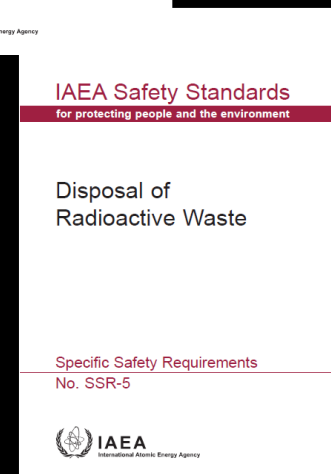
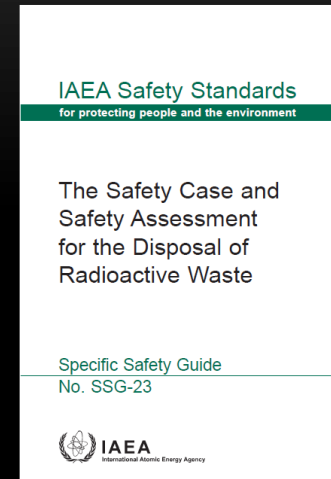


SAFETY ANALYSIS OF PREDISPOSAL ACTIVITIES AND FACILITIES

Eric K. Howell, Ph.D.
Facilia Projects GmbH
2-6 November 2015
Trieste, Italy

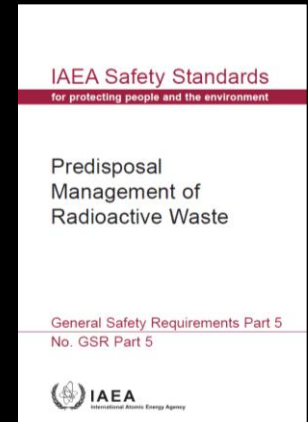
SUPPORTING IAEA DOCUMENTATION

- IAEA guidance for development of the Safety Case is mainly given in:
 - **SSR-5**, Disposal of Radioactive Waste
 - **SSG-23**, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste
 - **GSG 3**, The Safety Case and Safety Assessment for the Predisposal Management of Radioactive Waste
 - **GSR Part 4**, Safety Assessment for Facilities and Activities
 - **GSR Part 5**, Predisposal Management of Radioactive Waste
 - **SRS 25**, Review of Probabilistic Safety Assessments by Regulatory Bodies
 - **WS-G-1.1**, Safety Assessment for Near Surface Disposal of Radioactive Waste
 - **WS-G-5.2**, Safety Assessment for the Decommissioning of Facilities Using Radioactive Material
 - **SRS 77**, Safety Assessment for Decommissioning



GSR PART 5 SUMMARY

- GSR Part 5 defines Predisposal Waste Management as:
 - ***All the steps in the management of radioactive waste from its generation up to disposal, including processing (pre-treatment, treatment and conditioning), storage and transport.***
- A graded approach should be applied, depending on the hazards, the complexity of facilities and activities, and the characteristics of the waste.
- Legal, Regulatory & Policy (Requirements 1-3)
- Operator responsibilities (Requirements 4-7)
- Detailed requirements on waste generation, siting and design, safety assessment, operation and decommissioning of waste storage facilities (Requirements 8-22)



RESPONSIBILITIES

- For predisposal facilities, **the operator** shall:
 - Develop and maintain the **safety case**.
 - Carry out the **safety assessment**.
 - **Carry out all necessary activities** for site selection and evaluation, facility design, construction, operation, closure and, if necessary, surveillance after closure.
 - These activities shall be done **in accordance with** national strategy, legal, and regulatory requirements.



RESPONSIBILITIES

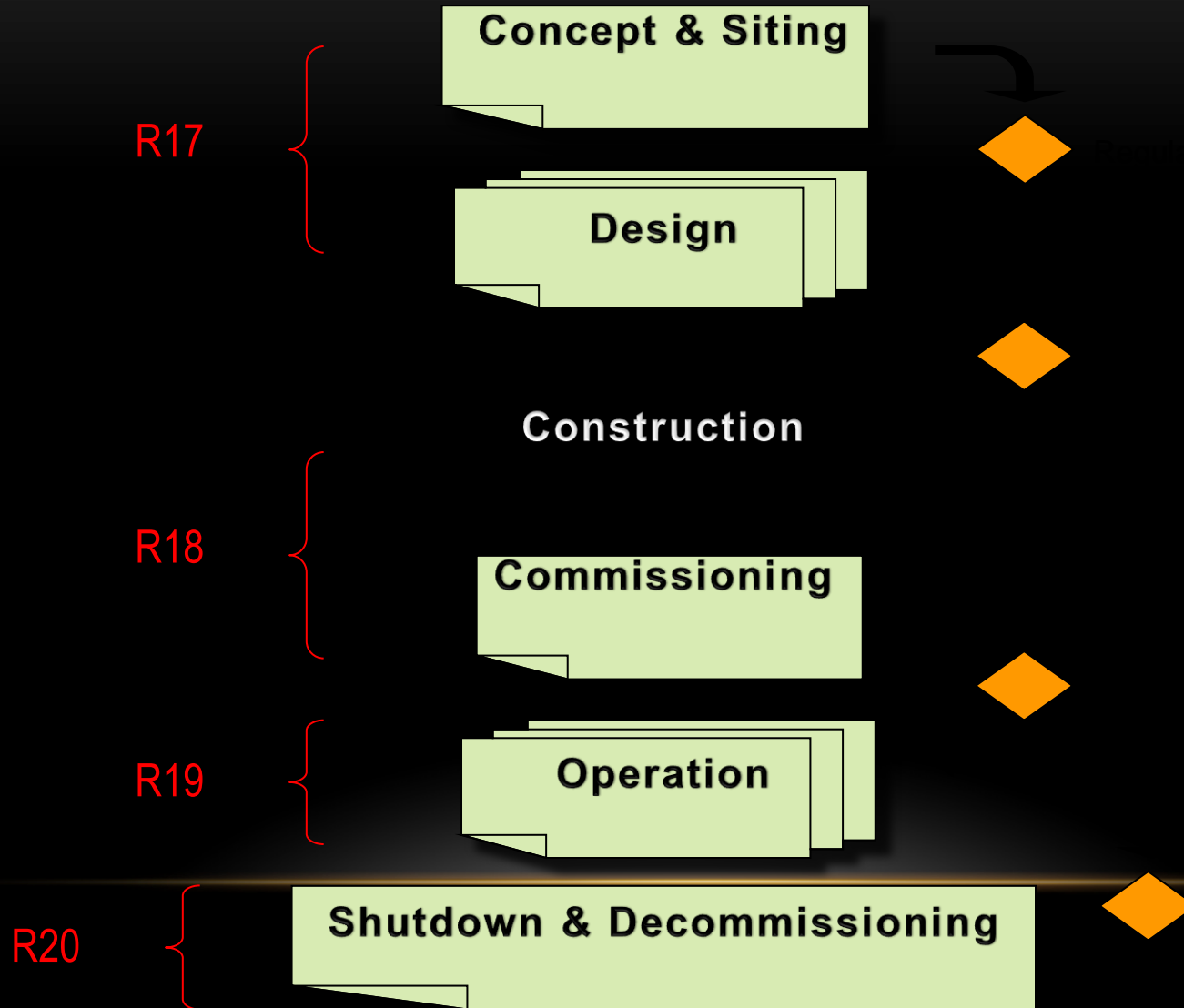
- For predisposal facilities, **the regulator** shall:
 - **Establish regulatory requirements** for the development of different types of facilities for radioactive waste.
 - Set out the **procedures** for meeting the requirements for the various stages of the licensing process.
 - Set **conditions** for the development, operation, and closure of each individual facility.
 - Carry out such activities as are necessary to **ensure that the conditions are met.**



HIGHLIGHTS FROM GSR PART 5

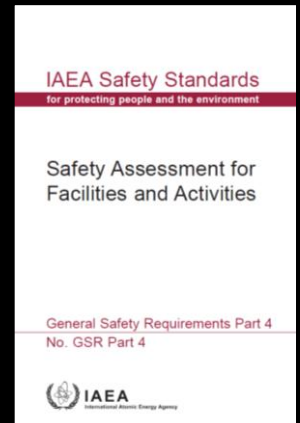
- Key activities relating to safety case as identified in GSR Part 5
 - Waste characterisation (Requirement 9)
 - Processing of waste (Requirement 10)
 - Storage of waste (Requirement 11)
 - Lifetime considerations
 - Passive safety features
 - Waste Acceptance Criteria (Requirement 12)
 - WAC developed based on safety case envelope
 - Requirement for operator to develop a safety case with supporting safety assessment for all aspects of scope (Requirements 13 & 14)
 - Safety case to be documented and periodically reviewed and used as basis for Regulatory approval
(Requirements 15 & 16)

FACILITY SAFETY CASE LIFECYCLE



GSR PART 4 SUMMARY

- GSR Part 4 defines generally applicable Requirements for facilities and activities that give rise to radiation risks
 - **Facilities** – nuclear reactors, enrichment facilities, fuel production plants, storage and processing facilities, medical, industrial and research facilities, etc
 - **Activities** – production, use, import/export, transport, decommissioning, closure, discharges and remediation
- A graded approach should be applied, depending on the hazards, the complexity of facilities and activities, and the characteristics of the waste
- Overall requirements (Requirements 1-4)
- Specific safety assessment needs (Requirements 5-12)
- Defence in depth and safety margins (Requirement 13)
- Safety Analysis (Requirements 14-19)
- Documentation and verification (Requirements 20 & 21)
- Management and maintenance (Requirements 22-24)



TERMINOLOGY

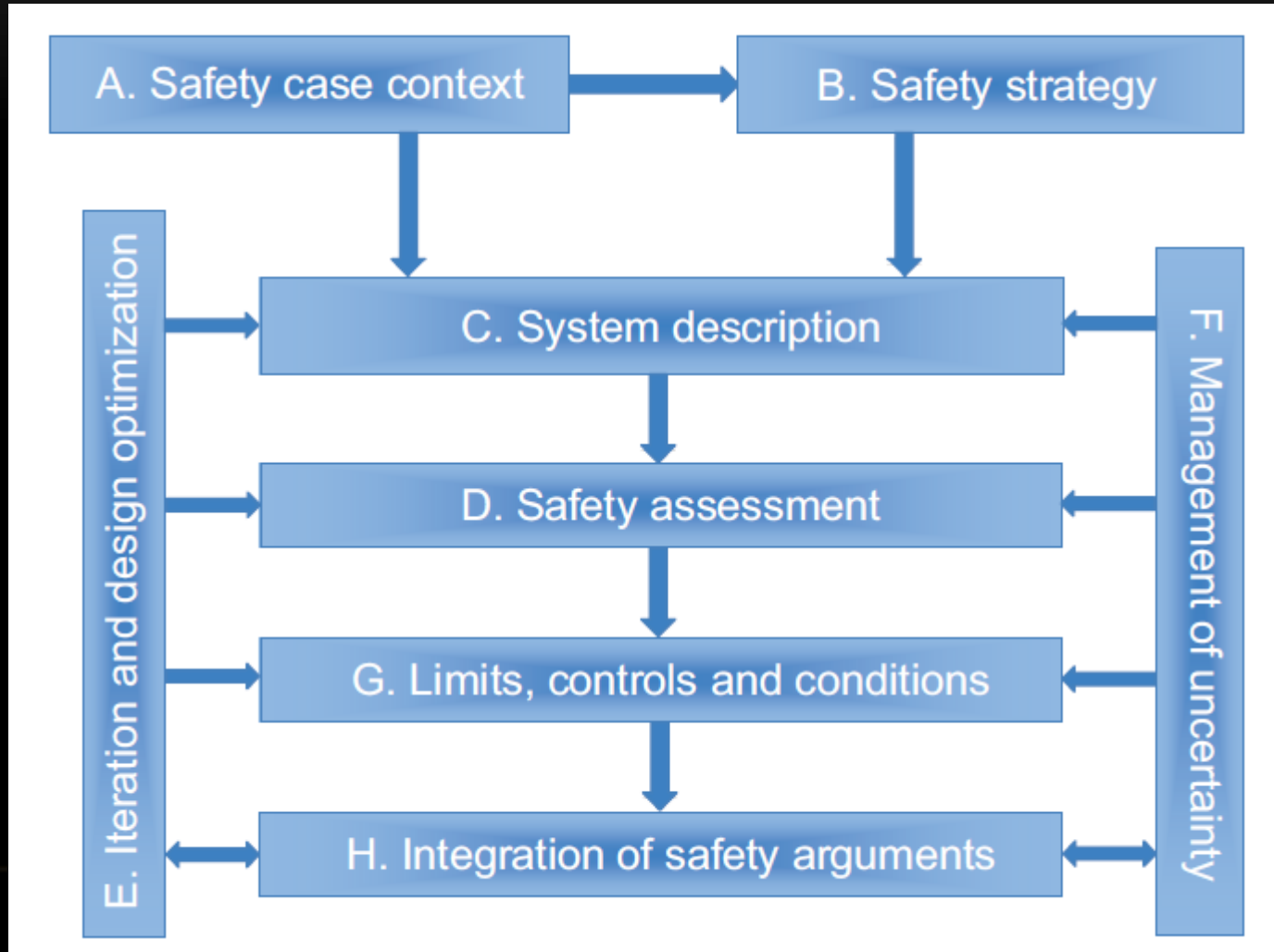
- Safety Case
 - A suite of scientific, technical, administrative, managerial arguments and evidence in support of the safety of a waste management facility
 - Demonstrates the suitability of the site location, design, construction and operation of the facility
 - Provides an assessment of radiation risks and provides assurance of the adequacy and quality of all activities
- Safety Assessment
 - The systematic process that is carried out to ensure that all the relevant safety requirements are met by the proposed (or actual) design. Safety assessment includes the formal safety analysis.
 - It involves the systematic analysis of:
 - Normal operation and its effects
 - The ways in which failures might occur and of the consequences of such failures
 - Safety assessments identify the safety measures necessary to control the hazard
 - Design and engineered safety features are assessed to demonstrate that they fulfil the safety functions required of them.
 - Where control measures or operator actions are called on to maintain safety, an initial safety assessment has to be carried out to demonstrate that the arrangements made are robust and that they can be relied on.

THE CONCEPT OF THE SAFETY CASE

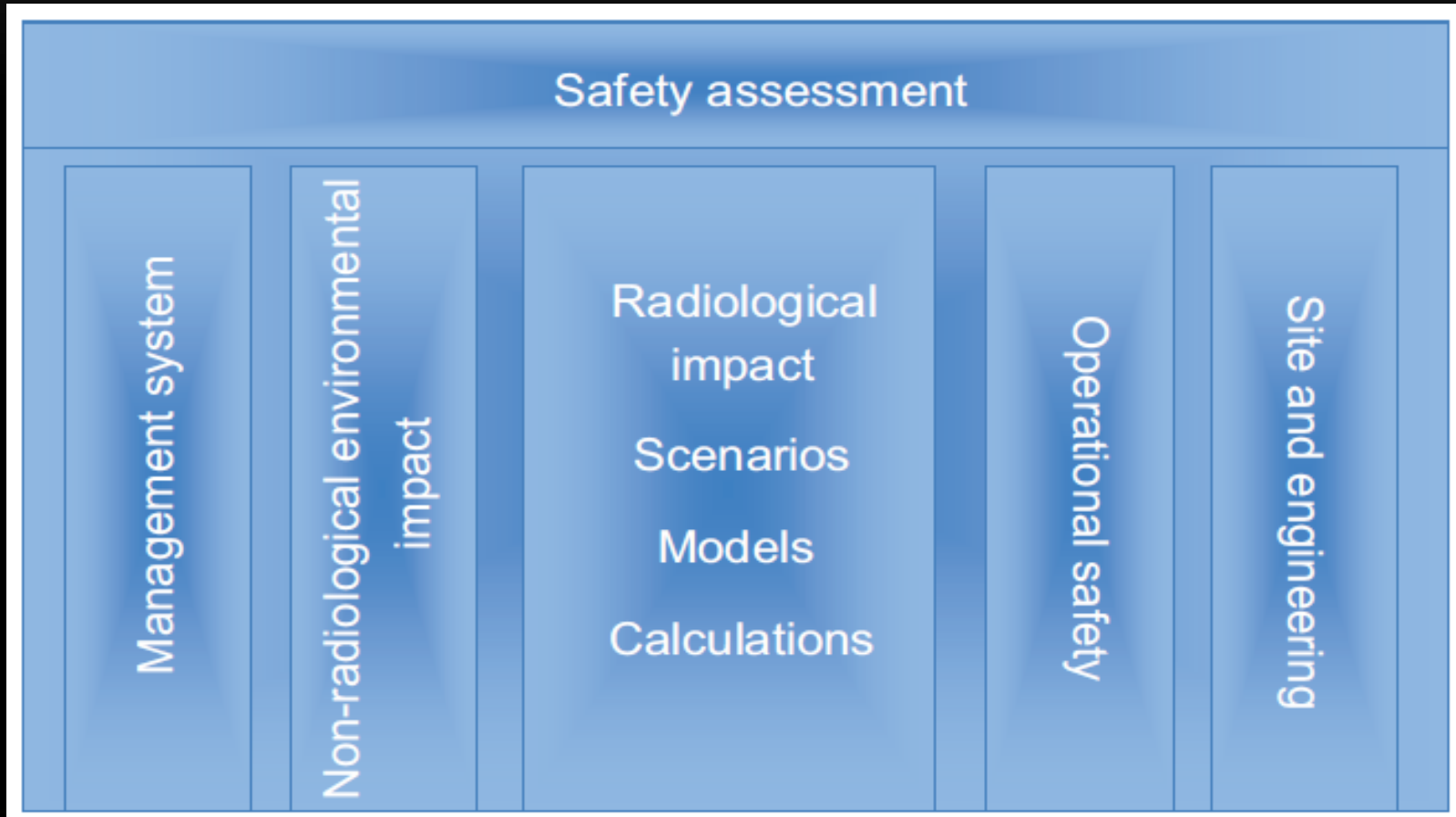
- Compatibility with a disposal option should be demonstrated, in the event that a disposal option has not been identified at that stage, **assumptions should be made** about the likely options and clearly set down.
- Identifying **uncertainties** in the performance of the facilities, describing the possible significance of the uncertainties, and identifying approaches for the management of significant uncertainties.

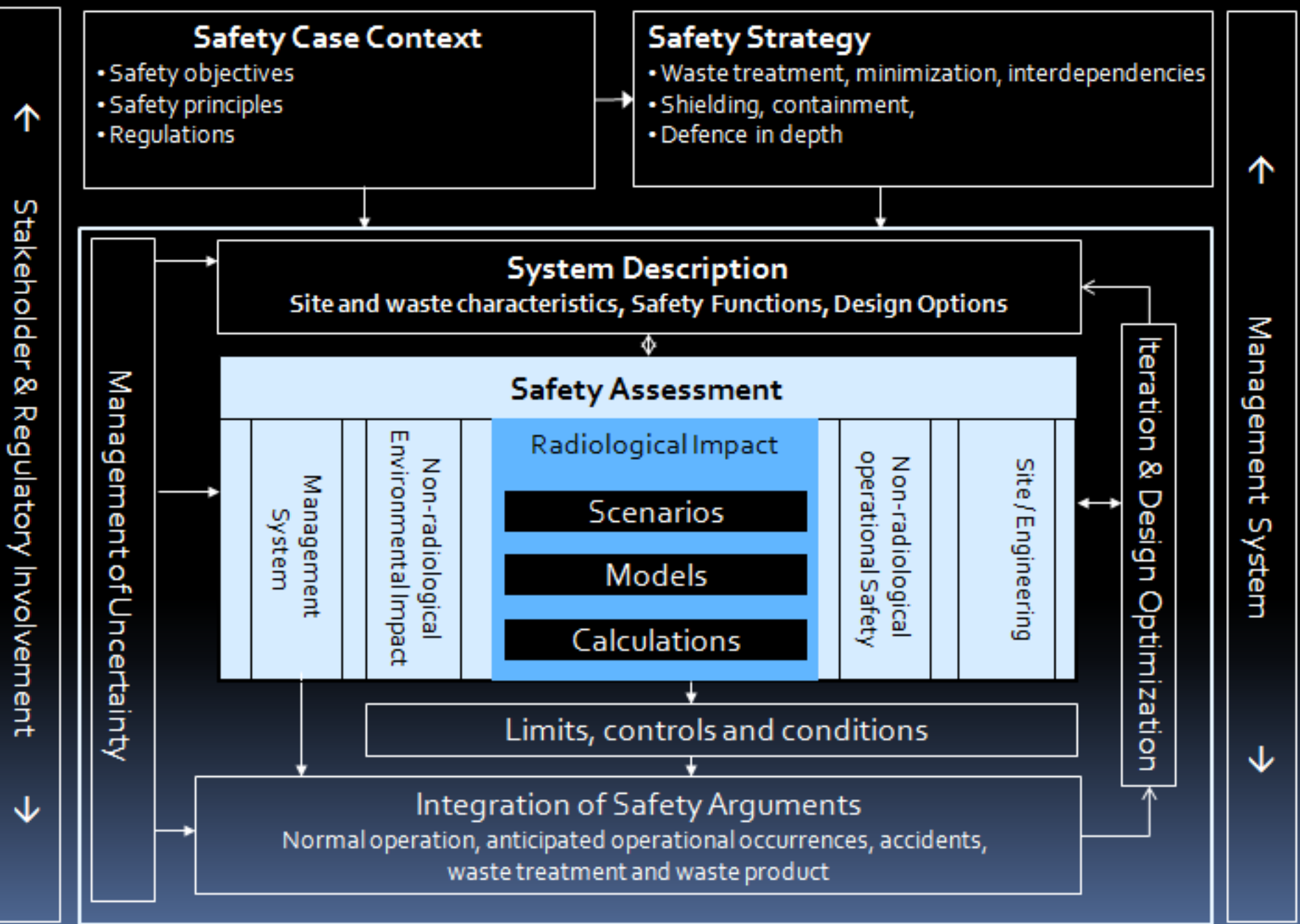


THE SAFETY CASE



SAFETY ASSESSMENT





SAFETY REQUIREMENTS (GSR PART 4)

- Requirement 1: Graded Approach
 - A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out in a particular State for any particular facility or activity, consistent with the magnitude of the possible radiation risks arising from the facility or activity.



SAFETY REQUIREMENTS (GSR PART 4)

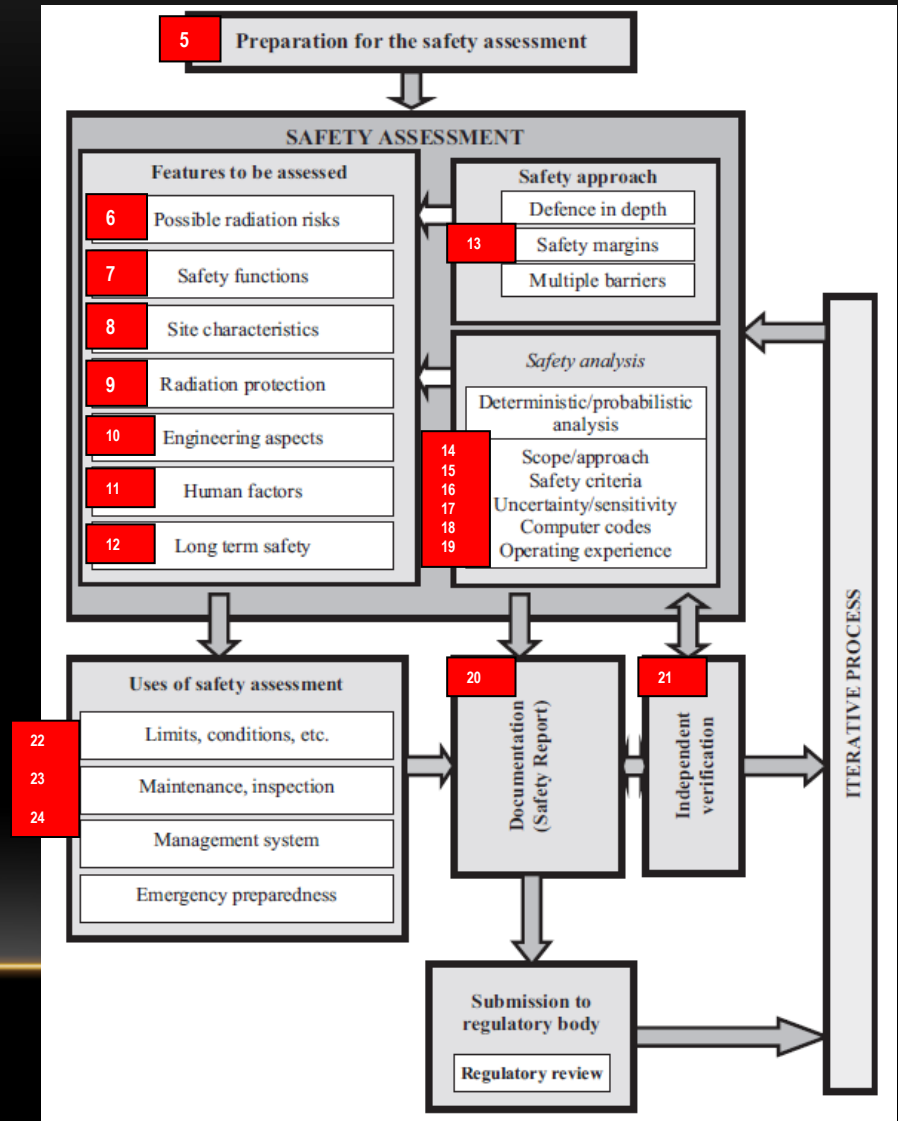
- **Requirement 2: Scope of the safety assessment**
 - A safety assessment shall be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities.
- **Requirement 3: Responsibility for safety assessment**
 - The responsibility for carrying out the safety assessment shall rest with the responsible legal person; that is, the person or organization responsible for the facility or activity.
 - In other words, not the Regulatory Body but the Operator

SAFETY REQUIREMENTS (GSR PART 4)

- Requirement 4: Purpose of the safety assessment
 - To determine whether an adequate level of safety has been achieved for a facility or activity
 - To determine whether the basic safety objectives and safety criteria established by the designer, the operating organization and the regulatory body have been met
 - To demonstrate compliance with the requirements for protection and safety as established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources
 - To ensure doses remain below limits, constraints and are as low as reasonably practicable
 - To consider risks to people locally and remote
 - To consider current and long term risks
 - To demonstrate defence in depth (layers of prevention)

SAFETY REQUIREMENTS (GSR PART 4)

- The process for Safety Assessment, verification and Regulatory Review
- This process map reflects the remaining Requirements of GSR Part 4 (R5 to R24)



SAFETY REQUIREMENTS (GSR PART 4)

- Requirements 5 to 12:
 - National strategies, legislation and resources are in place
 - Safety functions are engineering or operational measures that need to be in place to prevent or mitigate radiological consequences from normal or fault scenarios
 - Siting characteristics are suitable
 - Suitable engineering design standards are adopted, compatible with the activities to be undertaken over the lifetime of the facility
 - Human factors taken into account in the design
 - The full operating life of the facility is taken into account

SAFETY REQUIREMENTS (GSR PART 4)

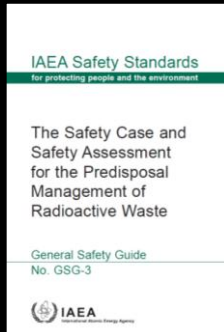
- Requirements 13 to 19:
 - Adequate layers of protection shall be established
 - Adequate safety margins are built into the design
 - Safety analysis comprehensively covers all operations and credible fault scenarios
 - Deterministic and probabilistic approaches. The latter may not be pertinent to simplistic facilities and simple activities.
 - Criteria for judging safety are established
 - Uncertainties and sensitivity of the assessment to assumptions is tested to show robustness
 - Models and calculations are verified and validated
 - Real operating performance data is used where possible

SAFETY REQUIREMENTS (GSR PART 4)

- Requirements 20 to 24:
 - The findings and conclusions of the safety assessment are documented in the Safety Case (or Safety Report)
 - Independent verification of the safety assessment is carried out, noting this is the Operator's responsibility to ensure this is done prior to submission to the Regulatory Body
 - The safety assessment is used as the basis for specifying maintenance, surveillance and inspection programmes for the facility
 - The safety assessment itself must be maintained to ensure it remains valid
-

GSG-3 ADDITIONAL GUIDANCE

- This Safety Guide aims to assist operators, regulatory bodies and supporting technical specialists in the application of a graded approach to the development and review of the safety case and supporting safety assessment
- Section 2 – Describes the overall process of demonstrating the safety
- Section 3 – Summarizes the main safety principles and safety requirements to be met in the preparation of the safety case.
- Section 4 - Elaborates on the concept of the safety case. The components of the safety case are described and possibilities for building confidence in the safety case are discussed.
- Section 5 – Addresses methodology for the safety assessment, including the management of uncertainties within the safety assessment, as well as on the use of the outcomes of assessments for comparison with assessment criteria.
- Section 6 – Discusses issues that arise in the preparation of a safety case
- Section 7 – Addresses the documentation of the safety case
- Section 8 – Provides guidance and recommendations on the regulatory review of the safety case.
- Annex I provides examples of hazards and initiating events
- Annex II provides a list of topical issues for the regulatory review of the safety case
- Annex III provides a template for the regulatory review report and
- Annex IV provides a framework for the overall safety assessment work.



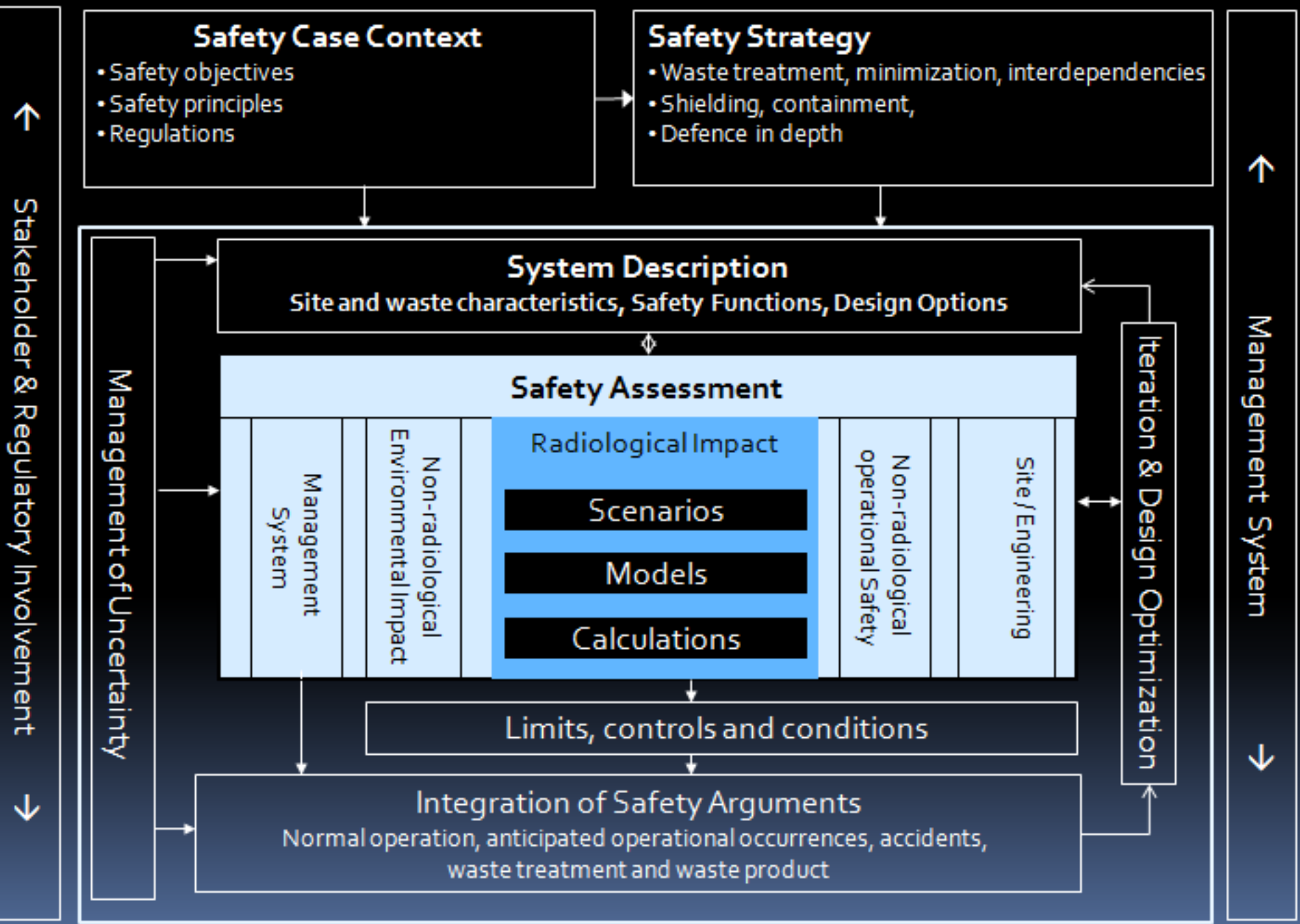
USES OF THE SAFETY CASE

- Basis for approval by the Regulatory Body (i.e. issuing of a License to the Operator)
 - GSR Part 5 - Requirement 3
 - GSG 1.2 – Review and assessment by Regulatory Bodies
 - GSG-3 – Section 8 and Annex II
 - SSG-12 – Licensing Process
- As a means of communicating to stakeholders
- Clear definition of boundaries for all scope of activities to be carried out by the Operator



MAIN COMPONENTS OF THE SAFETY CASE

- Safety Case Context
 - Safety Strategy
 - Management System
 - System Description
 - Safety Assessment
 - Limits, Control, & Conditions
 - Management of Uncertainties
 - Iteration and Design Optimization
 - Integration of Safety Arguments
 - Involvement of Stakeholders
-



MAIN COMPONENTS OF THE SAFETY CASE

- **Safety Case Context** is based upon:
 - **National Policy and Strategy**
 - Description of the responsibilities of national counterparts
 - Basis for the national waste management plan
 - **Regulations**
 - **International Guidance And Duties/Commitments**
 - **Financial Considerations**
 - Conceptualization
 - Siting
 - Design
 - Construction
 - Operation
 - Closure and ongoing monitoring
 - Research and development
-

MAIN COMPONENTS OF THE SAFETY CASE

- **Safety Case Context** includes:
 - **Philosophy and approaches**
 - Graded approach
 - Use of different assessment approaches
 - Probabilistic and deterministic approaches
 - Conservative and realistic assessments
 - **Target audience**/involvement of interested parties

MAIN COMPONENTS OF THE SAFETY CASE

- The **Safety Strategy**:
 - Is a high-level **integrated approach** adopted for achieving safe management of radioactive waste.
 - Is an **overall management strategy** for the activities required in planning, operation, and closure of a facility.
 - Should **identify** the intended safety functions, the **timeframes** over which they will be available, and how **degraded performance** of one barrier will be compensated for by another mechanism or component of the disposal system (robustness, defence in depth).
 - Includes **considerations** on how the following topics will taken into account:
 - Graded approach
 - Optimization
 - Robustness
 - Demonstrability
 - Multiple safety functions
 - Passive safety
 - Good engineering/scientific practices
 - Management of uncertainties

MAIN COMPONENTS OF THE SAFETY CASE

- The **Management and Stakeholders** component includes:
 - **Involvement of stakeholders**
 - **Management system** including providing for assurance of the quality of all safety related activities, systems, and components throughout all steps of the development, operation, and closure of a facility.
 - Organization
 - Staff competence
 - Quality assurance
 - Record keeping/traceability
 - **Regulatory process**
 - Management system
 - Licensing process
 - Early and continuous involvement

MAIN COMPONENTS OF THE SAFETY CASE

- The **System Description** should provide information on:
 - The **facility design** and the **reasons for its selection**.
 - The **near-field** – including:
 - The **wastes** (e.g., origin, nature, quantities and properties, radionuclide inventory, etc.)
 - System **engineering** (e.g., waste conditioning and packaging, disposal units, engineered barriers, disposal facility cap or cover, drainage features, etc.)
 - The extent and properties of the **zone disturbed by excavations**
 - The **far-field** – e.g., geology, hydrogeology, geochemistry, tectonic and seismic conditions, erosion rates, etc.
 - The **biosphere** – e.g., climate and atmosphere, water bodies, human activities, biota, near-surface geology, topography, geographical extent, location, etc.
- The System Description is based on the **level of knowledge** available at the considered stage.

MAIN COMPONENTS OF THE SAFETY CASE

- The **Safety Assessment** aims at:
 - Evaluating the **soundness of the safety strategy**.
 - Verifying that the facility/activity performs such that **adequate levels of protection** of man and the environment are reached.
 - Evaluating the global performance of the facility/activity against **plausible situations** (scenarios).
 - Providing a framework for the **treatment of uncertainties**.
 - Contributing to a hierarchy of **studies deserving particular attention** and that should be implemented in the **next stage** of facility development.
-

MAIN COMPONENTS OF THE SAFETY CASE

- For example, **calculations** should address:
 - The evaluation of the behaviour of the waste components **when no interactions are expected**, individually and globally.
 - The evaluation of the disturbances caused by **the interactions between the different waste components** and the **assessment of the consequences** of those disturbances on safety functions.
 - The modelling of the future behaviour of the repository for specific **scenarios**.
 - Individual **exposure limits**.
-

MAIN COMPONENTS OF THE SAFETY CASE

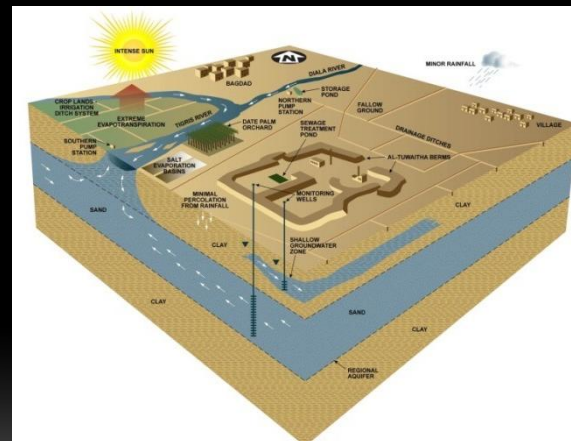
- **Safety Assessment** includes:
 - **Environmental impact assessment** – addressing the non-radiological hazards generated by the facility through its life cycle.
 - Potential **hazard identification**
 - **Hazard screening**
 - Identification of **scenarios**
 - Scenarios for normal operation
 - Scenarios for anticipated operational occurrences and design basis accidents
 - Scenarios for beyond design basis accidents (including serious accidents)
 - **Radiological impact** and performance assessment
 - **Operational safety**

MAIN COMPONENTS OF THE SAFETY CASE

- **Limits, Controls, & Conditions** includes:
 - **Limits**: dose/risk limits, activity limits per waste package, per disposal unit, and for the site.
 - **Controls**: active and passive institutional controls, controls for waste acceptance, conformity controls, compliance with design criteria and operational procedures, etc.
 - **Conditions**: quality management, nature of facility description, licensing conditions for operation, closure, etc.
- The fundamental bases for such limits, controls and conditions are the **safety requirements** and the **licensed conditions**. They generally are derived from formalized safety assessment, both operational and post-closure.

MAIN COMPONENTS OF THE SAFETY CASE

- **Surveillance** includes:
 - **Monitoring**
 - **Security**
- Surveillance and monitoring programmes should be developed and implemented to provide evidence **for a certain period of time** that the facility will be performing as predicted and that **components have the required level of performance** (safety function).



MAIN COMPONENTS OF THE SAFETY CASE

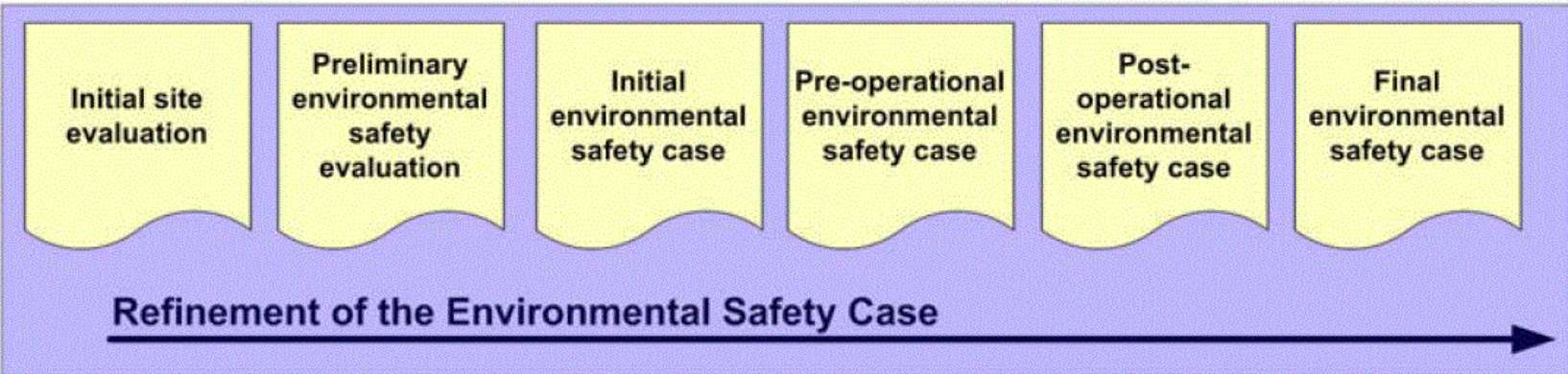
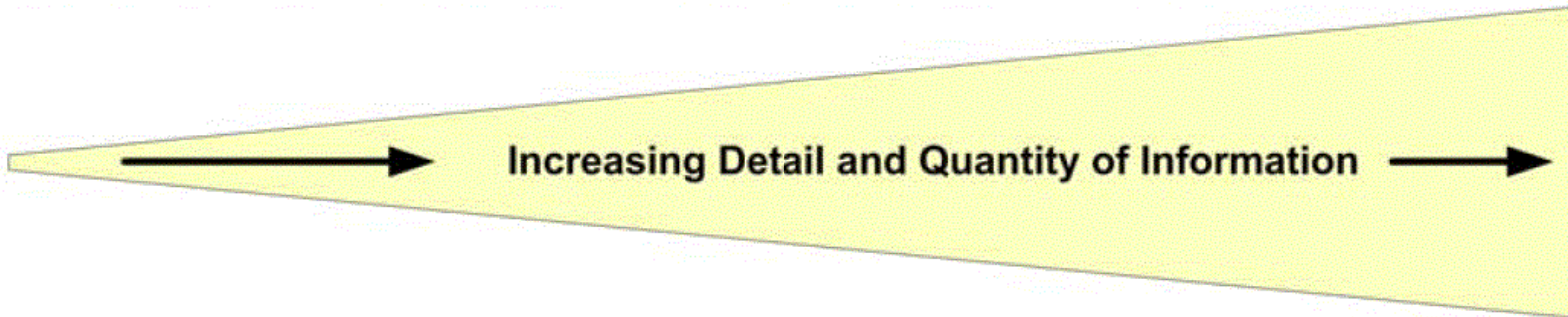
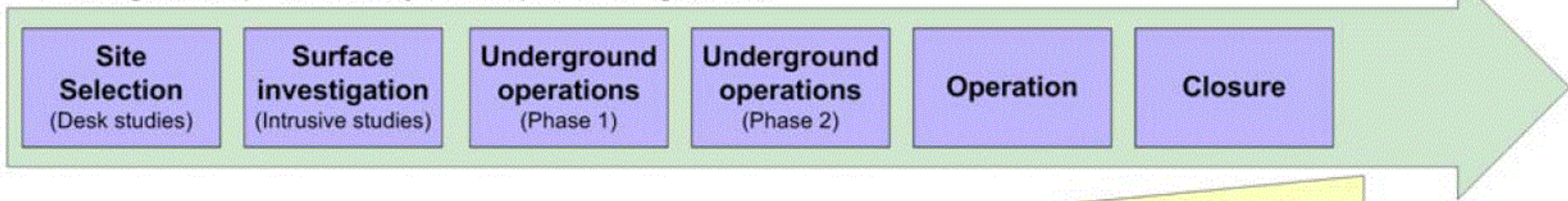
- **Management of Uncertainties** includes:
 - Formulation of **models**
 - Uncertainty and sensitivity analysis including **performing calculations** and **analyzing results**
 - **Explanation** of sources of uncertainties
- Analysis of uncertainties important for the **validity** of the results and for building **confidence**:
 - **Sensitivity studies** (systematic variation of input parameters)
 - Use of **conservative assumptions** (in particular for deterministic models)
 - Consideration of measured or estimated variation ranges in **probabilistic analysis**

MAIN COMPONENTS OF THE SAFETY CASE

- **Iteration and Design Optimization**
 - A safety case is multi-faceted in that several varied and sometimes **competing arguments** have to be brought together and reconciled to reach a **decision**.
 - The safety assessment process is **iterative**, although iteration need only proceed until the assessment is **judged fit for purpose**.
 - **Iteration** promotes:
 - Consideration of **improvements to and optimization** of the system.
 - **Confidence** in the understanding of the main safety related parameters and the **robustness** of the system under the assumed scenarios.
 - Collection of relevant **new data**.
-

ITERATION AND DESIGN OPTIMIZATION

Geological Disposal Facility Development Programme



MAIN COMPONENTS OF THE SAFETY CASE

- **Integration of Safety Arguments**
 - Simply showing that safety assessment results comply with quantitative regulatory criteria is not sufficient - **multiple lines of reasoning** should be used to compliment quantitative assessments.
 - These lines of reasoning may include discussion of:
 - The use of best available **techniques**
 - The history of design **optimization**
 - Consideration of **radiological protection** principles
 - Waste **isolation** and **containment**
 - **Passive safety**
 - **Robustness** and **defence in depth**
 - **Quality assurance** and **peer review**
 - **Conservatisms** in safety assessment
 - Application of **limits, controls and conditions**

SAFETY CASE SUMMARY

- In summary, the safety case should:
 - Provide a **synthesis** of the available evidence, arguments, and analyses.
 - Acknowledge any **limitations** of currently available evidence.
 - Highlight the principal reasons why planning, development, and use of the system should **continue**.
 - Describe an approach to the **management of uncertainty** through which any open questions and uncertainties with the potential to undermine safety will be **addressed**.
-

THANK YOU.

- Questions?

SAFETY ASSESSMENT

- The safety assessment is an integral part of the safety case.
- It provides:
 - Quantification of potential impacts and their probabilities – risks;
 - Understanding of the behavior and the safety of the facility or activity under normal operation conditions, anticipated operational occurrences and in the event of accidents.

Guidelines for safety assessment
applied to predisposal waste
management – *the SADRWMS methodology*

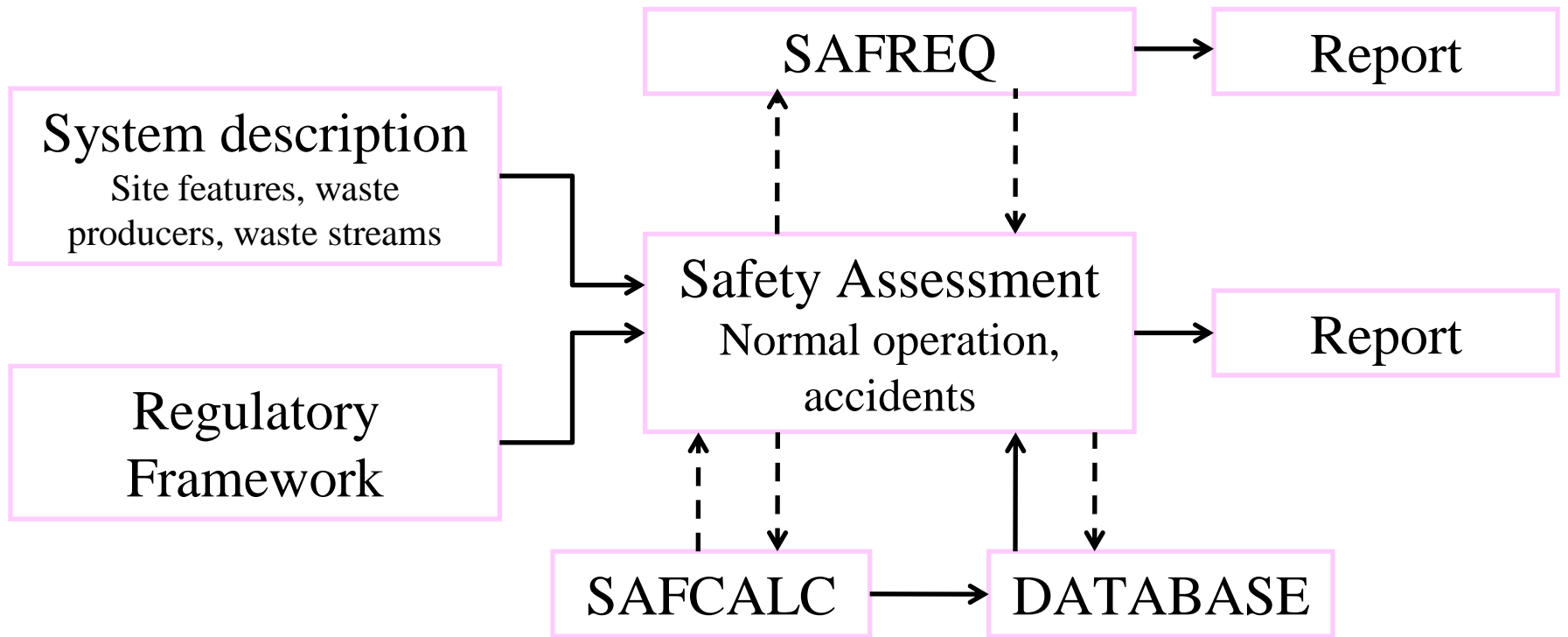
Last update: Oct 2011

CONTENT OF THE METHODOLOGY REPORT

1. Introduction
2. The Waste Identification and Predisposal Waste Management Process
3. Key Components of the Safety Assessment
4. Assessment Context of the Predisposal Waste Management Processes
5. Implementation of the Safety Assessment Methodology in the SAFRAN tool
6. Hazards Screening and Dose Assessments for Normal Operation Scenarios
7. Hazards Screening and Dose Assessments for Accident Scenarios
8. References

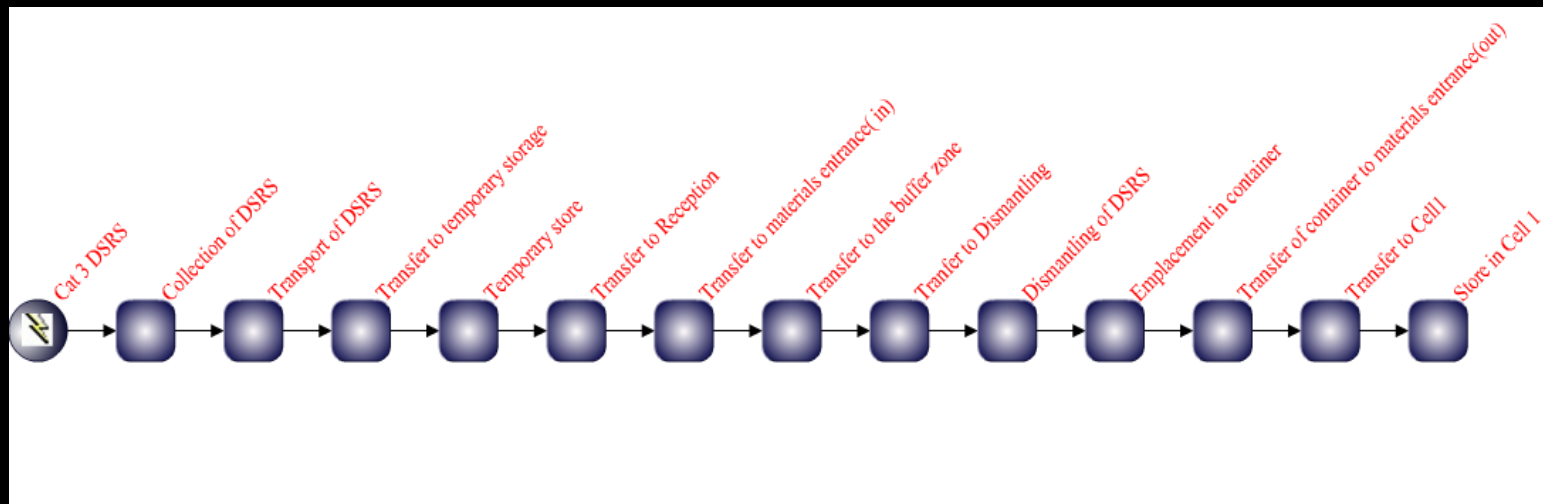
ANNEXES

SAFRAN COMPONENTS

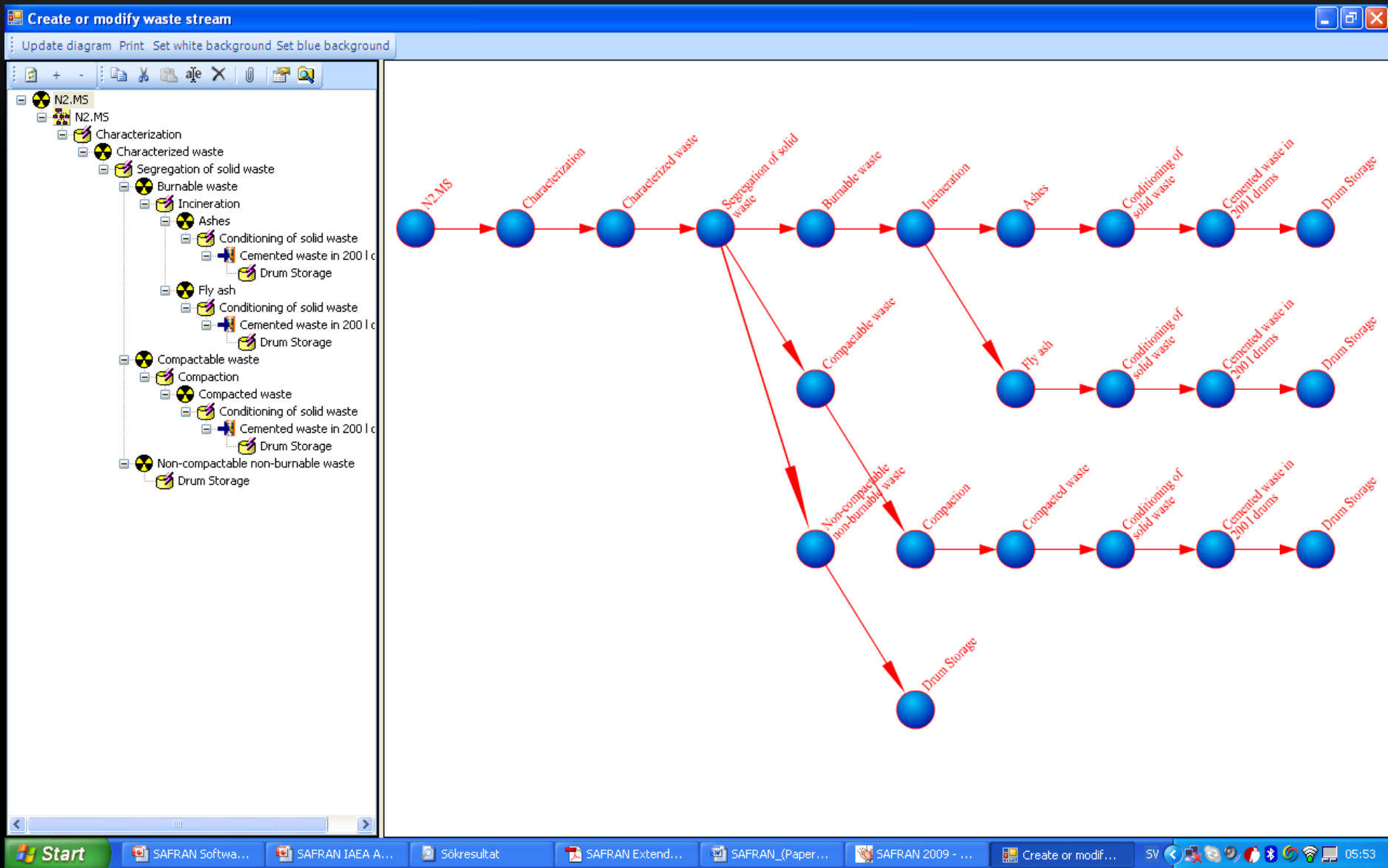


PROCESSES (SAFRAN)

- A process is a sequence of WMAs which can be used in definition of Waste Streams (WS)



SAFRAN



PROBLEM FORMULATION - SECTIONS 2, 3 AND 4

Waste and WM Processes –
Identification – Section 2

Required Safety Assessments
– Section 2

Steps of the Safety
Assessment – Section 3

Assessment Context for different
Safety Assessments – Section 4



PROBLEM
FORMULATION

WASTE IDENTIFICATION AND PREDISPOSAL WM PROCESS SECTION 2

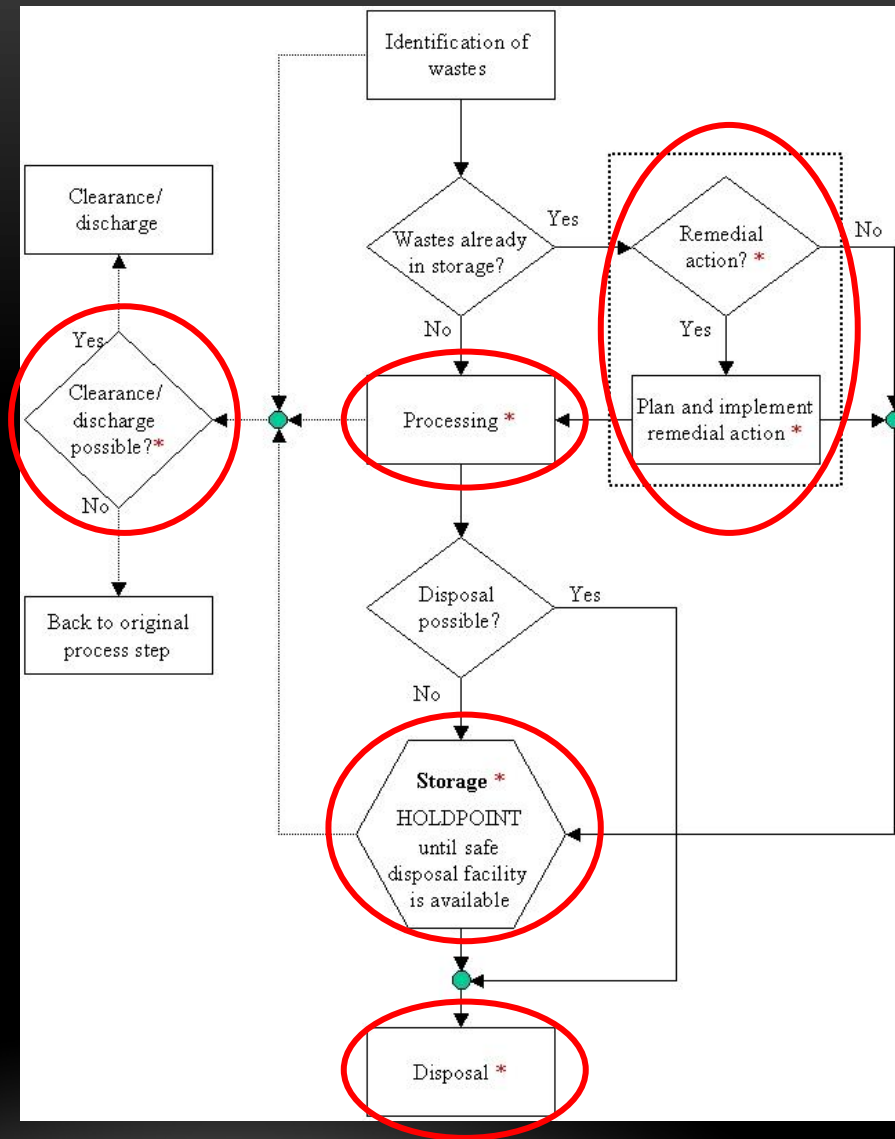
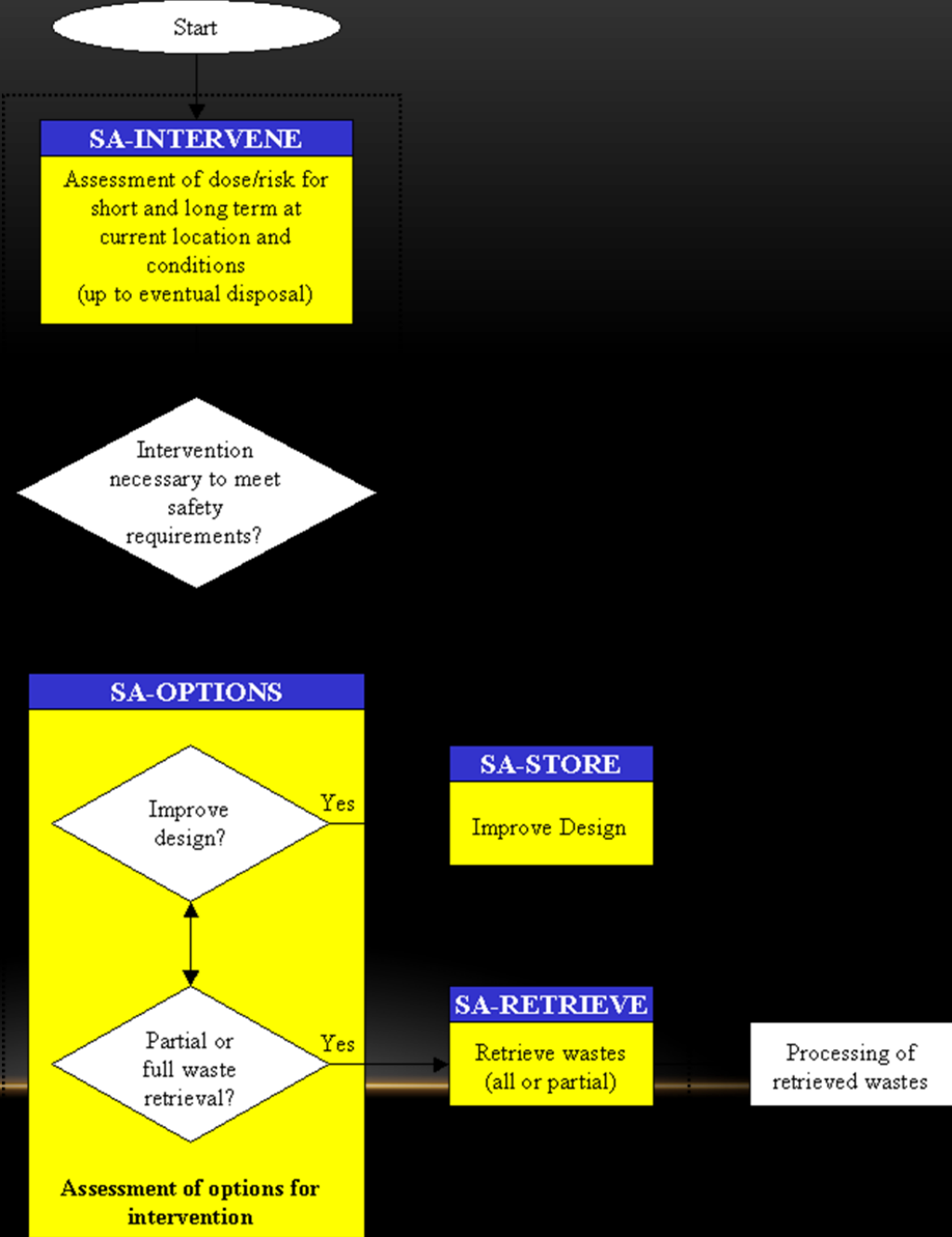
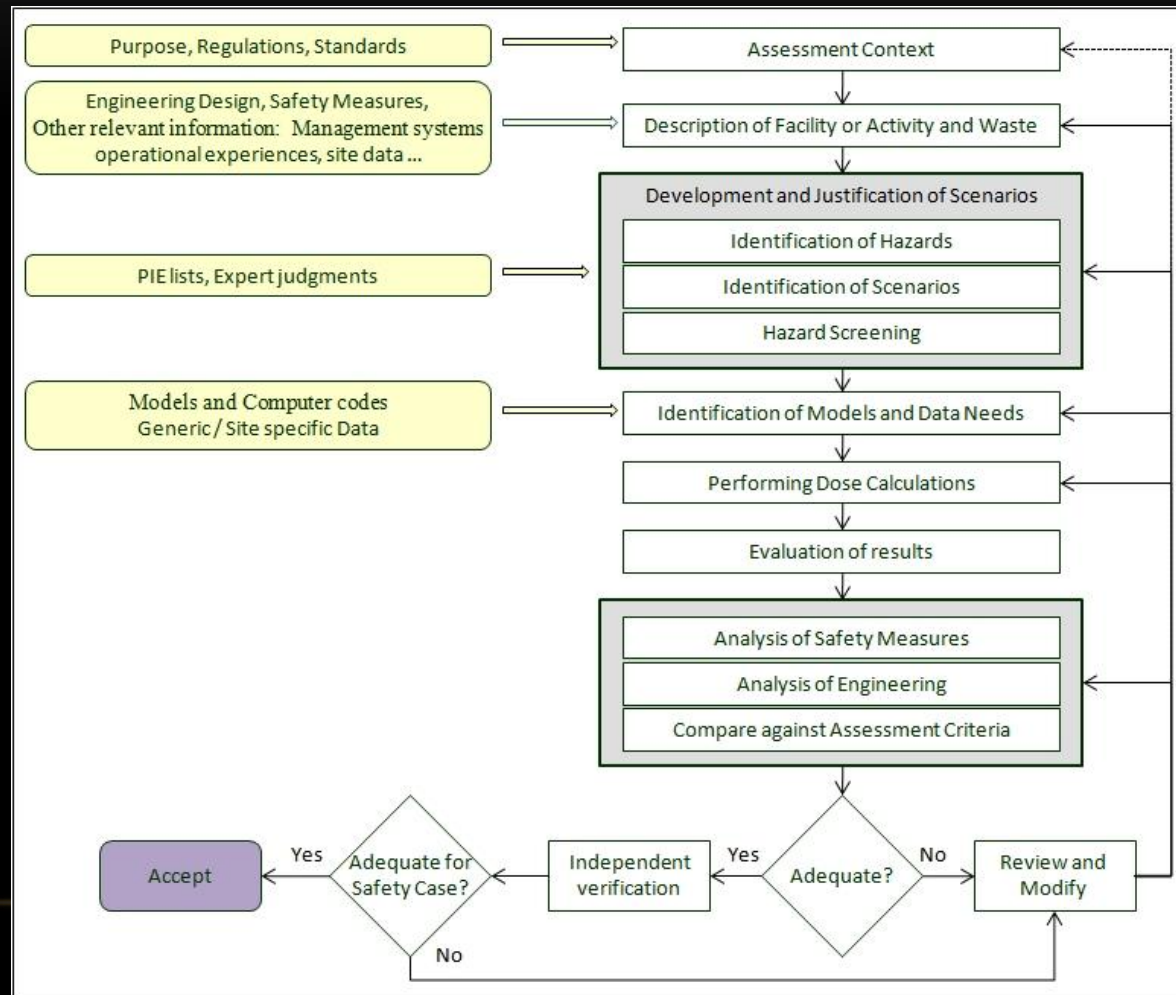


Fig. 2: Remedial Action?

Flow chart for the situation when remedial action might be required



STEPS OF THE SAFETY ASSESSMENT - SECTION 3



COMPONENTS OF THE ASSESSMENT CONTEXT

- 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 (Philosophy)
 - Safety objectives, principles, criteria and regulatory requirements, application of graded approach.
 - Timeframes
 - Lifetime of the facility, long term safety
-

PURPOSES - USES OF THE SAFETY ASSESSMENT

- To develop the program for maintenance, surveillance and inspection;
- To develop the procedures to be put in place for all operational activities significant to safety;
- To develop the procedures for responding to anticipated operational occurrences and accidents – Emergency Preparedness;
- To identify the necessary competences for the staff involved in the facility or activity;
- To evaluate the adequacy of safety functions and identify additional safety functions required;
- To demonstrate compliance with regulatory requirements criteria.

ASSESSMENT ENDPOINTS: RADIATION RISKS

- The level and likelihood of radiation exposure to
 - Workers;
 - Public;
 - Biota
 - Safety indicators such as possible releases of radioactive material to the environment, dose rates and radionuclide concentrations
 - Under conditions of:
 - Normal operation;
 - Anticipated operational occurrences;
 - Accidents.
-

OTHER TYPES OF ASSESSMENT ENDPOINTS

- Assessment of safety functions: engineered structures; systems and components; physical or natural barriers; inherent safety features; human actions necessary to ensure safety.
- Evaluation of site characteristics: factors that affect radionuclide migration if released, natural and human induced external events that have the potential to affect the safety of facility or activity.
- Evaluation of engineering: systems, structures and components of proven and robust design, evaluation of defense in depth, redundancy and diversity.
- Human factors: evaluation of interactions of humans with the facilities and activities.

ASSESSMENT APPROACH

- Description of the approach that will be adopted in the assessments and for managing the uncertainties: Conservative versus realistic, deterministic versus probabilistic calculations.
- A graded approach to the assessments is required.

ASSESSMENT TIMEFRAME

- The assessment timeframe is the period considered in the safety assessment calculations.
 - The assessment time frame should be defined taking into account:
 - National regulations and regulatory guidance
 - Characteristics of the facilities and activities
 - Characteristics of site
 - Characteristics of waste to be stored.
-

REGULATORY FRAMEWORK

- Risk – dose criteria for workers, members of the public, other biota in normal operation and for accidental situations.
 - Clearance levels, waste classification.
 - Other requirements – optimization, application of best available technologies, waste minimization.
 - Requirements on time frames for assessments.
-

DESCRIPTION OF FACILITIES, ACTIVITIES AND WASTE

- The description of the waste management facility and activities provides the basis on which the safety assessment is carried out.
 - The description should contain, depending on the type of disposal facility, information on the:
 - Site conditions;
 - Facilities and activities;
 - Waste.
-

SITE CONDITIONS

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

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.

THE 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.
-