of appropriate approaches to waste processing;
- ✓ Waste minimization;
- ✓ Waste management optimization with regard to reuse, recycling and clearing of materials;
- ✓ Interdependencies with other predisposal management steps and with disposal of the waste;
- ✓ Uncertainty management.

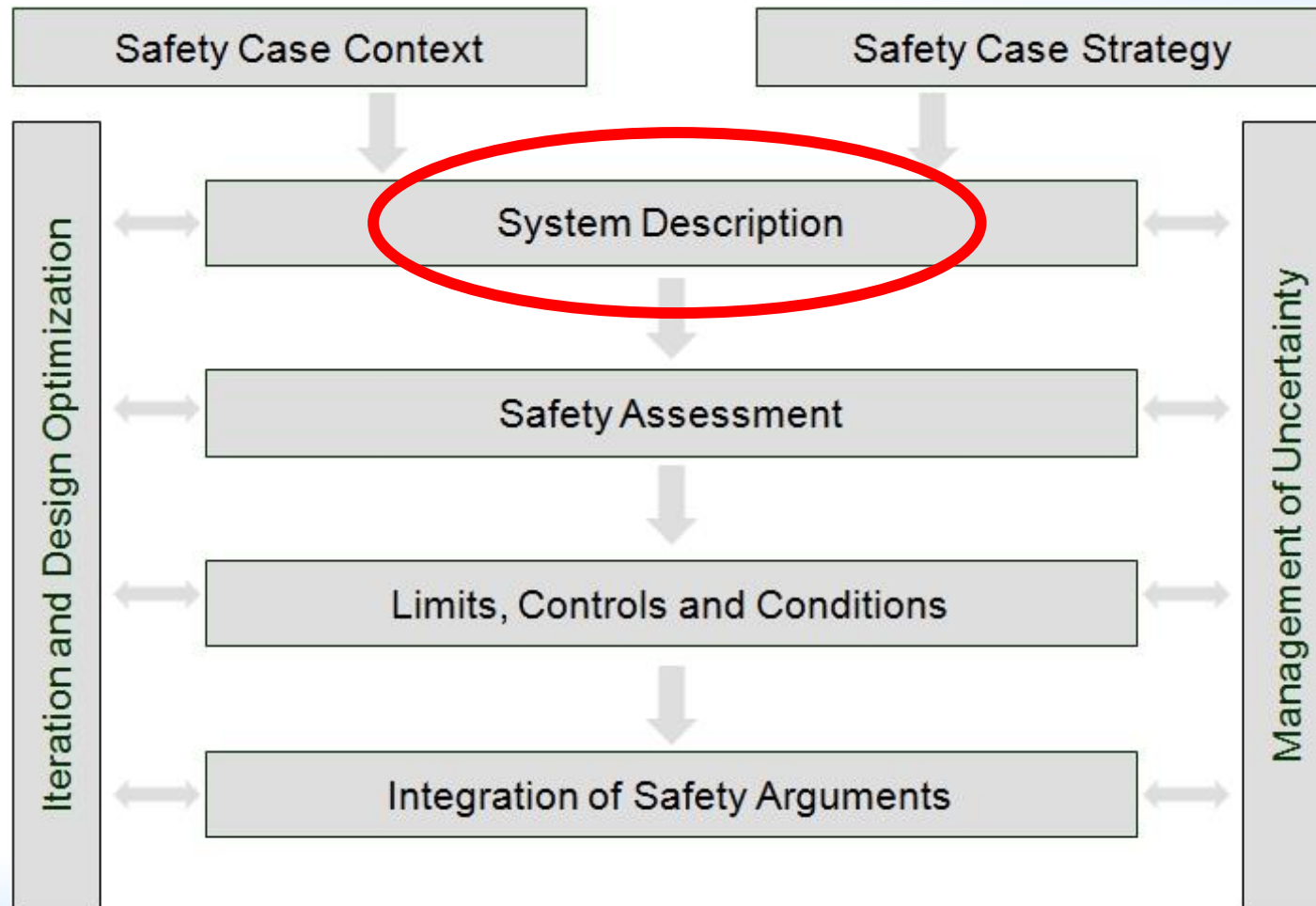
Safety case strategy (cont.)

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

Safety case strategy (cont.)

- The strategy for safety should set out the following:
 - The degree of caution that will be exercised when making decisions;
 - The rationale for selecting the assessment methodology and time frame and time windows for assessment, including a discussion of the various approaches to assessment and tools that will be used to verify, confirm and compare assessment findings;
 - How peer reviews will be conducted;
 - How consistency with international guidance and practices will be demonstrated;
 - Other high level arguments as appropriate.

COMPONENTS OF SAFETY CASE



Description of facility and waste

- The description of the waste management facility or activity should provide the basis on which the safety assessment is carried out
- The description should contain, depending on the type of pre-disposal facility, information on the:
 - ✓ Site conditions
 - ✓ Facilities and activities
 - ✓ Waste

Description of facility and waste (cont.): *Site conditions*

To be identified and described:

- Site conditions and the associated events, of both natural and man-made origin, that could:
 - ✓ influence safety and
 - ✓ impose demands on the facility or activities and its equipment and components;
- The objective is to establish:
 - ✓ the normal or average situation and
 - ✓ to identify any more extreme but credible events to be considered.

Description of facility and waste (cont.):



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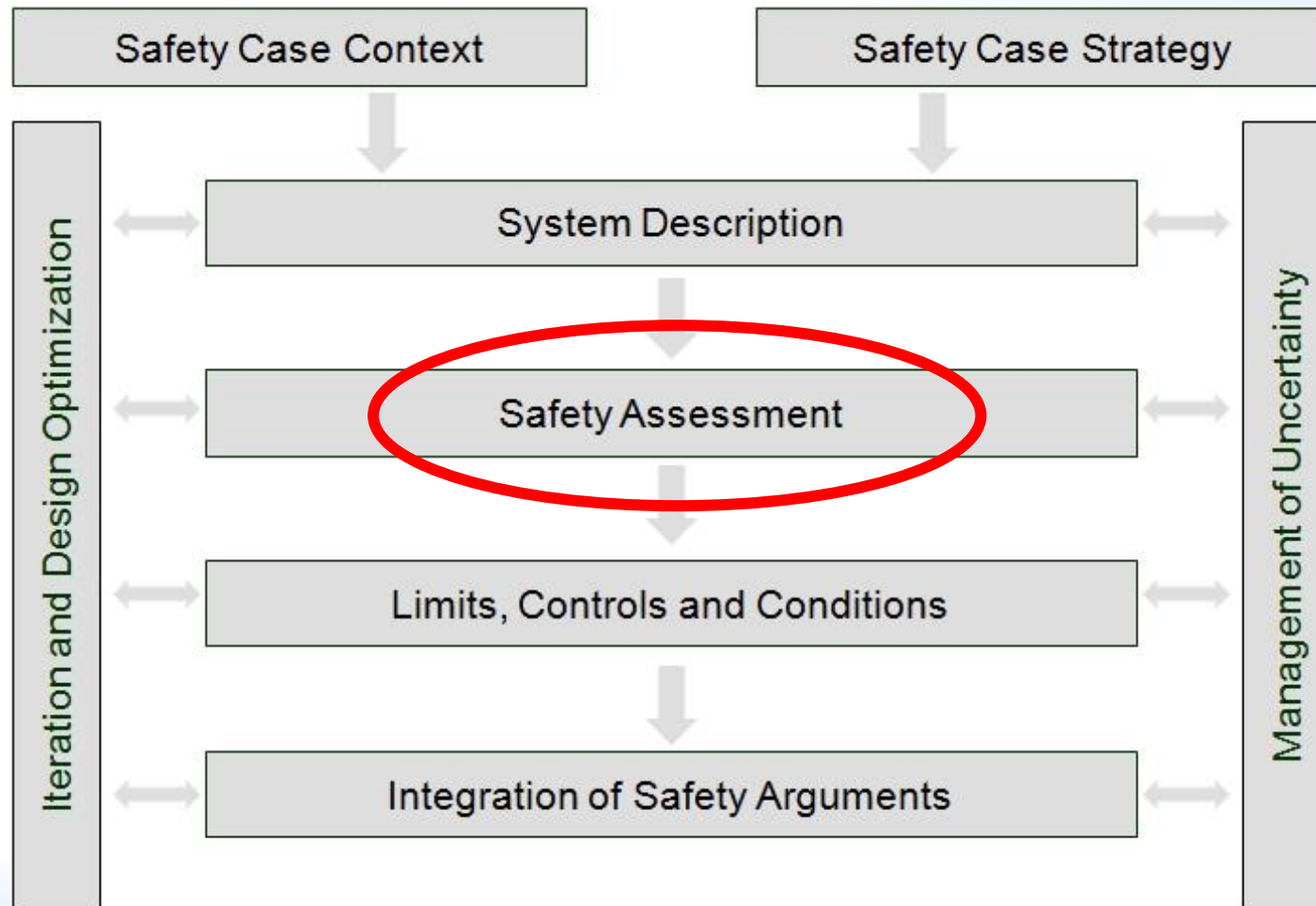
Facilities and activities

- Facility structures;
- Systems and components and their importance for safety;
- Range of conditions under which the facility may operate;
- Hazards to which the facility may be exposed;
- Interfaces;
- Operational aspects such as operating and maintenance procedures, controls and monitoring.

Description of facility and waste (cont.): *Waste*

- For each type of radioactive waste to be processed or stored, as well as material that is cleared/discharged at the facility or within the activity:
 - ✓ Volume and form,
 - ✓ Radionuclides of concern and the radioactive content;
 - ✓ Presence of fissile materials;
 - ✓ Other physical, chemical and pathogenic properties;
- Secondary waste streams that may arise from waste processing should be included.

COMPONENTS OF SAFETY CASE



Safety assessment

The term 'safety assessment' is used in GSG-3 to refer to all assessments performed as part of the safety case.

This encompasses all aspects that are relevant for the safety of the facility.

Thus, the safety assessment also addresses qualitative aspects, such as good engineering practice, and the management of non-radiological issues, such as conventional safety.

Safety assessment

The term ‘safety assessment’ is used differently in two respects:

- (a) ‘Safety assessment’ was defined as the overall process of performing quantitative assessments of radiological safety. This included the development of the context for the assessment and the description of the facility and its environment, as well as the interpretation of the results.
- (b) However, in terms of the broader context for the safety case, these elements are considered part of the overall safety case and are not only part of the quantitative safety assessment. Addressing these elements in a broader context, therefore, does not represent a change in the actual methodology for the performance of quantitative assessments.
- (c) ‘Safety assessment’ in GSG-3 relates to aspects relevant for safety beyond the quantitative assessment of radiation risks. This broadening of the term ‘safety assessment’ is a logical consequence of the adoption of the broader concept for the safety case as a basis for this Safety Guide.

Safety assessment

Shall address and assesses number of features of facility or activity, such as:

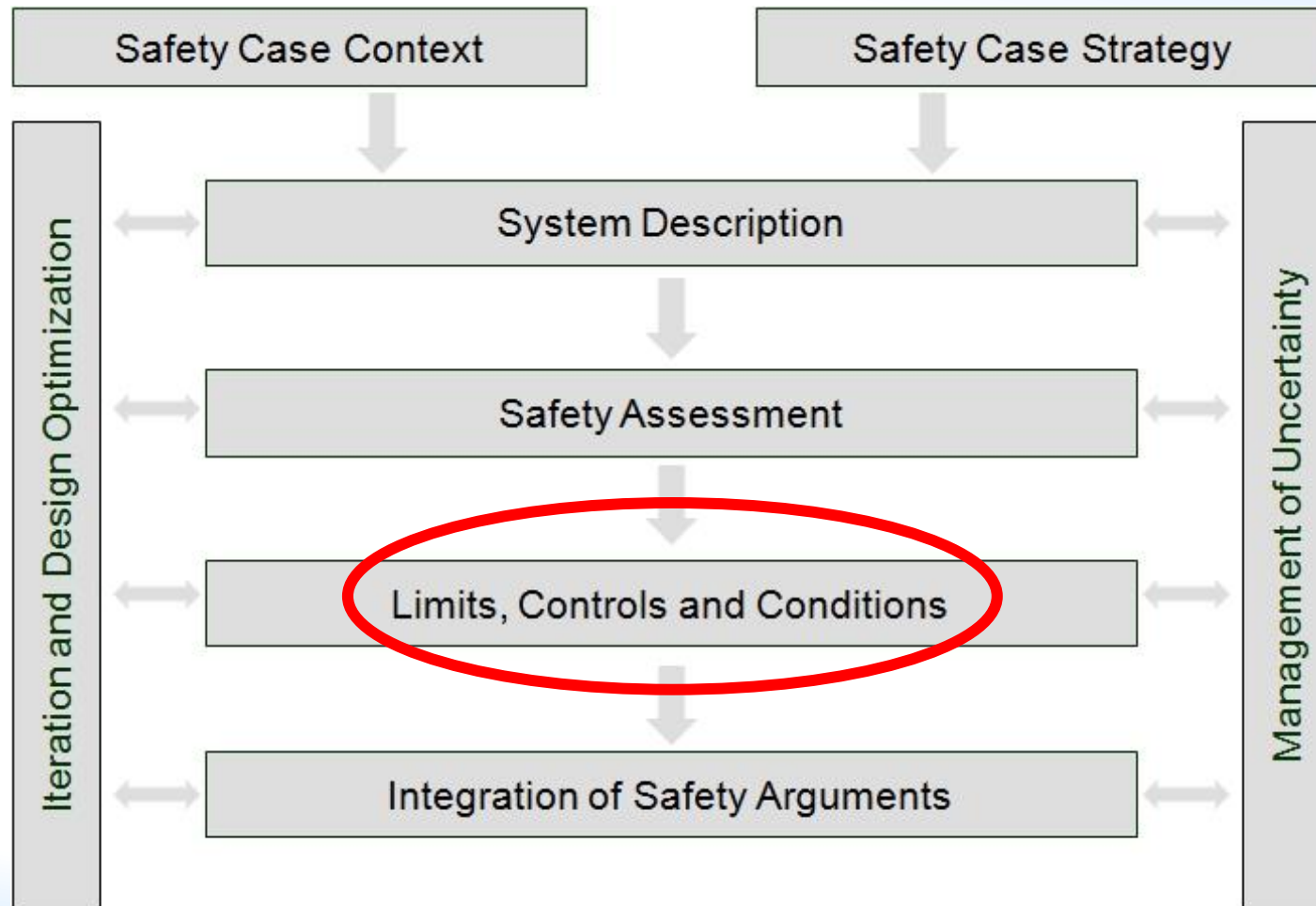
- ✓ Radiological impact assessment
- ✓ Site and engineering aspects
- ✓ Engineering analysis
- ✓ Passive safety
- ✓ Defence in depth
- ✓ Scientific and engineering principles
- ✓ Quality of the site characterization
- ✓ Operational safety aspects
- ✓ Non-radiological environmental impact
- ✓ Management system

Safety assessment

The safety assessment will not necessarily be performed at the same level of detail at all stages in the lifetime of the facility or activity (e.g. there may be a lack of design information at the site selection stage).

The safety assessment should be updated at appropriate intervals (e.g. at least before the beginning of each stage, or as required by the regulatory body), with account taken of new information, such as feedback from operating experience.

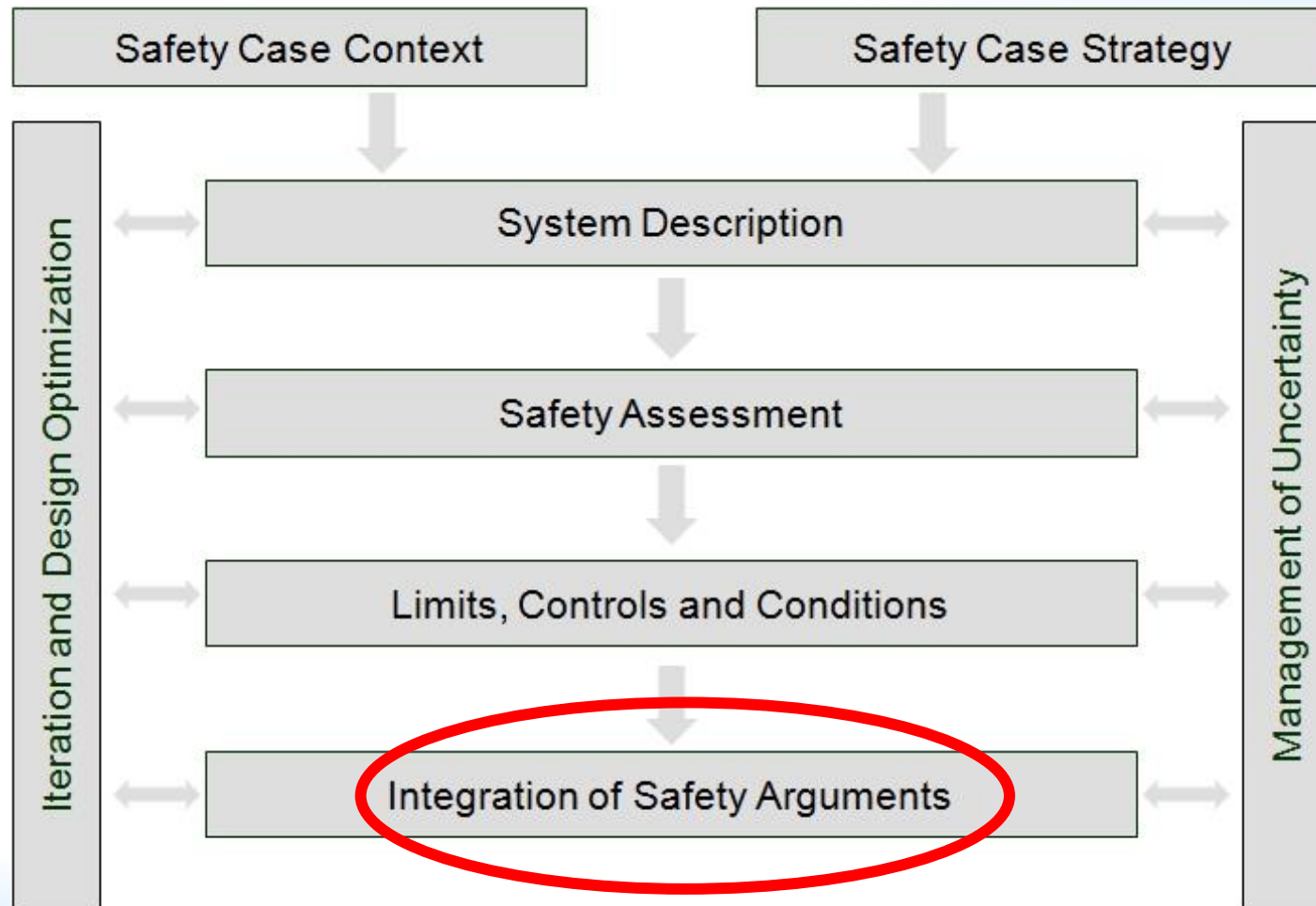
COMPONENTS OF SAFETY CASE



Limits, controls and conditions

- The safety case assists in the establishment of license conditions and other controls and requirements;
- The safe operating specifications are used as an input to designing of operational programmes and procedures, including maintenance, inspection and testing requirements.

COMPONENTS OF SAFETY CASE



Integration of safety arguments

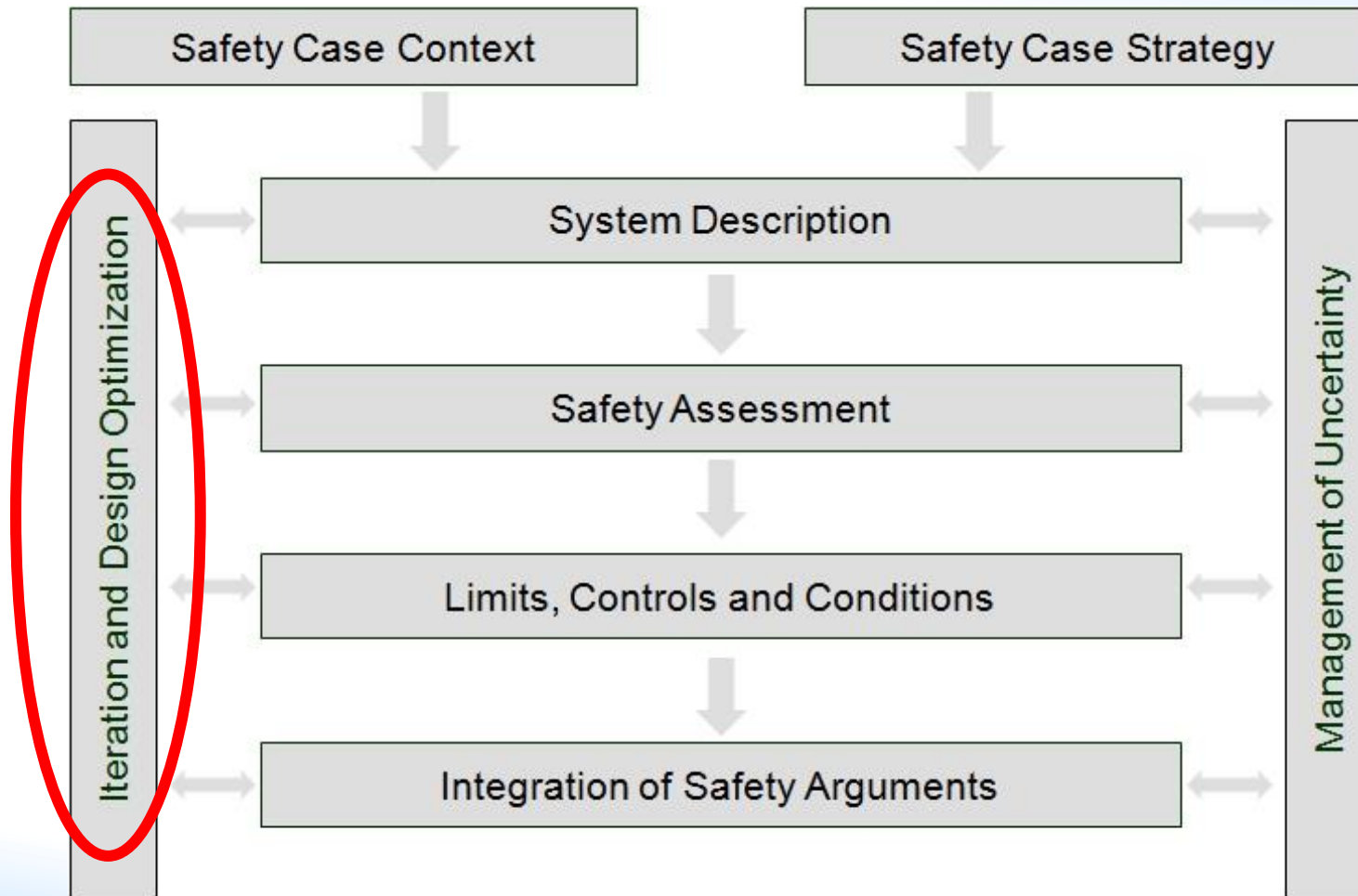
The safety case should provide a synthesis of the available evidence, arguments and analyses:

- ✓ How relevant data and information have been considered, how models have been tested;
- ✓ How a rational and systematic assessment procedure has been followed;
- ✓ What are limitations of currently available evidence, arguments and analyses;
- ✓ What are principal grounds on which a judgments respect to the planning and development of facility or activity have been made.

Integration of safety arguments (cont.)

- Safety case includes all the different lines of evidence, arguments and analyses that assess the quality and performance of facility at a given stage of planning and development.
- Confidence in safety case at any stage will be enhanced if each safety case version will include a plan for further work as necessary to address remaining and unresolved issues.

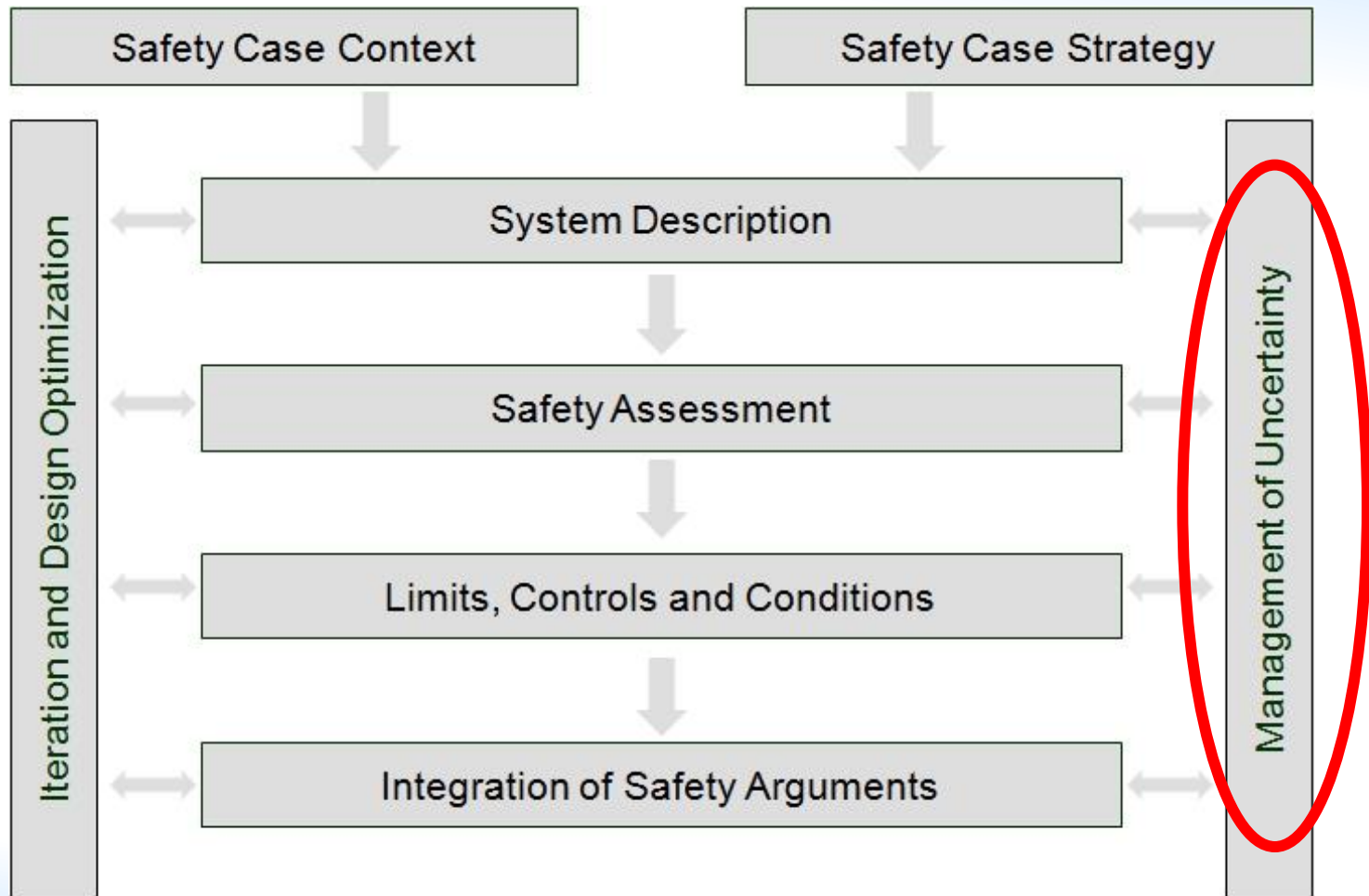
COMPONENTS OF SAFETY CASE



Iteration and design optimization

- The actual decision making process is multifaceted in that several varied and sometimes competing factors have to be brought together and reconciled to reach a decision;
- This process will be iterative in most practical cases;
- Iterations will depend on the status of facility development, the required decisions as well as the availability of data their quality.

COMPONENTS OF SAFETY CASE



Management of uncertainties

- Uncertainties may have implications on the outcome of the safety analysis and the decisions made.
- Treatment of uncertainties
 - ✓ Identify uncertainties in the performance of facility;
 - ✓ Identify the possible significance of the uncertainties;
 - ✓ Identify approaches for the management of significant uncertainties.

Documentation and use of Safety Case

Example of a Content

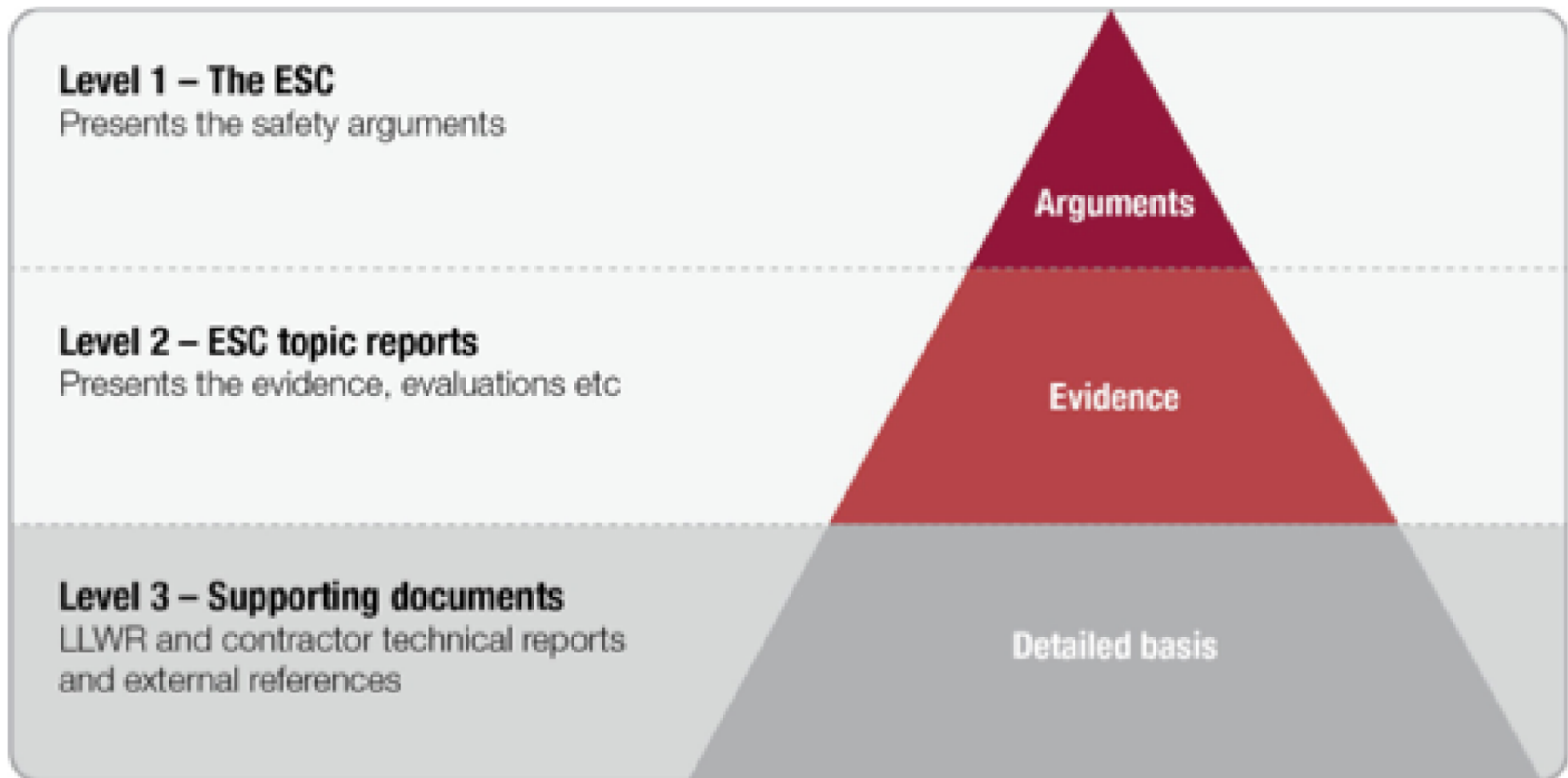
- **Executive summary**
- **Introduction**
- **Safety case context**
- **Safety strategy**
- **Safety assessments**
- **Follow-up programmes and actions**
- **Public involvement (other parties)**

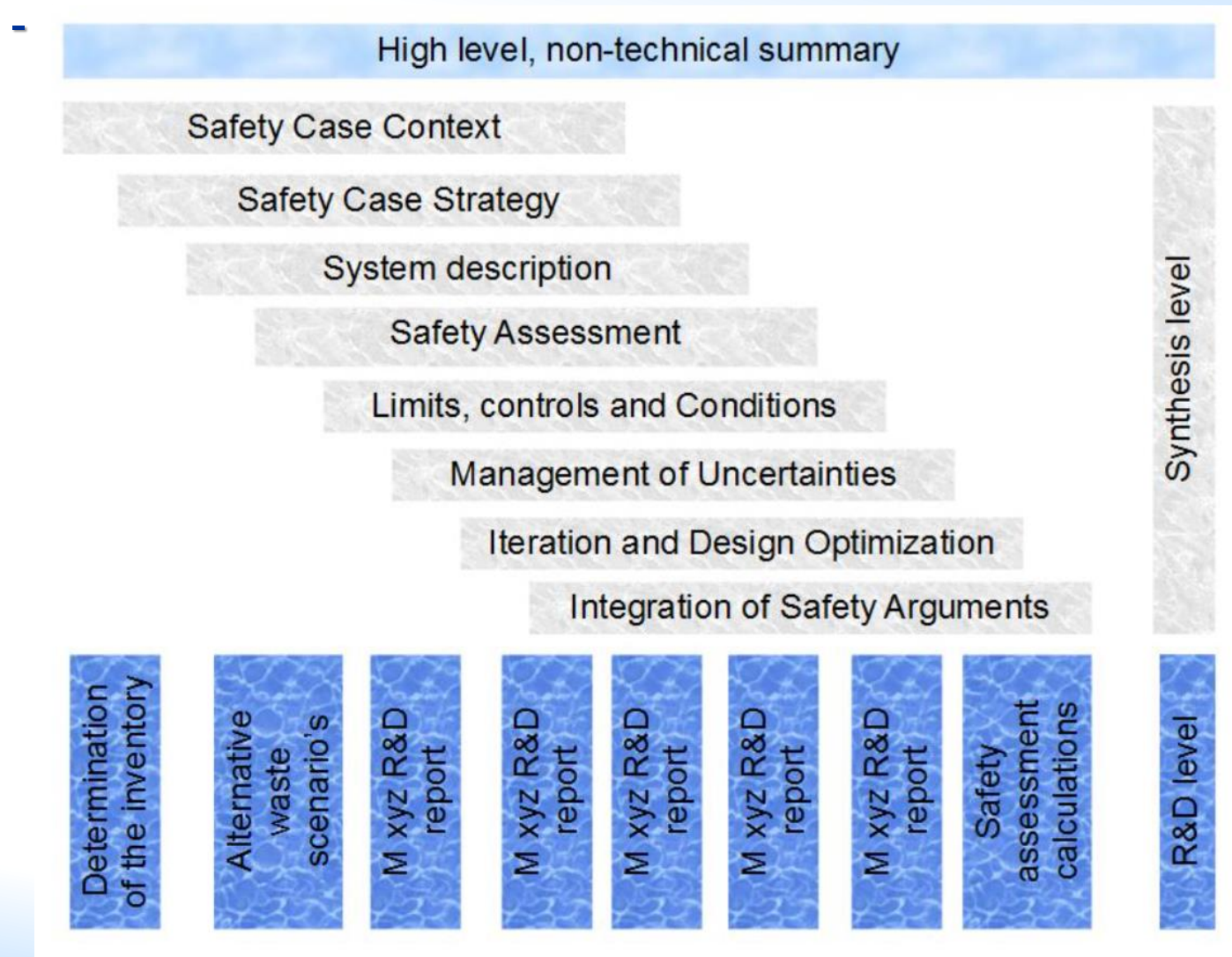
Use

- **Licensing**
- **Design**
- **Construction**
- **Commissioning**
- **Derivation of limits, conditions and controls**
- **Operation**
- **Monitoring**
- **Management controls**

Example Safety Case Document Structure

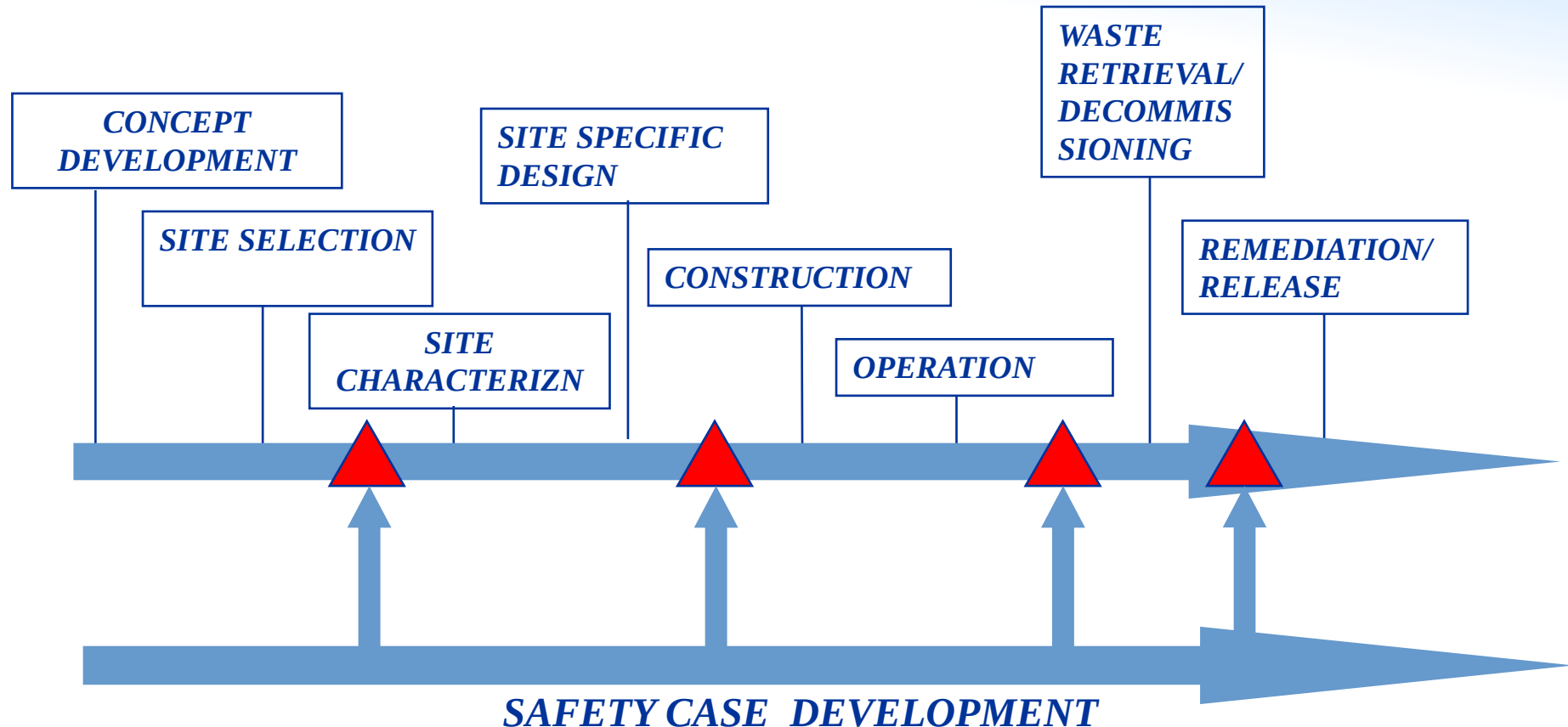
- from the United Kingdom Low Level Waste Safety





Safety case development

FACILITY DEVELOPMENT



Summary: Safety Case

- Needed **at all stages** of facility lifecycle
- **Demonstrates safety through defence in depth**
 - Describes wastes, facility, lifecycle plans
 - Describes management, training, finance
 - Includes safety assessment
- **Evolves at each stage** to reflect new context and information
- **Needs to be understood and applied by operators**



IAEA

60 Years

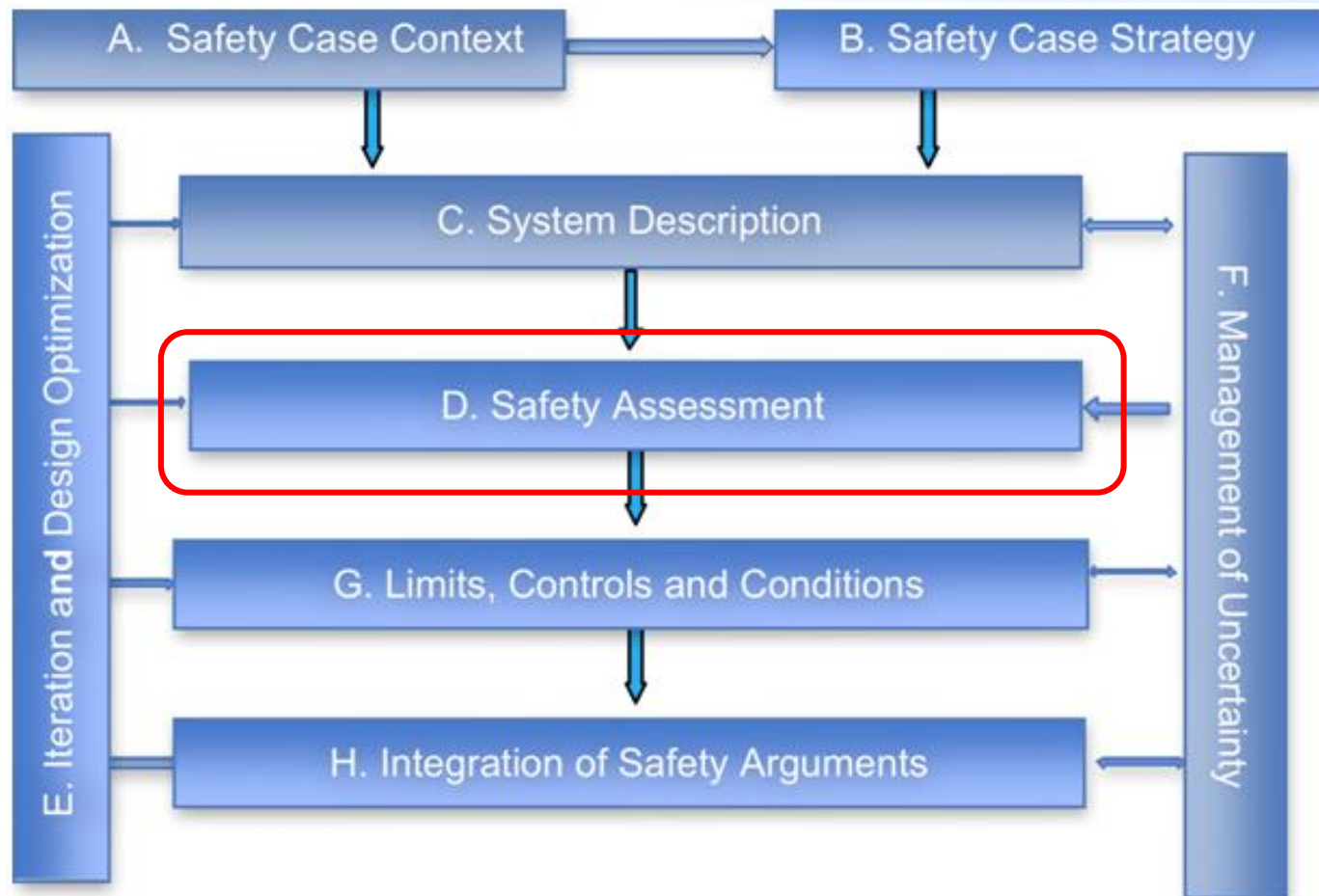
Atoms for Peace and Development

Overview of Safety Assessment for Predisposal Waste Management

Components of the Safety Case



60 Years
Atoms for Peace and Development



Safety Assessment

- Safety Assessment (SA) is the main component of the Safety Case
- SA is the systematic process of evaluating the safety of a predisposal facility or activity and quantifying its potential impact on human health and the environment
- SA should be developed in a systematic manner using a graded approach, proportionate to the hazards, the complexity of facilities or activities and the characteristics of the waste
- SA includes both the quantification of the overall level of system performance and the analysis of the associated uncertainties

Safety Assessment

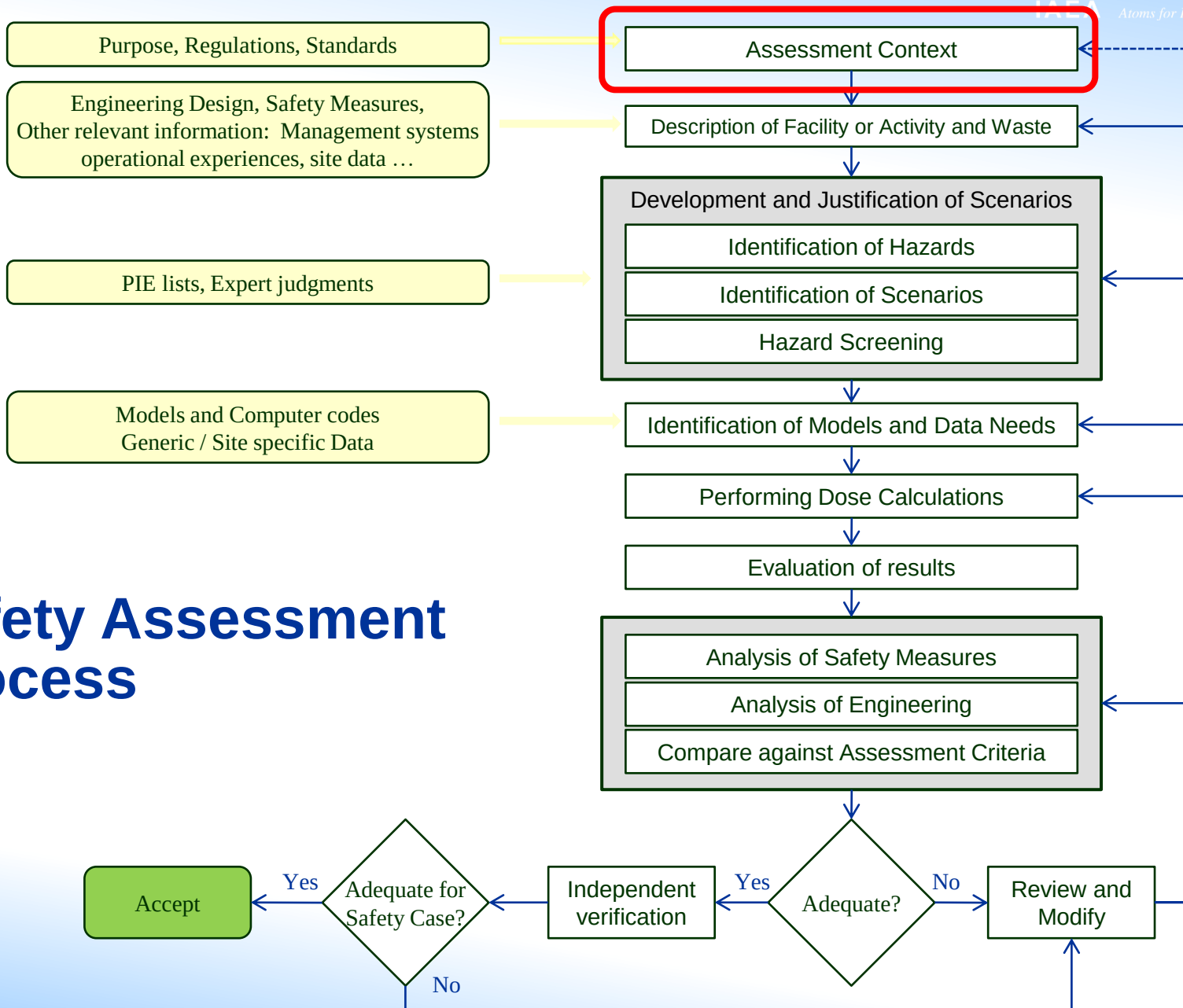
Shall address and assesses number of features of facility or activity, such as:

- ✓ Radiological impact assessment
- ✓ Site and engineering aspects
- ✓ Engineering analysis
- ✓ Passive safety
- ✓ Defence in depth
- ✓ Scientific and engineering principles
- ✓ Quality of the site characterization
- ✓ Operational safety aspects
- ✓ Non-radiological environmental impact
- ✓ Management system

Safety Assessment

The recommended approach to safety assessment includes the following key components:

- Specification of the context for the assessment;
- Description of the predisposal waste management facility or activity and the waste;
- Development and justification of scenarios;
- Formulation of models and identification of data needs;
- Performance of calculations and evaluation of results;
- Analysis of safety measures and engineering aspects, and comparison with safety criteria;
- Independent verification of the results;
- Review and modification of the assessment, if necessary (i.e. iteration).

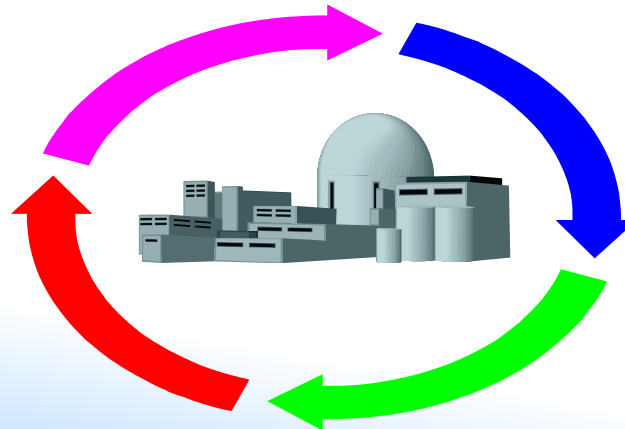


Safety Assessment Process

Safety Assessment Context

The context for the assessment involves the following key aspects:

- the purpose of the assessment
- the philosophy underlying the assessment
- the regulatory framework
- the assessment end points
- the time frame for the assessment
- target audience and involvement of interested parties



Safety Assessment Context

The purpose of the assessment might address

- demonstration of safety
- detailed understanding of facility behaviour
- design optimisation
- optimisation of working procedures
- derivation of waste acceptance criteria

Safety Assessment Context

Philosophy underlying the assessment

The philosophy underlying the assessment, i.e. the choice of approach taken in conducting the assessment with regard to quantitative assessment should address some relevant specific aspects:

- use of different approaches to assessment
- probabilistic and deterministic approaches
- conservative assessments and realistic assessments

Safety Assessment Context

Philosophy underlying the assessment

Use of different approaches to assessment

- The safety assessment should be performed using an appropriate selection of approaches that, when used in a complementary manner, can increase confidence in the safety of the facility or activity.

The different approaches that can be considered include:

- reasoned arguments,
- the use of simple conservative models,
- probabilistic and deterministic approaches, and
- the use of more complex and more realistic models.

Safety Assessment Context

Philosophy underlying the assessment

Probabilistic and deterministic approaches

- GSR Part 4 establishes requirements on the use of probabilistic and deterministic approaches.

Complex or hazardous facilities are required to meet these requirements, but simple facilities may only need qualitative analysis, in accordance with a graded approach.

A combination of probabilistic and deterministic approaches in the safety assessment may contribute to increased confidence in the outcomes of the assessment.

It is, however, important to be aware of the benefits and limitations associated with these two approaches.

Safety Assessment Context

Philosophy underlying the assessment

Probabilistic and deterministic approaches

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

Safety Assessment Context

Philosophy underlying the assessment

Probabilistic and deterministic approaches

- A *strength* of the probabilistic approach lies in its ability to provide a more comprehensive and explicit representation of the facility or activity under consideration and of the remaining uncertainties. Such approaches also provide for more thorough and systematic sensitivity analyses, and can be used to derive risk estimates. *Challenges* associated with a probabilistic approach include difficulties in obtaining or specifying appropriate probability distributions for the parameters, the possibility that the statistical sampling method applied may result in a choice of parameter combinations outside the range of validity of the sampling method, the difficulty in communicating probabilistic assumptions and results, and the additional resources necessary.

Safety Assessment Context

Philosophy underlying the assessment

Conservative assessments and realistic assessments

- GSR Part 4 provides a discussion of the role of conservatism and realism in relation to the use of deterministic and probabilistic analyses.

A realistic assessment is aimed at providing an indication of the most likely behaviour of the facility or activity. In general, this requires complex conceptual and mathematical models.

A conservative assessment, on the other hand, is aimed at simplicity by deliberately overestimating the likelihood and magnitude of exposures and/or underestimating the ability of the engineering and safety measures to provide protection.

Safety Assessment Context

Philosophy underlying the assessment

Conservative assessments and realistic assessments

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

Safety Assessment Context

Philosophy underlying the assessment

Conservative assessments and realistic assessments

- The decision to use a conservative approach, a realistic approach or both approaches will depend on a number of factors, such as
 - the nature and objective of the assessment,
 - regulatory requirements,
 - the availability and reliability of data,
 - the complexity of the site and the facility or activity, and
 - available resources.

Safety Assessment Context

Philosophy underlying the assessment

Conservative assessments and realistic assessments

- If the safety assessment is to be used for optimizing the design of the facility or demonstrating a detailed understanding of its behaviour, the safety assessment should be as realistic as possible, given the availability of data with which to parameterize the models. Undertaking a realistic assessment may, however, require complex calculations involving a large number of parameters, and significant resources may be necessary to demonstrate that the data and models used lead to a realistic representation of the facility. Realistic assessment necessitates the use of relevant and reliable available data, including radiological and environmental monitoring results, operating experience and information on historical events relevant to safety (e.g. at the facility or at similar facilities within the State or in other States).

Safety Assessment Context

Philosophy underlying the assessment

Conservative assessments and realistic assessments

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

Safety Assessment Context

End points for the assessment

- A clear description and justification of the end points for the assessment corresponding to the associated regulatory safety requirements and criteria should be provided, with account taken of assumptions used in the assessment such as time frame and the receptors used.

Assessment end points can include:

- The safety criteria considered for radiological impact such as dose or risk: These will usually relate to the regulations applicable to the facility or activity, and it will be necessary to demonstrate that the selected assessment end points are consistent with the purpose of the assessment and with relevant regulatory requirements and guidance.
- Other safety indicators such as dose rates, radionuclide releases, concentrations of radionuclides in the environment, concentrations and releases of non-radiological contaminants and impacts on non-human species.
- A description of how the assessment end points will be used, for example, to determine compliance with radiological or environmental standards.

Safety Assessment Context

The time frame for the assessment

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

Safety Assessment Context

Receptors

- The receptors (persons or groups receiving a radiation dose from the facility or with a risk of exposure, or, in the case of species other than humans, members of that species receiving a radiation dose or with a risk of exposure) associated with each of the various end points should be clearly specified and described. The use of a range of potential receptors should be considered, which may include individuals, populations and other species.

Safety Assessment Context

Receptors

- The International Commission on Radiological Protection recommends the use of the concept of a ‘representative person’ for the assessment of public exposure.
Either the dose or the risk to a representative person of a potentially exposed group can be used as an end point for the assessment, depending on regulatory requirements.

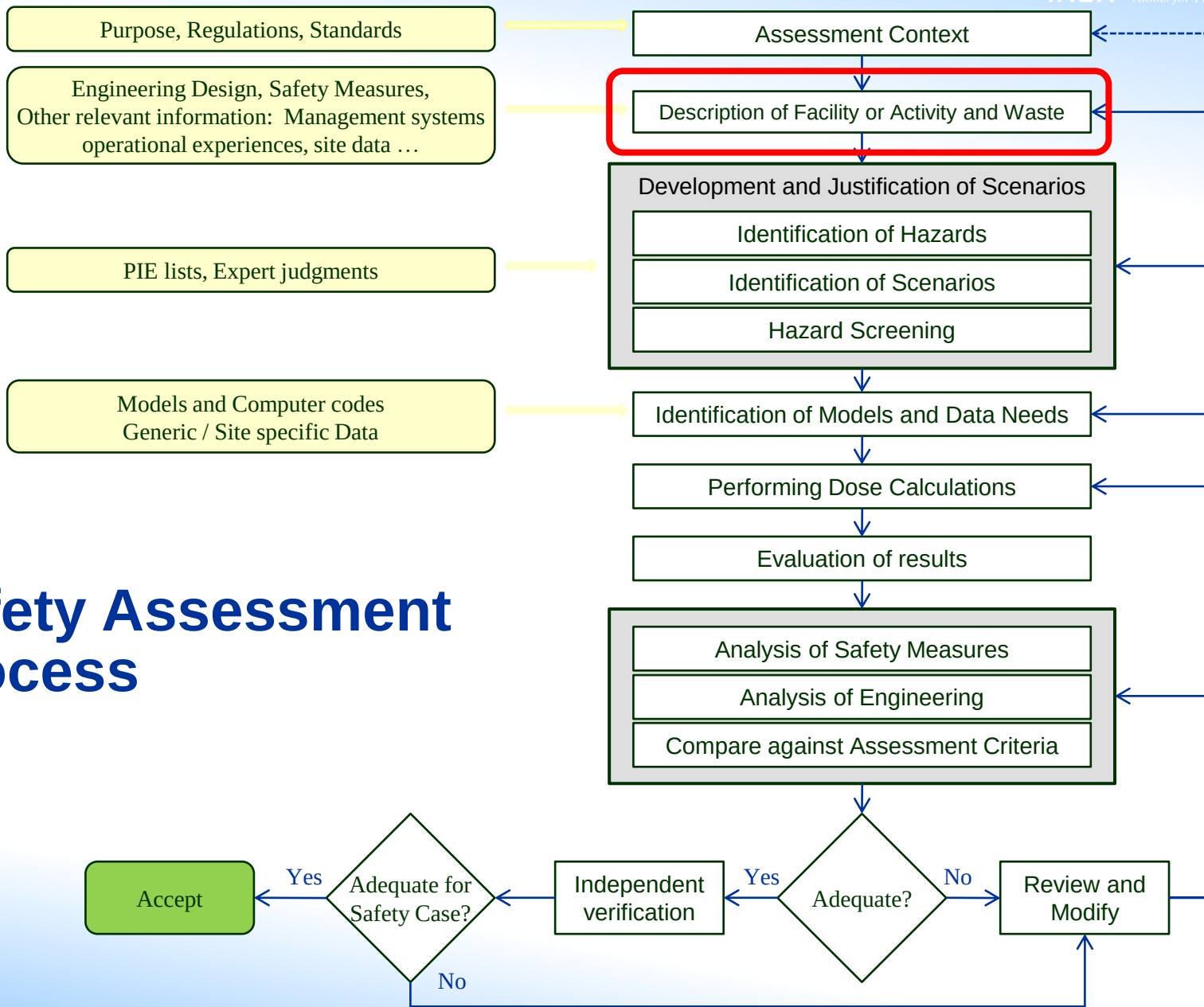
Safety Assessment Context

Receptors

- The ability of the environment to support or sustain a potentially exposed group of which the representative person is a member should be considered.

It should also be ensured that the assumed characteristics of this group are consistent with the capability of the biosphere to support such a group.

For example, the assumed environmental conditions (location, climate, land use, etc.) may limit the type or size of the group that can reasonably be expected to be present.



Safety Assessment Process

Description of facility or activity and waste

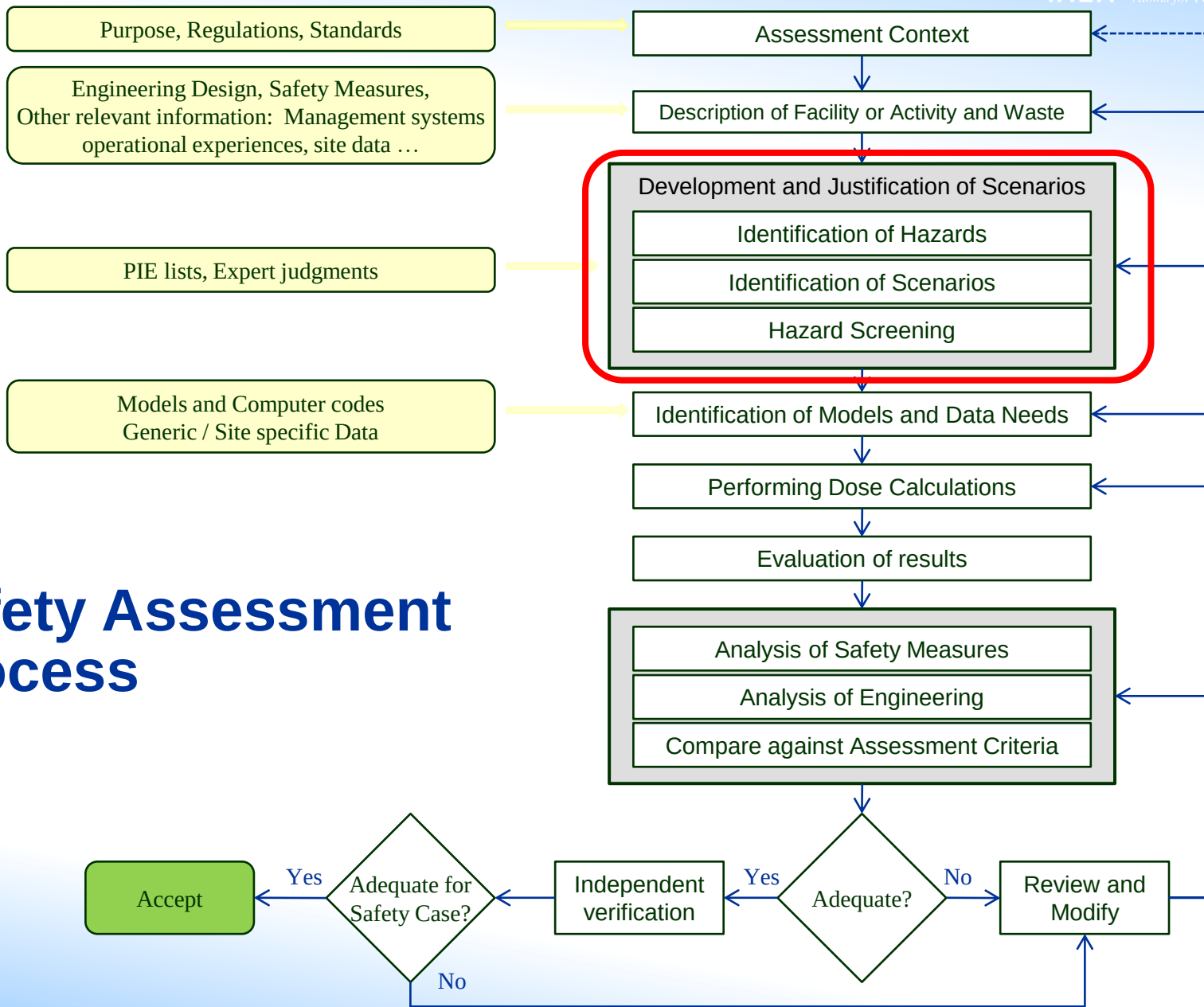
- Site conditions
- System description
- Facilities and activities
- Waste
- Safety measures
- Engineering design
- Operational experience
- Management systems
-



Description of facility or activity and waste

- Needed, to a certain extent, for all elements of the safety case and safety assessment;
- The quantitative analysis of impacts may pose additional data requirements. These are determined by the scenarios considered and models used;
- Collection of additional data usually is an iterative process proceeding in parallel to the development and refinement of scenarios and models;





Safety Assessment Process

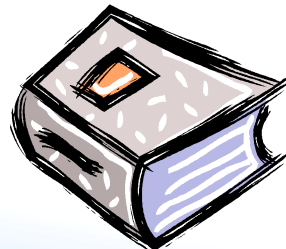
Development and justification of scenarios

- Scenario is a postulated set of conditions and/or events that can lead to impacts (e.g. human exposure, environmental contamination);
- Scenarios are to be developed in accordance with the safety context and should consider:
 - ✓ All relevant existing and potential hazards arising from facilities or activities
 - ✓ Interrelation of hazards
 - ✓ Evolution of hazards over the considered time frame
- Scenarios are to be identified for:
 - ✓ normal operation
 - ✓ anticipated operational occurrences and design basis accidents
 - ✓ beyond design basis accidents
 - ✓ severe accidents

Development and justification of scenarios



- Following steps should be applied in an iterative manner:
 - ✓ Identification of hazards
 - ✓ Identification of activities and initiating events
 - ✓ Identification of scenarios
 - ✓ Hazard screening



Development and justification of scenarios

Hazards may arise from:

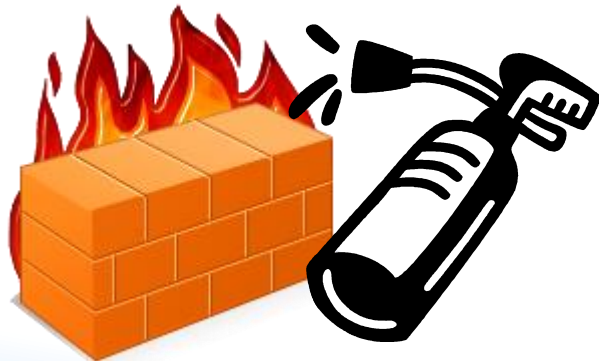
- ✓ Inventory, activity, physical conditions and location of the radioactive materials;
- ✓ Non-radiological hazardous materials (e.g. chemo-toxic, flammable) or physical conditions (e.g. high temperature, pressure);
- ✓ Management activities and processes;
- ✓ Software reliability;

Etc.

Consideration should also be given to how the failure of one process can affect associated processes. For example, in identifying hazards associated with the emplacement of waste by crane, consideration should be given to faults that could occur in normal operation of the crane

Development and justification of scenarios. Initiating events

- Postulated Initiating Events (PIE's)
 - ✓ natural event,
 - ✓ human induced outside the facility
 - ✓ human induced inside the facility



Development and justification of scenarios. Initiating events

- Identification of postulated initiating events (PIEs) and their evolution should be carried out using an appropriate technique, such as
 - ✓ Hazard and operability analysis (HAZOP)
 - ✓ Event tree analysis (ETA)
 - ✓ Fault tree analysis (FTA)
- And information on the:
 - ✓ Site
 - ✓ Design and operation of facility or activity
 - ✓ Operational experience
 - ✓ Feedback from other facilities or activities



Development and justification of scenarios

- For new facilities or activities, a comprehensive identification and assessment of all design basis events (activities) should be carried out
- For modifications of existing facilities or activities, the assessment should focus on those design basis events that could impact on the modification, either directly or indirectly
- For predisposal facilities or activities, special attention should be given to **human factor** and **technological procedures** as this often can represent the main scenario generating component

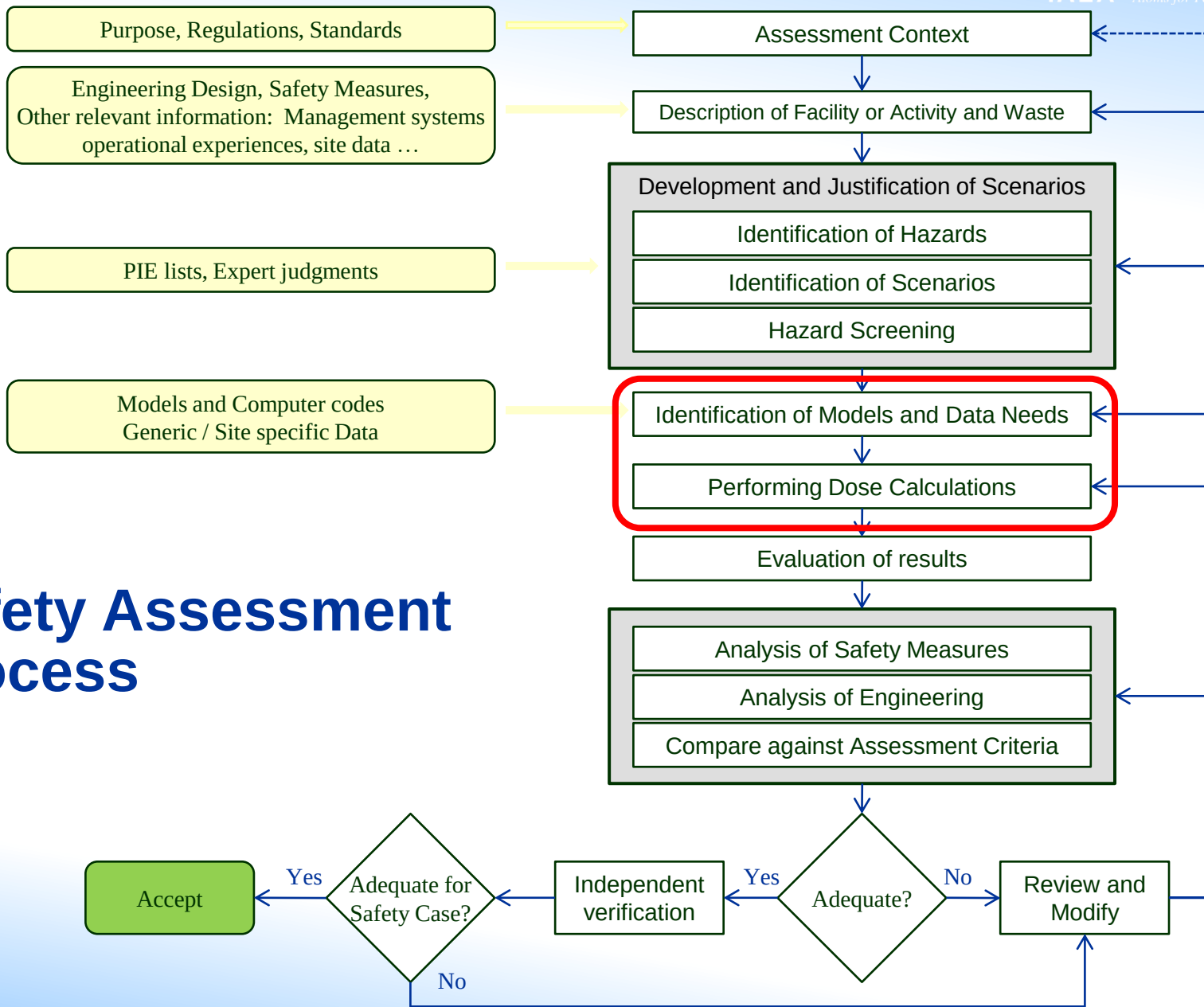
Development and justification of scenarios

Scenarios for normal operation should address:

- All conditions under which the facility systems and equipment are being operated or activity is carried out as expected, with no internal or external challenges
- Normal operation conditions includes all the phases of operation for which the facility is designed to operate (including start up and shutdown where appropriate) and maintenance over the considered time frame
- Scenarios for normal operation should be defined with the goal to assess whether the activity can be carried out safely or the facility operated safely under normal operation

Development and justification of scenarios

- **Anticipated operational occurrences** are those events
 - ✓ Which exceed the bounds of normal operation and have the potential to challenge the safety of facility
 - ✓ Which might be expected to occur at least once during the lifetime of facility
- **Design basis accidents** have a lower frequency of occurrence than the anticipated operational occurrences:
 - ✓ They would not be expected to occur during the lifetime of the facility but have to be considered in the design of the facility.



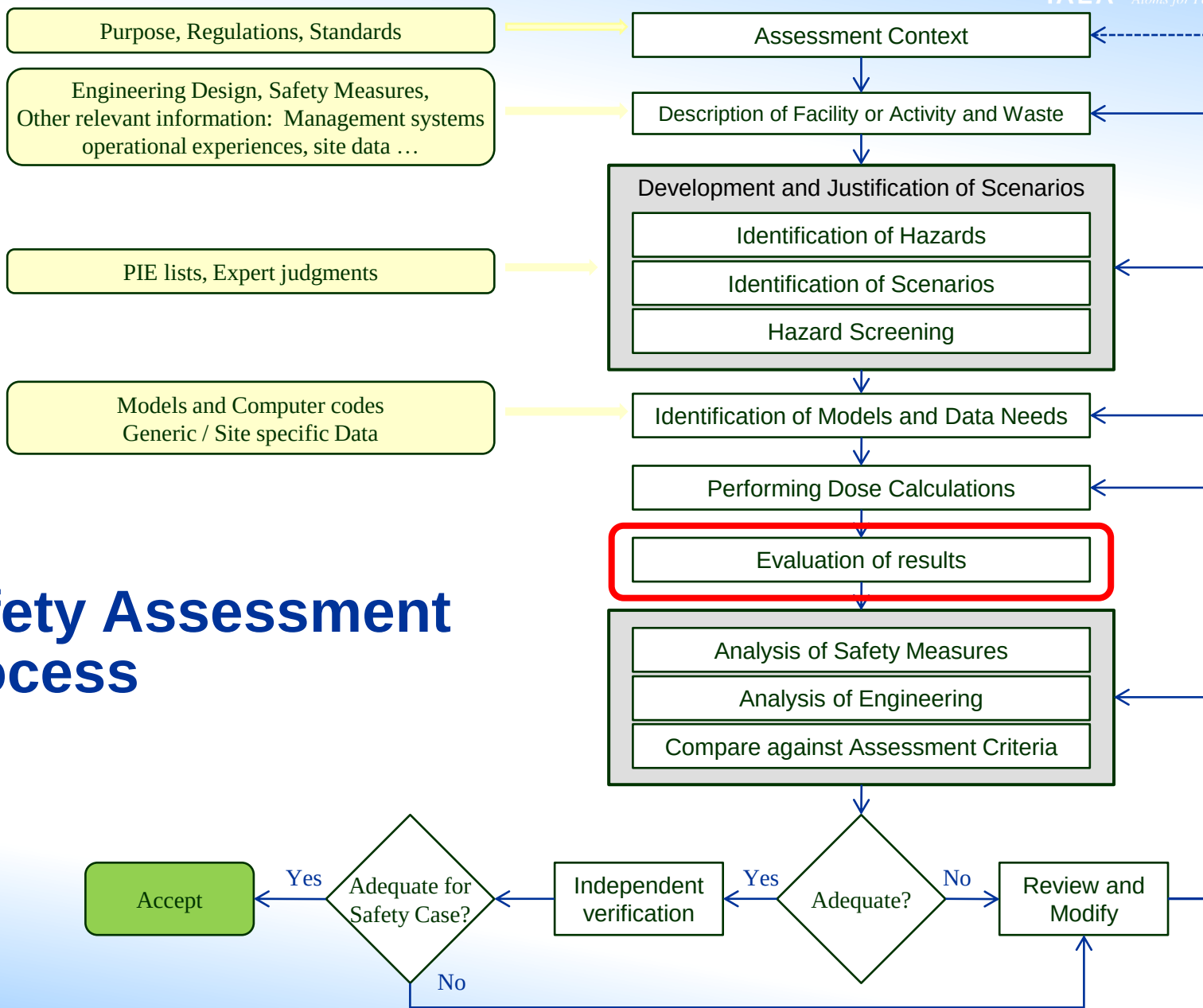
Safety Assessment Process

Modelling and Calculations

- Once the scenarios are defined (and not being screened out), the corresponding assessments shall be carried out. This is commonly done using assessment models.
- Assessment model includes:
 - Conceptual model
 - ✓ Provides description of the components of the system and the interactions between; Includes assumptions concerning the system geometry, the chemical, physical, biological and mechanical behavior;
 - Mathematical model
 - ✓ Is representation of the conceptual model using mathematical equations;
 - Computer code
 - ✓ Is software implementation of mathematical model and facilitates performing of calculations.

Modelling and Calculations

- In predisposal waste management facilities or activities, this model **can represent a certain component or process during normal operation** (e.g. when evaluating the effectiveness of shielding) **or during and after an accident** (e.g. to estimate releases from waste forms during a fire).
- The model **may also represent other parts of the facility** (e.g. structures acting as barriers) **or parts of the biosphere** (e.g. if the modelling is used to assess the consequences of releases over atmospheric or aquatic pathways).
- In all of these cases, the conceptual model **provides a description of the components and the interactions between these components**. It also includes a set of assumptions concerning the geometry of the facility or activity and the chemical, physical, biological and mechanical behavior of the facility or activity, consistent with the available information and knowledge.



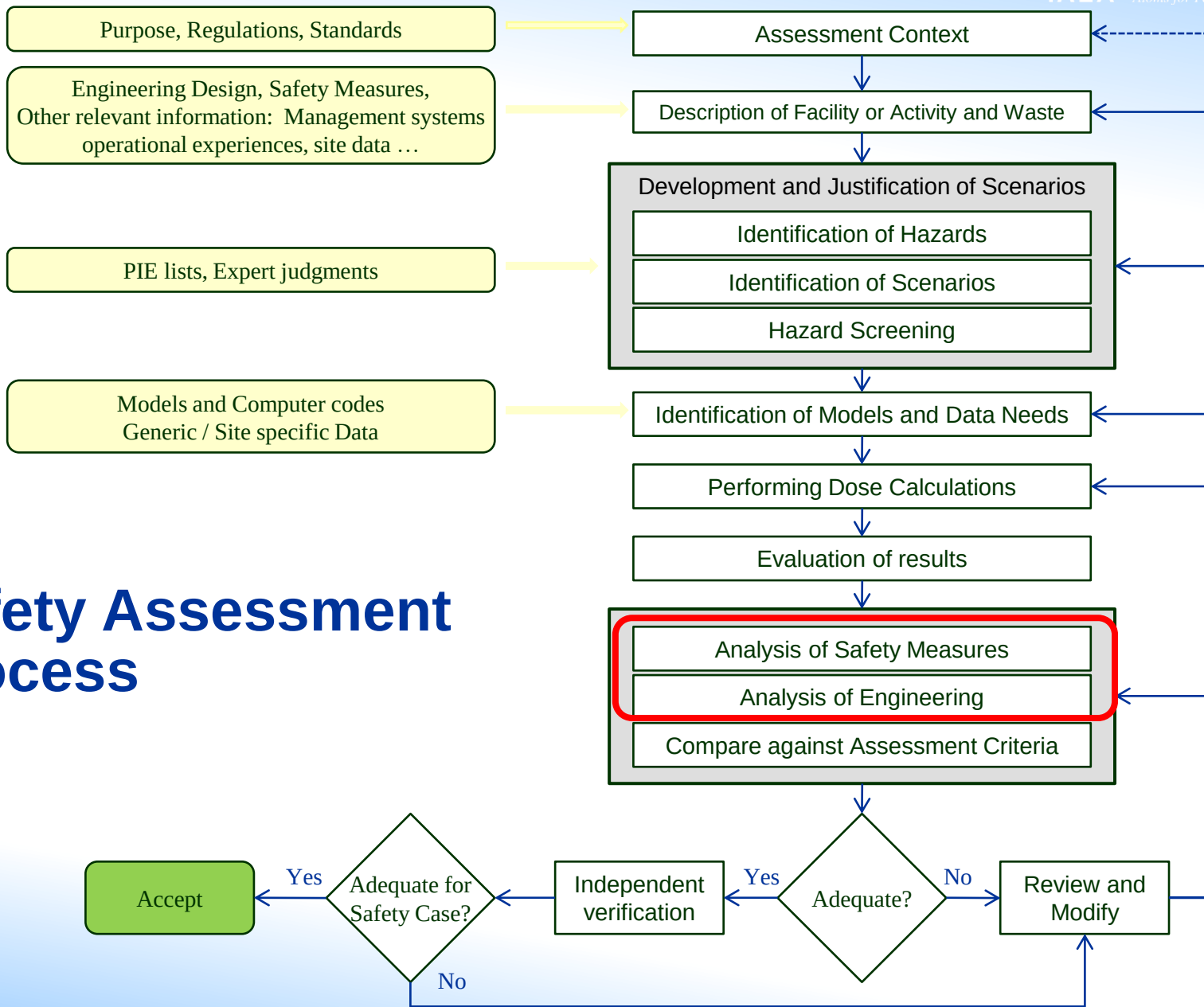
Safety Assessment Process

Evaluation of Results

- Once the calculations have been undertaken, the results need to be collated, interpreted and compared against the relevant assessment criteria
- Ensure that an understanding of the results from each component of the assessed system is developed
- Intermediate calculation outputs should be analysed, as well as those relating to end-points such as dose and/or risk

Evaluation of Results

- It should be kept in mind that the achievement of a level of protection such that calculated doses are less than a dose constraint is not in itself sufficient for the acceptance of a safety case, since protection is also required to be optimized
- Conversely, an indication that calculated doses could, in some unlikely circumstances, exceed the dose constraint need not necessarily result in the rejection of a safety case



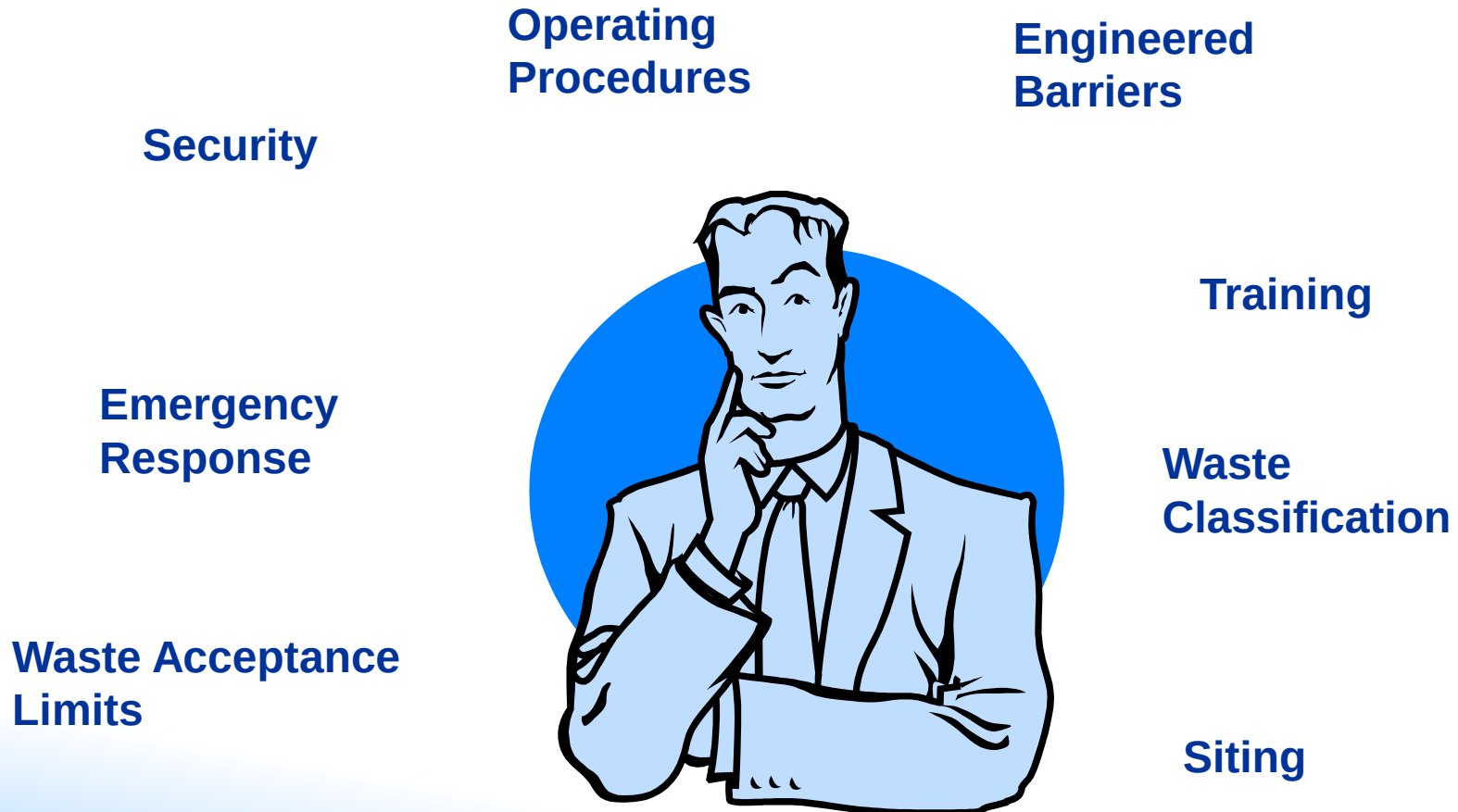
Safety Assessment Process

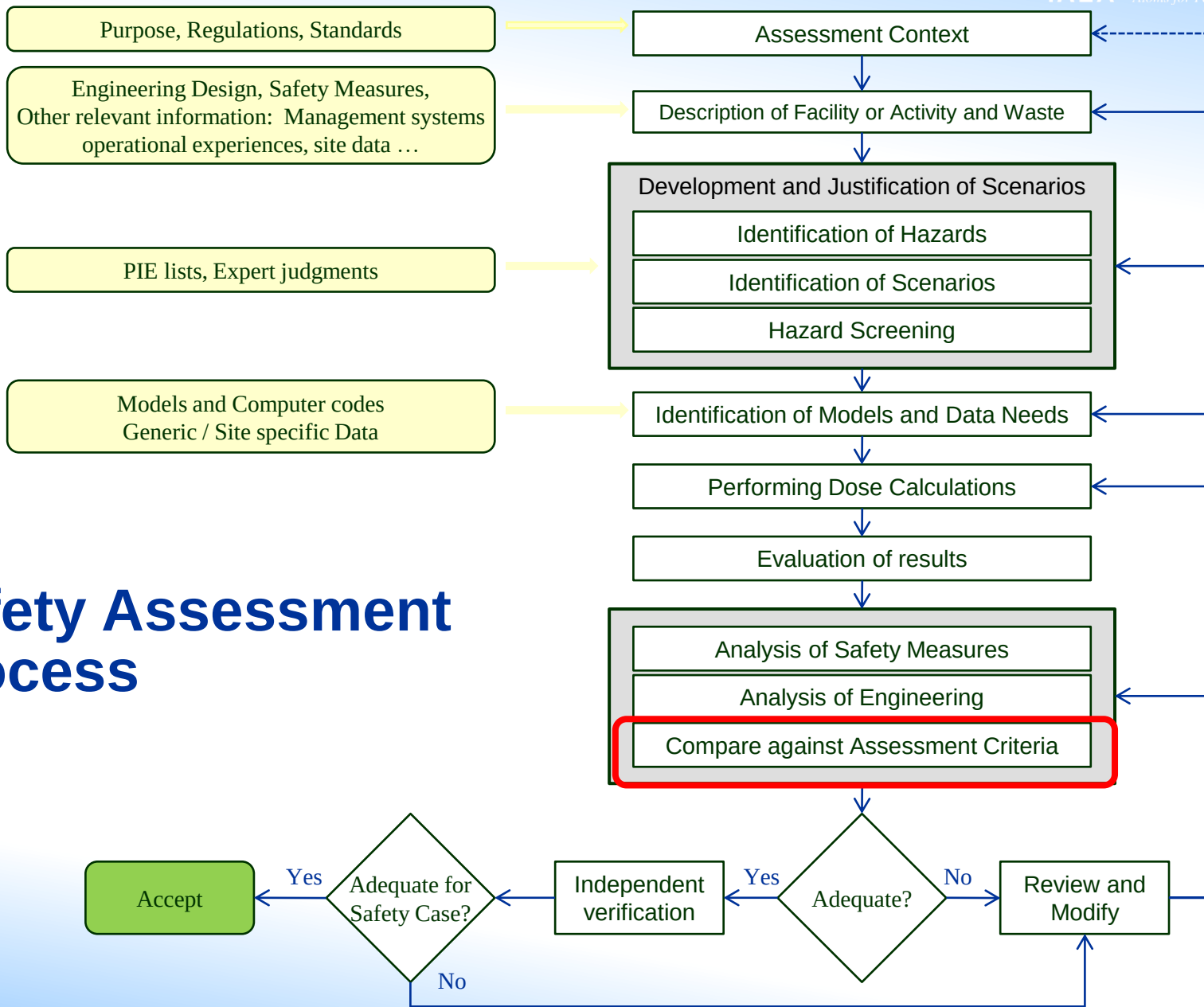
Analysis of Engineering and Safety Measures

- Safety functions provided by structures, systems and components (SSC's)
- Administrative safety measures, e.g.
 - ✓ Definition of limits, controls and conditions (LCC's)
 - ✓ Operational procedures
 - ✓ Management systems
- Adequacy of existing or planned safety measures
- Identification of additionally required safety measures:
 - ✓ Improvement of design
 - ✓ New or improved administrative safety measures

Analysis of Engineering and Safety Measures

Defence in Depth





Safety Assessment Process

Compare against Assessment Criteria

Assessment criteria and end points as defined in the Context can include:

- **Radiation protection targets such as doses or risk**
 - ✓ They usually are related to the relevant regulatory requirements
- **Safety indicators such as:**
 - ✓ Dose rate
 - ✓ Concentrations / releases of radionuclides
 - ✓ Concentrations / releases of non-radiological, contaminants
- **Receptors (individuals, population, non-human species) associated with different endpoints should be identified and described in the Assessment Context**

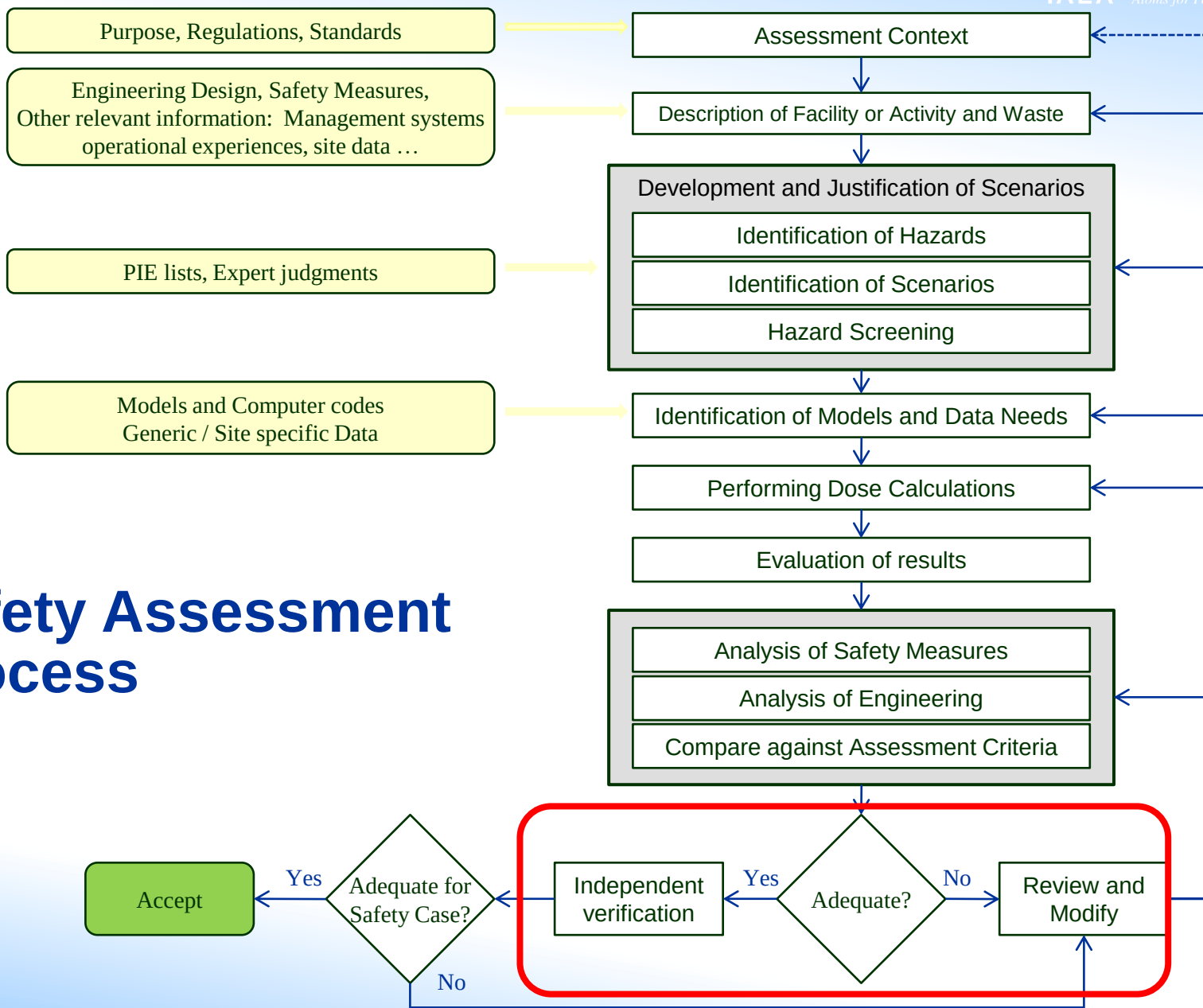


Use of assessment results

Safety assessment provides basis for:

- ✓ identification of safety significant design features and necessary mitigation measures
- ✓ definition of safe operating envelope
 - operational limits, conditions and controls (LCCs) to prevent unacceptable exposures and releases
- ✓ derivation of operational procedures to ensure that operations remain within the LCCs





Safety Assessment Process

Operator's review and update

- ✓ SA shall be updated as necessary.
- ✓ SA is reviewed periodically when:
 - There is any significant change that may affect the safety of the facility or activity.
 - There are significant developments in knowledge and understanding.
 - Lessons learned can result in operational changes and modifications to safety assessment documentation.
 - There is an emerging safety issue owing to a regulatory concern or an incident.
 - There have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis.



SADRWMS Methodology

IAEA TECDOC SERIES

IAEA-TECDOC-1777

Methodology for Safety Assessment Applied to Predisposal Waste Management

Report of the Results of the International Project on Safety Assessment Driving Radioactive Waste Management Solutions (SADRWMS) (2004–2010)

