

Review and Assessment for Safety

KINS-IAEA Workshop on Safety Review and Inspection Methodologies for
Quality Assurance

Korea Institute of Nuclear Safety (KINS)

13-17 May 2019

Zia H. Shah

***Regulatory Activities Section
Nuclear Safety and Security Department***

Overview

- Purpose and scope of safety assessment
- Responsibilities of the Operating Organization / Licensee regarding safety assessment
- Responsibilities of the Regulatory Body regarding safety review and assessment
- Management of Review and Assessment Process

IAEA Fundamental Safety Principles

- Safety assessments must be conducted to demonstrate that the safety measures necessary to control the hazard, and the design and engineered safety features fulfill 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.
- A facility may only be constructed and commissioned or an activity may only be commenced once it has been demonstrated to the satisfaction of the regulatory body that the proposed safety measures are adequate.
- Safety has to be assessed consistent with a graded approach.



Safety Assessment for Facilities and Activities

General Safety Requirements Part 4

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 radiation protection and safety have been fulfilled

IAEA Safety Standards
for protecting people and the environment

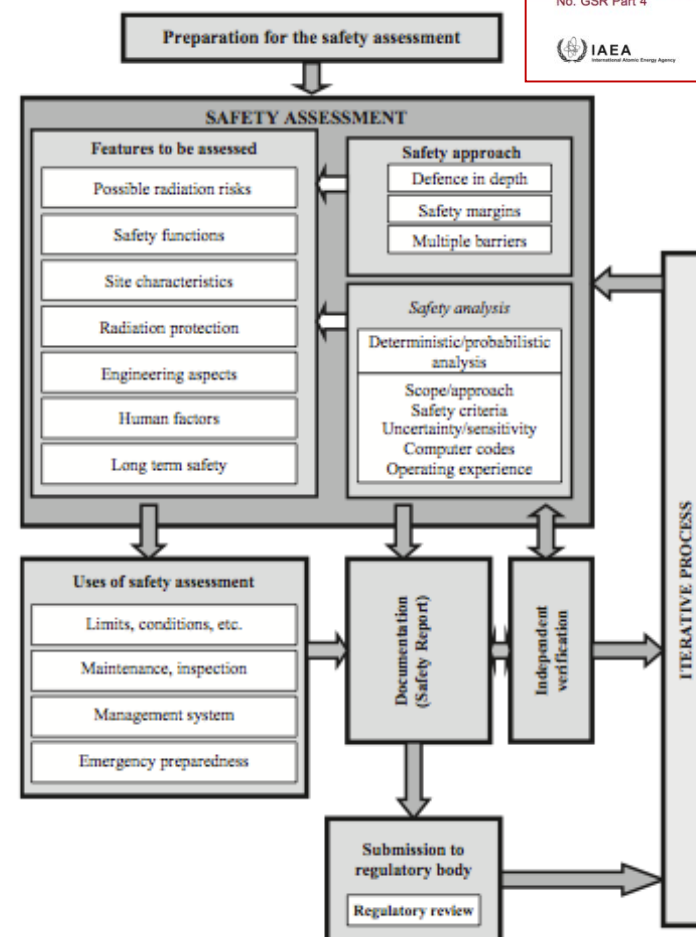
Safety Assessment for
Facilities and Activities

General Safety Requirements Part 4
No. GSR Part 4



Safety Assessment

- is the assessment of all aspects of a practice that are relevant to protection and safety;
- is a means of evaluating compliance with safety requirements (and thereby the application of the fundamental safety principles) for all facilities and activities and to determine the measures that need to be taken to ensure safety
- is a systematic process that is carried out throughout the lifetime of the facility or activity to ensure that all the relevant safety requirements are met by the proposed or actual design.

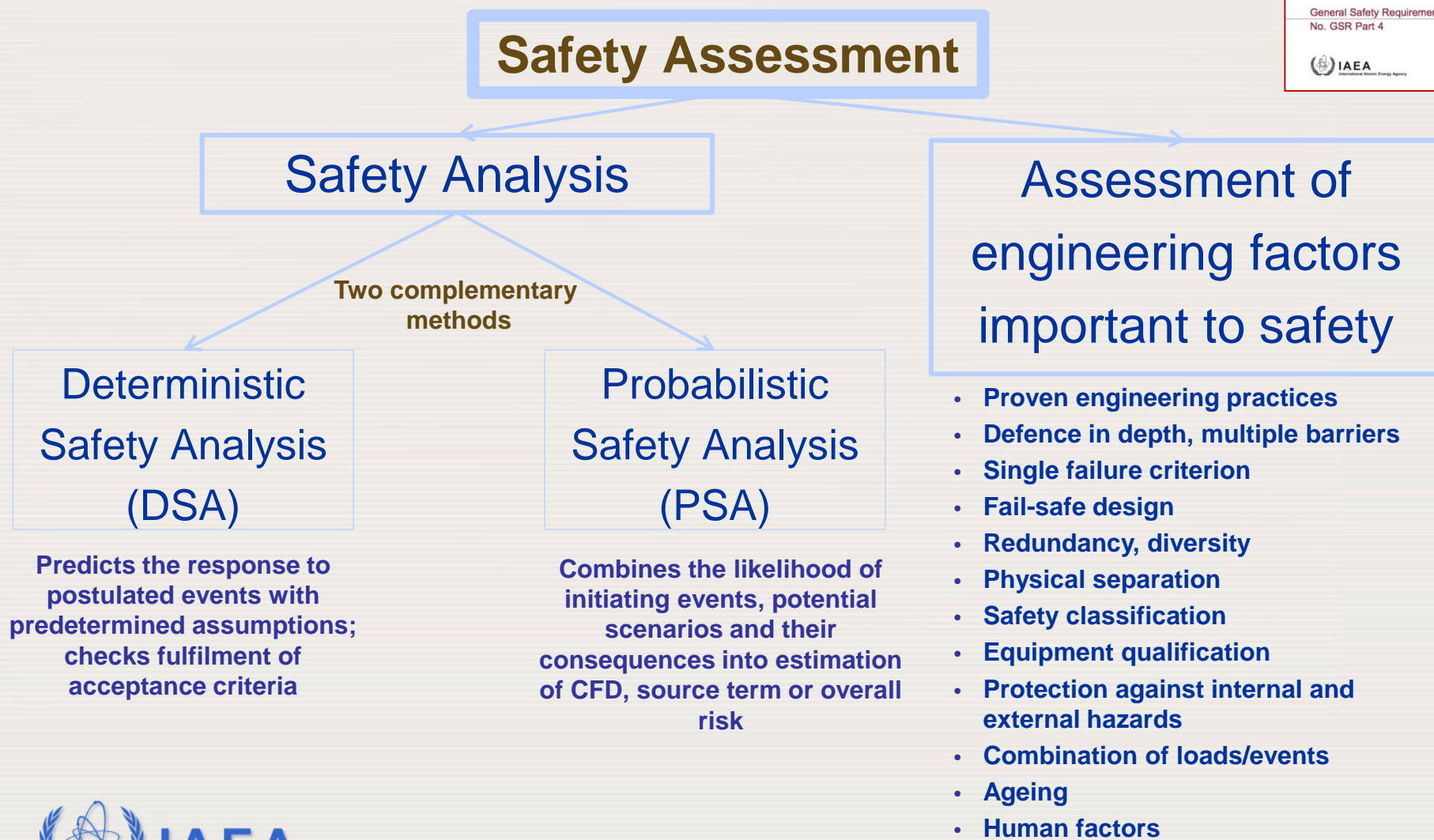




Safety Assessment

- Identification of the possible radiation risks resulting from normal operation, anticipated operational occurrences or accident conditions;
- Identification and assessment of a comprehensive set of safety functions;
- Assessment of the site characteristics that relate to the possible radiation risks;
- Assessment of the provisions for radiological protection;
- Assessment of engineering aspects to determine whether the safety requirements for design relevant to the facility or activity have been met;
- Assessment of human factor related aspects of the design and operation of the facility or the planning and conduct of the activity;
- Assessment of safety in the longer term, which is of particular concern when ageing effects might develop and might affect safety margins, decommissioning and dismantling of facilities, and

Safety Assessment and Safety Analysis





THE SAFETY ANALYSIS

‘Safety analysis’ is the evaluation of the potential hazards associated with a facility or an activity. And it shall:

- assess the performance of a facility or activity in all operational states and, as necessary, in the accident conditions to determine whether there is compliance with the relevant safety requirements;
- address both the consequences arising from all normal operational conditions as well as the probabilities and consequences associated with all identified abnormal or accident conditions;
- identify the abnormal and accident conditions that challenge nuclear safety (all internal and external events and processes that may impact on physical barriers to confine the radioactive material);
- determine the cause of the abnormal or accident conditions, its significance and determine the effectiveness of the proposed corrective action.
- shall incorporate **deterministic and probabilistic approaches**, as appropriate.

APPROACHES TO SAFETY ANALYSIS

- **Deterministic approach** defines and applies a set of conservative rules and requirements for the design and operation of a facility or activity. If these rules and requirements are met, they are expected to provide a high degree of confidence that the level of radiation risk to the public and workers will be acceptably low.
- It predicts the response to PIEs with predetermined assumptions; checks fulfilment of acceptance criteria
- The deterministic safety analysis mostly use conservative assumptions. 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.



APPROACHES TO SAFETY ANALYSIS

- **Probabilistic approach** determines all significant contributors to the radiological risk from a facility or activity and to evaluate the extent to which the overall design is well balanced and meets probabilistic safety criteria if been defined.
- It uses a comprehensive, structured approach to identify failure scenarios, then combines the likelihood of initiating events, potential scenarios and their consequences into estimation of CFD, source term or overall risk.
- The probabilistic safety analysis use realistic assumptions whenever possible and is able to quantify uncertainties explicitly.
- Probabilistic approaches may provide insights into system performance, reliability, interactions and weaknesses in the design, the application of defence in depth, and risks, that it may not be possible to derive from a deterministic analysis.



Assessment of Engineering Factors

- Proven engineering practices
- Defence in depth, multiple barriers
- Single failure criterion
- Fail-safe design
- Redundancy, diversity
- Physical separation
- Safety classification
- Equipment qualification
- Protection against internal and external hazards
- Combination of loads/events
- Ageing
- Human factors

While the assessment of engineering aspects important to safety may not be explicitly addressed in the safety analysis, it constitutes an important part of the safety assessment.

For some of these aspects, no well-defined acceptance criteria are available and therefore the assessment of the compliance with the safety requirements is *based on* good engineering judgement.

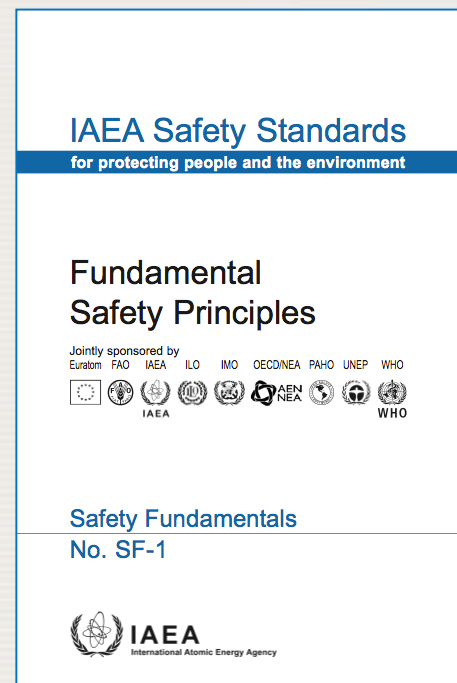
Responsibilities for Safety Assessment

The IAEA Fundamental Safety Principles SF-1

Principle 1: Responsibility for safety

The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.

- The licensee retains the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated.
- Other groups, such as designers, manufacturers and constructors, employers, contractors, and consignors and carriers, also have legal, professional or functional responsibilities with regard to safety.



Responsibilities for Safety Assessment

Safety Assessment for Facilities and Activities GSR-Part 4

Requirement 3: Responsibility for safety assessment

- A safety assessment is to be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities
- The responsibility for carrying out the safety assessment shall rest with the responsible legal person, i.e. the person or organization responsible for the facility or activity.

Responsibilities for Safety Assessment

Governmental, Legal and Regulatory Framework for Safety GSR-Part 1

Requirement 5: Prime responsibility for safety

- The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.

Requirement 24: Demonstration of safety for the authorization of facilities and activities

- The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.



Specific Safety Guide SSG-16

Action 157

- Operating organization should, in coordination with the vendor, prepare all the safety documents as required in the licensing process for submission to the regulatory body.

Action 178

- The operating organization should conduct an adequate safety review of the designs proposed by the vendors in the submitted bids, including an assessment of the associated sets of codes and standards.



Specific Safety Guide SSG-16

Action 179

- The operating organization should establish proper interaction with the selected vendor for the preparation of the safety documents.

Action 181

- The operating organization should prepare and provide to the regulatory body the safety documents required in the licensing process.



Documents and information submitted by the licensee

More specific and detailed guidance regarding the documents and information should be submitted by the applicant/licensee to regulatory body for review and assessment are provided in the following IAEA Safety Guides

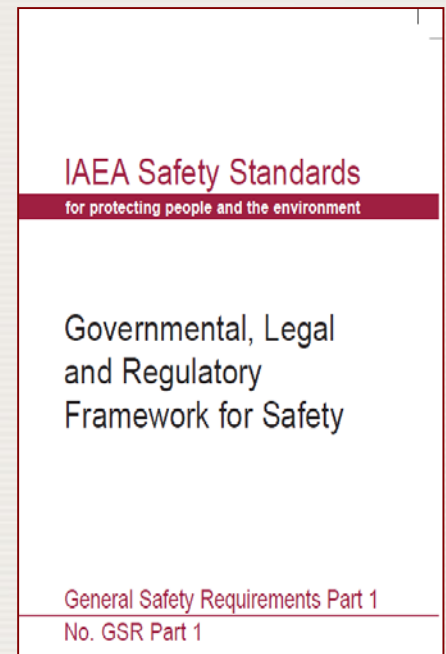
1. Licensing Process for Nuclear Installations **SSG-12**
2. Documentation for Use in Regulating Nuclear Facilities **GS-G-1.4**
3. Format and Content of the Safety Analysis Report for Nuclear Power Plants **GS-G-4.1**
4. Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body **GS-G-1.3**

<http://www-ns.iaea.org/standards/documents/pubdoc-list.asp?s=11&l=83>

Responsibility for Review and Assessment

GSR-Part 1 –Req. 25: Review and assessment of information relevant to safety

- The regulatory body shall review and assess relevant information —**whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere** — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization.
- This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.





Responsibility for Review and Assessment

GSR-Part 1 –Req. 26: Graded approach to review and assessment of a facility or an activity

- Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

IAEA Safety Standards

for protecting people and the environment

Governmental, Legal
and Regulatory
Framework for Safety

General Safety Requirements Part 1

No. GSR Part 1



Specific Safety Guide SSG-16

Action 38.

- The RB should review and assess programmes to be implemented by the operating organization, as appropriate.

Action 84.

- The RB should review and assess the operating organization's programme on safety management.

Action 97.

- The RB should review and assess the operating organization's programme with regard to human resources management.

Action 164.

- The RB should review and assess the site evaluation report, and should make a decision regarding the acceptability of the site selected and the site related design bases.

Specific Safety Guide SSG-16

Action 120.

- The regulatory body should carry out a comprehensive review and an independent verification of the safety analysis reports submitted by the operating organization to verify compliance with the regulatory requirements.

Action 182.

- The regulatory body should review and assess the safety documentation such as the safety analysis reports, and should verify the compliance of the design with regulatory requirements.

Action 183.

- The operating organization should ensure the adequate validation and verification of the design of the nuclear power plant and its structures, systems and components, and the regulatory body should review this validation and verification.

Specific Safety Guide SSG-16

Action 111.

- The regulatory body should review and assess the radiological environmental impact analysis for the site selected, as appropriate.

Action 115.

- The regulatory body should review and assess the operating organization's programmes with regard to radiation protection and relevant environmental protection, and should verify compliance with the regulatory requirements.

Action 129.

- The regulatory body should review and assess the operating organization's programmes for waste management and spent fuel management and for decommissioning, and should verify their compliance with the regulatory requirements.

Specific Safety Guide SSG-16

Action 144.

- The regulatory body should review and assess the emergency programme, plans and procedures for nuclear power plants, and should verify compliance with the regulatory requirements.

Action 188.

- The regulatory body should review and assess the commissioning programme, should verify compliance with requirements and should prepare a programme to oversee the commissioning of systems important to safety in the next Phase.

Establishment of an Management System

GSR Part 1 ‘Governmental, Legal and Regulatory Framework for Safety’

- Requirement 19 : The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.
- 4.14 : The regulatory body shall establish and implement a management system whose processes are open and transparent.



Management of Review and Assessment

What is ‘Management System’?

- **IAEA glossary(2007) defines** that ‘management system’ is a set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.
- **IAEA glossary(2007)** also explains that ‘management system’ integrates all elements of an organization into one coherent system to enable all of the organization’s objectives to be achieved. These elements include the organizational structure, resources and processes.

Establishment of an Management System

GSR Part 2 ‘The Management System for Facilities and Activities’

- Process Implementation” stipulates the requirements for developing processes and process management
- The development of each process shall ensure that
 - Process requirements (legal, etc.) are specified and addressed;
 - Interactions with interfacing processes are identified;
 - Process inputs are identified;
 - Process flow is described;
 - Process outputs are identified; etc.

IAEA Safety Standards

for protecting people and the environment

Leadership and
Management for Safety

General Safety Requirements
No. GSR Part 2

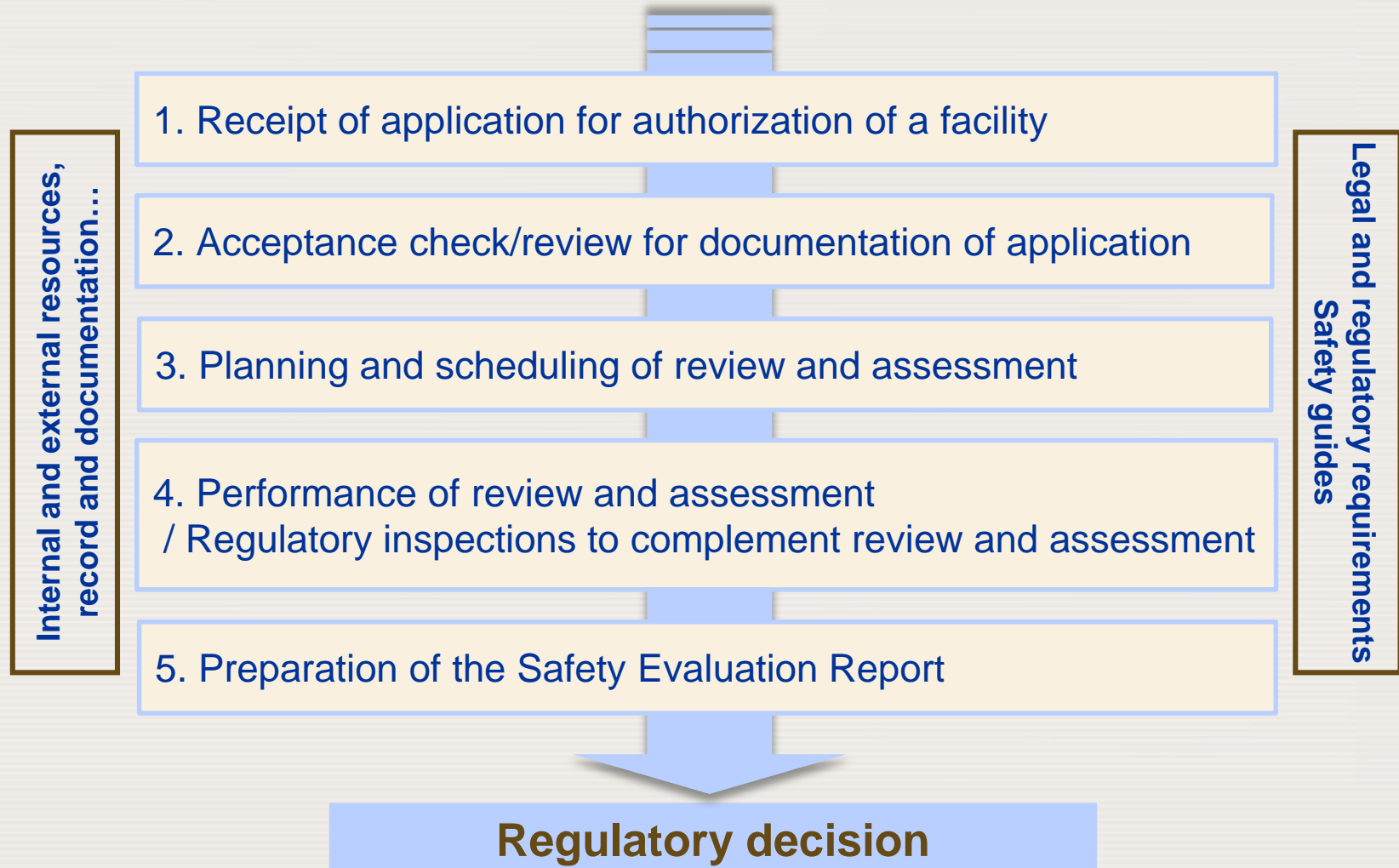




Lifecycle Stages subjected to RB review and assessment

- The site evaluation
- Design
- Construction
- Commissioning
- Operation
 - Major Design Modifications/ Amendment to initial authorization
 - Periodic Safety Review
- Decommissioning
- Release from the regulatory control

Steps of the review and assessment process



Management responsibilities for the R&A

- **Specific individuals or organizational units should be designated to have responsibilities for:**
 - Planning and directing and monitoring the review and assessment process;
 - Preparing, approving and revising the procedures to be followed in accordance with the management system;
 - Coordinating the RB personnel and other necessary resources;
 - Making arrangements for coordination between reviewers and the operator, for coordination between review activities and inspection activities, and for liaison with consultants, advisory committees or any other relevant organizations;
 - Qualification and training of personnel;
 - Record keeping of the process inputs and outputs;
 - Communication with the Applicant/Licensee;
 - Planning for public consultation or any hearing process; etc.



Review and assessment plan

In carrying out a review and assessment of an operator's submission, the regulatory body should employ a systematic plan to provide assurance that all topics significant to safety will be covered.

The plan should cover:

1. Definition of the scope of the review and assessment process;
2. Specification of the purpose and technical bases for the review and assessment process (these could be acceptance criteria);
3. Identification of the additional information necessary;
4. Performance of a structured procedure to determine whether all applicable safety objectives and regulatory requirements have been met for all topics;
5. Decisions on the acceptability of the operator's safety arguments or the need for further submissions.



Internal guidance

- The regulatory body should provide internal guidance on the procedures to be followed in the review and assessment process and guidance on the safety objectives to be met.
- Detailed guidance on specific topics should also be provided, as necessary.
- Consideration should be given to the extent to which the regulatory body's internal guidance may be made available to operators and the public.



Reference/Generic NPP R&A

If the national approach provides for reference or generic submissions to be considered:

- inappropriate to give full authorization on the basis of the reference facility or generic facility (factors as siting related, managerial and operational aspects; differences in regulatory requirements),
- the authorization should be limited to the generic design,
- give particular attention for differences from the reference design
- even if the design has been authorized in another country, the regulatory body should still perform its own independent review and assessment as much as possible
- establish close contact with the previously authorized RB of other country in order to facilitate the review and assessment process.



Reference/Generic NPP R&A

Safety evaluations performed by regulatory body in the country of origin may be used to support the regulatory review and assessment for authorization/licensing. However, special attention should be given to :

- regulatory requirements that are different from the country of origin,
- design changes, including new technologies, that have not been approved by regulatory body in the country of origin,
- country's unique site characteristics, and
- operating experience since other regulatory authority's approval.



Organization and Resources

- Review and assessment are principal functions of the regulatory body. Adequate resources should be provided to the regulatory body for an effective conduct of regulatory review and assessment.
- Regulatory may use external support (such as TSOs or consultants within or outside the state) when appropriate and necessary during the performance of the regulatory review and assessment.
- The size and composition of the regulatory body, the number of consultants used and the use of advisory committees should reflect the number and the size, nature and stage in the lifetime of the facilities that it regulates.
- The regulatory body should have, at a minimum, adequate core staff who have sufficient technical knowledge enabling them to identify problems, to determine whether it would be appropriate to seek assistance from an external expert, to manage the external support while the advice is being developed and, at the end of the process, to understand, evaluate and use any relevant advice from the external expert. (**Intelligent Customer**)

Organization and Resources

- In considering its future tasks and the best use of available resources, the regulatory body will need to define which activities must be retained 'in-house' as core activities, and any which it might delegate to out source.
- The regulatory body must possess an adequate number of staff qualified to specify, monitor and evaluate the work of the TSO. Necessary arrangements should be in place to ensure that the Regulatory Body retains its responsibility for making all decisions on regulatory and safety issues and is not unduly influenced by any provider of external expert support.



Scheduling of the submissions

The regulatory body should indicate to the Applicant/Licensee the period of time that is considered necessary for the review and assessment process so as to facilitate the process and to minimize delays in the granting of any necessary authorizations. It is appropriate to reach agreement on an indicative schedule.

The regulatory body should make all efforts to complete its review and assessment process in accordance with the agreed schedule, but this objective should in no way compromise the regulatory body's responsibilities.

Records of the submission

- The formal exchange of information should be through agreed channels of communication. Certain formal documentation will be required by the laws and regulations of the State or by the requirements of the regulatory body.
- Other formal submissions will be made in response to specific requests from the regulatory body or at the initiative of the operator. The records of official meetings and hearings may also constitute means for formal exchanges of information and should also be suitably recorded and stored.



Proprietary information and confidentiality

Certain information provided by the Operator or its contractors should be considered confidential because of its proprietary nature, for security reasons or because of the rights of individuals (e.g. commercial).

Such confidential information should be made available as necessary without restriction, to the regulatory body staff, consultants and advisory committees who should be advised of its confidential nature and should be obliged to protect its confidentiality.

In using external assistance, issues of security need special attention.



External Relationships

- **Relationship with the operator**

The regulatory body and the operator should establish formal relations based on independence and mutual respect.

- **Relationship with the operator's contractors**

Much of the information needed by the regulatory body may be prepared for the operator by its contractors, hence it may permit the participation of contractors in meetings with the operator to clarify issues concerning safety and facilitate the exchange of information.

These contacts should not diminish the responsibility of the operator for the safety of the facility.



External Relationships

- **Relationship with other governmental bodies**

- Other governmental bodies may participate in the regulatory process, hence the regulatory body should establish and maintain liaison with them. Therefore, other governmental bodies may participate in the regulatory process in accordance with national legislation, regulations and practices.
- The regulatory body should establish and maintain liaison throughout the lifetime of the facility with other governmental bodies as appropriate; and it should develop and, where practicable, formalize working procedures with such bodies, whether at the national, regional or local level. **Areas of the review and assessment in which such bodies might participate should be identified.**
- The nature of the relation between the operator and other governmental bodies should be determined by national laws, regulations and practices.



External Relationships

- **Relationship with regulatory bodies of other States and international bodies**

SSG-16 Action 19 *“The regulatory body should implement a cooperation programme with the vendor State and with other regulatory bodies that have experience of oversight of nuclear power plants of the same type as that selected.”*

- The regulatory body should extend its contacts to gain feedback from regulatory bodies in other States. Assistance from the regulatory body of the supplier State, as well as from other regulatory bodies that have oversight experience with other nuclear power plants of the same type as that selected, including temporary assignments of staff, should be sought to the extent possible.
- Exchange of results of safety reviews and joint inspections with regulatory bodies in other States having oversight experience with nuclear power plants of the type selected could be used for increasing the understanding of important safety issues.



Records of the RB's review and assessment

- The review and assessment process includes the production of reports and documents by various experts in the RB and by any consultants hired.
- A document control system should be set up for keeping records of the process so as to allow such documents and records to be readily retrieved.
- The basis for the regulatory decisions should be recorded and documented in an appropriate form.
- This documentation should summarize the review and assessment performed and should present a clear conclusion about the safety of the activity authorized.
- It should be possible to access the bases for previous decisions so as to achieve consistency and to facilitate any reassessment made necessary by new information.



Monitoring of the review and assessment process

The regulatory body should have a system to audit, review and monitor all aspects of its review and assessment process so as to ensure that it is being carried out in a suitable and efficient manner and that any changes to the process necessitated by advances in knowledge or improvements in methods or for similar reasons are implemented.

THANK YOU