Review and Assessment Process

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Learning Objectives

After going through this presentation the participants are expected to be familiar with:

- **Relevant IAEA standards**
- **Basic concepts**
- **Development of the process**
  - **Objectives, Responsibilities, etc.**
- **Performance of review and assessment**
  - **Topics covered by review and assessment,**
  - **Documentation submitted by the operator, etc.**

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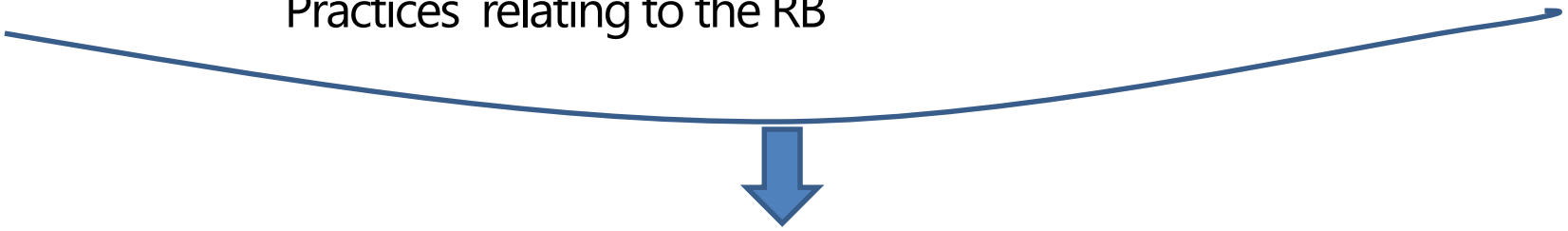
Part I. Introduction

(I.a) IAEA Standards

- **GS-G-1.2,** Review and Assessment of Nuclear Facilities by the RB(2002)
- GS-G-1.3, Regulatory Inspection of Nuclear Facilities and Enforcement by RB (2002)
- **GS-G-1.4**, Documentation for Use in Regulating Nuclear Facilities(2002)
- GS-G-1.5, Regulatory Control of Radiation Sources(2004)
- **SSG-12**, Licensing Process for Nuclear Installations relating to the Functions and Processes of the RB
- WS-G-5.1, Release of Sites from Regulatory Control on Termination of Practices relating to the RB



GSG-13, Functions and Processes of the Regulatory Body for Safety(2018)

(I.a) IAEA Standards

- **GS-R-3 'The Management System for Facilities and Activities' (supersede by GSR Part2(2016))**
  - **5. 'Process Implementation' stipulates the requirements for developing processes and process management**
  - **5.4 : 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;**
    - **The process flow is described;**
    - **Process outputs are identified; etc.**

(I.a) IAEA Standards

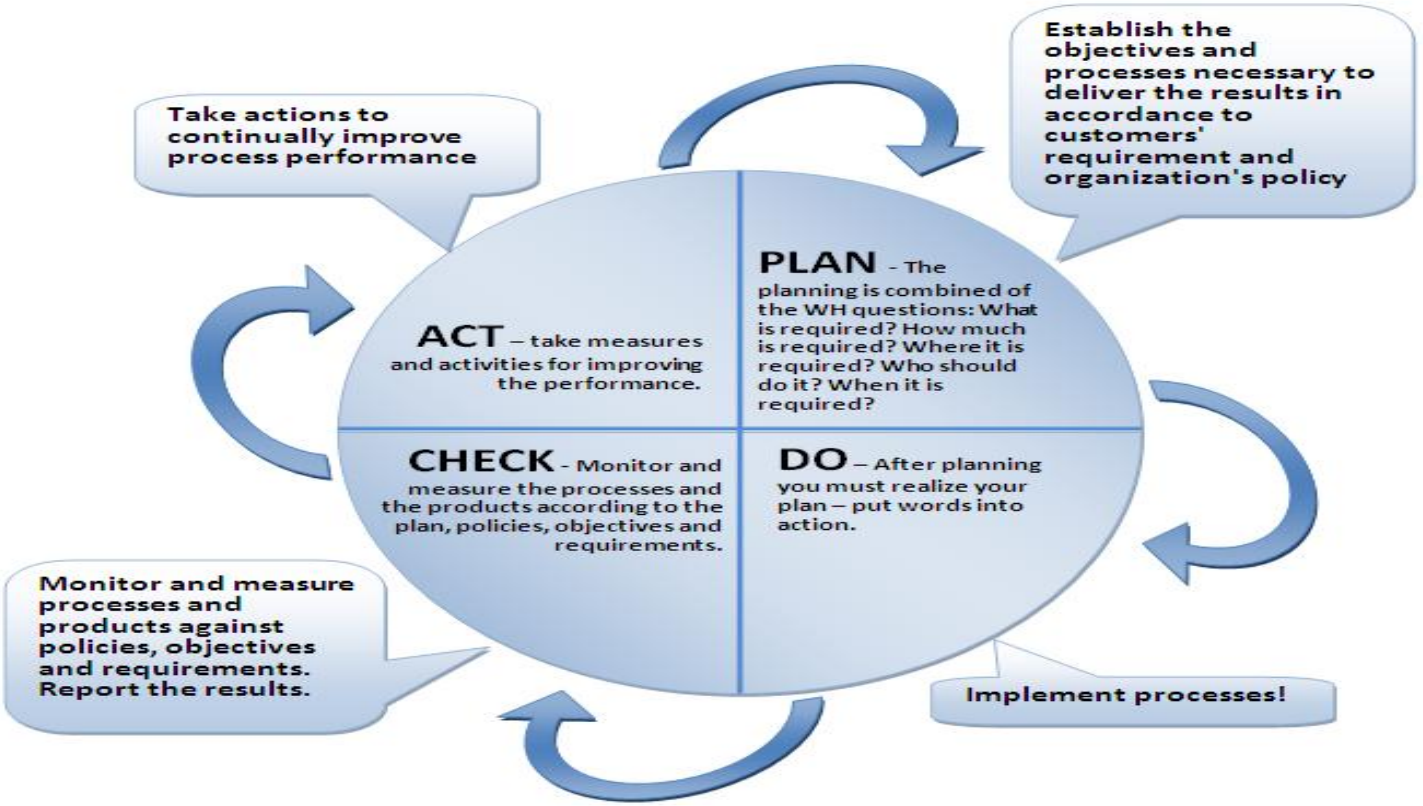
- **GS-G-1.2 'Review and Assessment of Nuclear Facilities and Facilities by the Regulatory Body'**
  - **1.4 : The purpose of this Safety Guide is to provide recommendations for regulatory bodies on reviewing and assessing the various safety related submissions made by the operator of a nuclear facility to determine whether the facility complies with the applicable safety objectives and requirements.**
  - **1.6 : Objectives, management, planning and organizational matters relating to the review and assessment process are presented in Section 2. Section 3 deals with the bases for decision making and conduct of the review and assessment process.**

(I.b) Basic Concepts

- **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.**

(I.b) Basic Concepts

- **Concept of establishment, implement, assessment and improvement of 'management system'**



(I.b) Basic Concepts

- **What is 'Process' ?**
  - **IAEA glossary(2007) defines that 'process' is a set of interrelated or interacting activities that transforms inputs into outputs.**
- **So, 'review and assessment process' is**
  - **A set of interrelated or interacting activities that are performed to produce outputs (regulatory decision on whether the facility complies with the safety objectives and requirements) from inputs (informations submitted by the operator like 'safety analysis report').**

(I.b) Basic Concepts

- **The process is materialized into management system(MS) documents like procedures.**
  - **GS-R-3 'The Management System for Facilities and Activities' 5.9 states that the work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means.**
- **What to do to develop review and assessment procedures?**
  - **Investigate and analyze all elements that should be included in the review and assessment process, and**
  - **Write down all elements appropriately in the procedures, that should be referred to for implementing the review and assessment process.**

(I.b) Basic Concepts

- **Typical contents of a procedure suggested by GS-G-1.2 'Application of the Management System for Facilities and Activities' 2.58 are:**
  - **Purpose: The specific objectives of the document;**
  - **Scope: The type of work and situations covered by the document;**
  - **Responsibilities: The individuals by title and their responsibilities;**
  - **Definitions and abbreviations;**
  - **References: The Regulations and Guides used in the document;**
  - **Details: The sequence of actions necessary to accomplish the work (planning and scheduling, administrative and technical information, work steps, interfaces, lines of communication, etc.);**
  - **Records: The records that demonstrate the appropriate completion of the work;**
  - **Appendices.**

Part II. Development of the R & A Process

(II.a) Objectives

- The basic objective of review and assessment process is
  - to determine whether the operator's submissions demonstrate that the facility complies with the safety objectives and requirements.
- Specific objectives should be identified for each process and clearly stated in the relevant procedure.
- For example, the objective of review and assessment process for site evaluation can be
  - to determine whether the site chosen is suitable for the proposed facility, account being taken of the interaction between the site and the facility and of anticipated changes to the environment of the site during the proposed period of commissioning and operation.

(II.b) Responsibilities

- **Specific individuals or organizational units should be designated to have responsibilities for:**
  - **Planning and directing review and assessment activities, and monitoring the progress of activities;**
  - **Preparing, approving and revising the procedure;**
  - **Performing review and assessment activities;**
  - **Monitoring the progress of review and assessment activities;**
  - **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;**
  - **Planning for public consultation or any hearing process; etc.**

(II.c) Work Flow and Administrative Control

1. **Receipt** of application for authorization of a facility
2. **Planning and scheduling** of review and assessment
3. **Acceptance review** for documentation of application
4. **Performance** of review and assessment
5. **Regulatory inspections** for review and assessment
6. **Regulatory decision** on the acceptability of application

(II.c) Work Flow and Administrative Control

- **Receipt of application for authorization of a facility**
  - **Keeping all the information regarding the documents sent or received (title, date, name of sender or recipient, etc.)**
- **Planning and scheduling the review and assessment**
  - **The regulatory body should indicate to the operator the period of time considered necessary for review and assessment process**
  - **In determining the period of review and assessment process, several time-consuming factors should be considered (acceptance review, possibility of safety issues, preparing additional information by the operator, etc.)**

(II.c) Work Flow and Administrative Control

- **Docket review to confirm the completeness of submissions**
  - **As the information initially submitted by the operator may be incomplete, the regulatory body should perform docket review to make the information complete enough to initiate review and assessment process.**
- **Performance of the review and assessment**
  - **The scope and depth of the review and assessment should be graded on the basis of the consideration of safety significance, available regulatory resources, etc.**

(II.c) Work Flow and Administrative Control

- **Regulatory inspection for review and assessment**
  - **Although a fundamental feature of the review and assessment process is the consideration of the documentation provided by the operator, the regulatory body should also verify claims made in the documentation, as a necessary part of the process.**
- **Decisions on the acceptability of the application**
  - **Based on the result of review and assessment, the regulatory body notifies to the operator the decision on whether the authorization is issued or not.**

(II.c) Work Flow and Administrative Control

- **Interactions with the operator and other organizations**
  - **Proper channels of communication between the operator and the regulatory body should be established, because:**
    - **The operator should submit its documentation and additional information requested by the regulatory body in a timely manner;**
    - **The operator and the regulatory body should continue to hold meetings to discuss topics and safety issues.**
  - **The regulatory body should establish and maintain liaison with other governmental bodies as appropriate.**
  - **When using consultants, the regulatory body should carefully define the terms of reference for the review and assessment.**

(II.c) Work Flow and Administrative Control

- **Records and documentation of review and assessment**
  - **The review and assessment process will invariably involve the production of reports by various experts in the regulatory body and by any consultants employed.**
  - **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 decision on the application should be recorded and documented in an appropriate form which should summarize the review and assessment performed and should present a clear conclusion about the safety of the facility.**

(II.d) Resource Control

- **Organization of the regulatory body**
  - **As the review and assessment are principal functions of the regulatory body, 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.**
  - **In line with IAEA GS-G-1.1(GSG-12(2018)) 'Organization and Staffing of the Regulatory Body for Nuclear Facilities' 3.14, the regulatory body should form necessary teams of specialists for the review and assessment, depending on the complexity of the facility under review and the scale and nature of the review and assessment work.**

(II.d) Resource Control

- **Consultants and advisory bodies**
  - **In using consultants, the regulatory body should carefully define the terms of reference for the review and assessment and should have permanent staff with tie competence to manage the work of consultants and to evaluate the quality and results of their work.**
  - **The regulatory body may establish advisory bodies to get expert opinion and advice for review and assessment of facilities.**
  - **Although consultants or advisory bodies may be available, using them shall not relieve the regulatory body of its assigned responsibilities. [IAEA GSR Part 1 'Governmental, Legal and Regulatory Framework for Safety' Requirement 20]**

(II.d) Resource Control

- **Competence of personnel performing review and assessment**
  - **A systematic approach should be taken for qualification and training of the personnel engaged in the review and assessment.**
  - **In line with IAEA GS-G-1.1 'Organization and Staffing of the Regulatory Body for Nuclear Facilities' 5.2, the regulatory body, depending on the number and complexity of the facilities that it is regulating, should have:**
    - **A training policy;**
    - **Budgetary provisions for training;**
    - **A formal training programme;**
    - **A training plan for personnel performing review and assessment; etc.**

(II.e) Monitoring and Audit of the 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 change to the process necessitated by advances in knowledge or improvements in methods or for similar reasons are implemented**

- **This system should cover:**

  - **Regulations and guides;**
  - **Procedures for assessment within the regulatory body**
  - **Availability of suitable staff for review and assessment;**
  - **Procedures for using consultants and advisory committees**
  - **Records of documentation; etc.**

(II.e) Monitoring and Audit of the Process

- **IAEA GS-R-3(GSR-p2) 'The Management System for Facilities and Activities' Chapter 6 sets forth the requirements on measurement, assessment and improvement of management system(MS) of the regulatory body.**
  - **The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement.**
  - **By conducting self-assessment and independent assessment, the opportunities for improvement of processes shall be identified and actions to improve the processes shall be selected, planned and taken.**

Part III. Performance of the R & A Process

(III.a) Topics covered by review and assessment

- The scope and depth of review and assessment will depend on several factors such as novelty, complexity, previous history, the experience of the operator and the associated risk.
- A major feature of the operator's submission will be its analysis of normal and fault(deviation from the normal operation) conditions.
  - The value of a safety analysis is in extending knowledge and understanding of the facility and its behavior, and in identifying shortcomings in areas in which safety can be improved.

(III.a) Topics Covered by Review and Assessment

- **IAEA GS-G-1.2 'Review and Assessment of Nuclear Facilities by Regulatory Body' Appendix provides a generic list of topics that should be considered in the review and assessment.**
  - **The physical nature of the facility and its environment;**
  - **Infrastructural aspects;**
  - **Safety analysis**
  - **The operating organization and the management system;**
  - **Operational procedures;**
  - **Equipment qualification;**
  - **Management of ageing;**
  - **Operator's safety performance;**
  - **Experience from other facilities and research findings.**

(III.a) Topics Covered by Review and Assessment

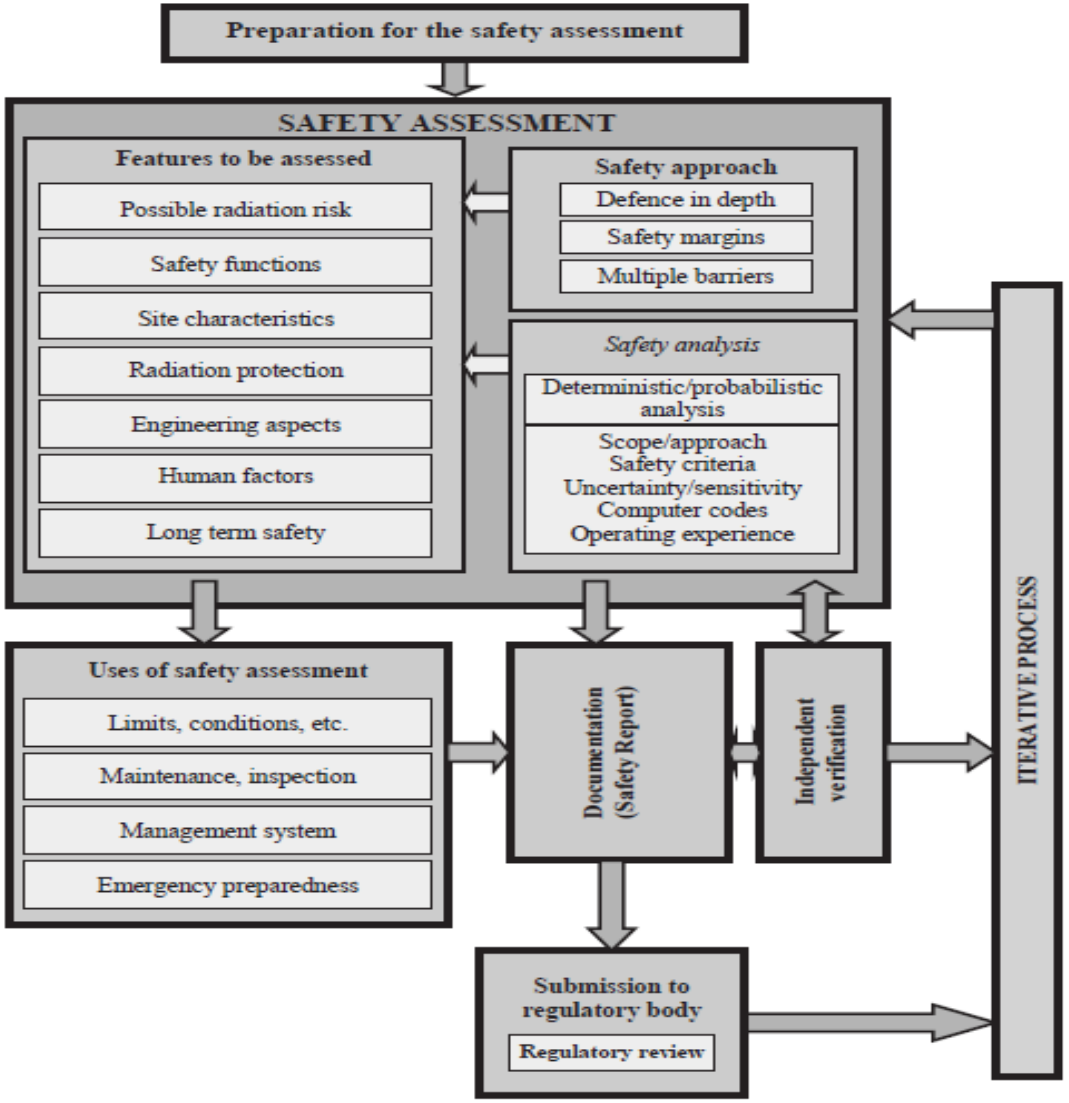


Fig. Overview of Operator's Safety Assessment Process (from GSR-p4)

(III.a) Topics Covered by Review and Assessment

- **For an example, a list of information covered in the topic of 'safety analysis' by IAEA GS-G-1.2 Appendix is:**
  - **A compilation of the safety analysis and its assumptions;**
  - **Structures, systems and components important to safety;**
  - **Limits and permitted operational states;**
  - **Anticipated operational occurrences;**
  - **Initiating events for the safety analysis (external, internal);**
  - **List of features, events and processes;**
  - **Analytical methods and computer codes used in the safety analysis and the verification and validation of such codes;**
  - **Radioactive release and radiation exposures;**
  - **The operator's safety criteria (single failure criteria, …).**

(III.b) Documentation Submitted by the Operator

- **Responsibilities of the operator**
  - At each stage of the authorization process the operator should be required to demonstrate that the facility can be sited, designed, constructed, commissioned, operated, decommissioned or closed without giving rise to undue radiological risks to workers, the public and the environment.
  - The totality of the documentation which the operator uses in making this demonstration, some of which may not be in the initial formal submission, should cover all appropriate topics, depending on the stage of the authorization process and the nature of the facility.

(III.b) Documentation Submitted by the Operator

- **Records of the operator's submissions**
  - 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.

(III.b) Documentation submitted by the operator

- **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 right if individuals to privacy, in accordance with national law and regulations.
  - Such confidential information should be made available as necessary without restriction, to the regulatory body. Those to whom such information is entrusted should be advised of its confidential nature and should be obliged, consistently with national law and regulations, to protect its confidentiality.

(III.c) Bases for Review and Assessment

- **Safety objectives and requirements**
  - **At all stages of the authorization process, the regulatory body should have a clear understanding of the safety objectives and regulatory requirements that will be used in the review and assessment. The safety objectives and regulatory requirements should be communicated to the operator for guidance in preparing its documentation.**
  - **Safety objectives and regulatory requirements should specify safety goals for levels of performance in the protection to be achieved at the facility. The regulatory body should refrain from prescribing specific designs, safety management systems or operational procedures.**

(III.c) Bases for Review and Assessment

- **Safety objectives and requirements (cont'd)**
  - The regulatory body may develop safety objectives and requirements itself, or it may adopt those issued by international organizations or by regulatory bodies in other States with a good understanding of their bases.
  - The safety objectives and requirements should cover:
    - Application of the principle of defence in depth;
    - Meeting the single failure criterion for safety systems;
    - Requirements for redundancy, diversity and separation;
    - Dose limits and dose constrains;
    - Emergency preparedness; etc.

(III.c) Bases for Review and Assessment

- **Regulations and guides**
  - **Regulations (mandatory) should be developed on a generic basis or on the basis of facility type and should provide for more detailed requirements to be incorporated into individual authorizations.**
  - **Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator.**
  - **In some instance, the operator may propose an alternative approach to that suggested in a guide to achieving a safety objectives.**

➔ The operator should be required to demonstrate that its proposed approach will provide an equivalent level of safety.

(III.c) Bases for Review and Assessment

- **Comparison with regulations, guides and industrial standards**
  - **The regulatory body should establish which requirements, regulations, guides and industrial standards are applicable to the facility and should determine the requirements to be placed on the operator.**
- **Reference (generic) submissions**
  - **If submissions for a particular type of facility may be repeated many times, it may be appropriate for an operator to provide a submission for a 'reference facility' or a 'generic facility'.**
  - **The authorization should be limited to the generic design because of some missing information (siting related, etc.). Therefore, supplementary submission by the operator should follow for the full authorization of the specific facility.**

(III.d) Verification of the Safety Analysis

- **General**
  - The safety analysis should cover both normal and fault conditions in order to demonstrate that the safety of the facility meets the safety objectives and requirements.
  - It should be the responsibility of the regulatory body to determine whether these submissions have provided a sufficiently complete, detailed and accurate demonstration.
  - The general aim of the regulatory review of the safety analysis report, whether deterministic or probabilistic, is to verify that the safety measures provide sufficient capability of protection against the release of radioactive materials.

(III.d) Verification of the Safety Analysis

- **Structures, systems and components (SSCs)**
  - The review and assessment should ensure that the operator has used the safety analysis to determine the requirements on the SSCs and that the requirements will be met by the equipment and in operational procedures.
  - Specific features that should be subject to review and assessments include:
    - Safety functions and classification of SSCs;
    - Quality of engineered features;
    - Control of the facility in normal or fault condition; and
    - Quality assurance covering SSCs and operational aspects.

(III.d) Verification of the Safety Analysis

- **Operation and management**
  - The operator should demonstrate by documentation that there is an effective safety management system in place which gives nuclear safety the highest priority. Specific aspects covered by regulatory review include the following:
    - The operator's safety policy and commitment for safety;
    - The operator's organization that can implement the policy;
    - The systems to ensure adequate performance of work;
    - The systems to review and audit the performance of work;
  - The review and assessment should cover all aspects of the operator's managerial and organizational procedures and systems which have a bearing on nuclear safety.

(III.d) Verification of the Safety Analysis

- **Radiological consequences in normal conditions**
  - **The assessment of normal operation is directed towards the determination of occupational radiation doses and radioactive discharges. Factors that influence radiological consequences for workers, the public and the environment in normal operation includes:**
    - **Sources and inventory;**
    - **Occupational radiation protection programme;**
    - **Radiation protection of the public, with all pathways of exposure taken into account;**
    - **Radioactive waste management;**
    - **Discharge, dilution and dispersion of radioactive effluents.**

(III.d) Verification of the Safety Analysis

- **Safety analysis of fault conditions**
  - As the potential radiological consequences from fault conditions may be much more severe, the major part of the review and assessment effort should be directed to the safety analysis of fault conditions. Safety analysis can be considered to consist of two major steps:
    - Identification of postulated initiating events(PIEs) and their frequencies;
    - Evaluation of how these PIEs develop and their consequences.

(III.d) Verification of the Safety Analysis

- **Identification of PIEs**
  - PIEs can be grouped in various ways. One commonly used method is to separate them into:
    - external hazards (seismic event, aircraft crash, etc.)
    - Internal faults (mechanical or electrical failures, etc.)
    - Internal hazards (fire, spillage, etc.)
  - It is usual to classify the PIEs relating to internal faults according to the initiating frequencies of the PIEs and their potential consequences. The purpose of such a classification is to help decide on the type and level of analysis that should be undertaken.

(III.d) Verification of the Safety Analysis

- **Analysis of PIEs**
  - The regulatory body should determine the type of analytical considerations and assumptions that will apply in its review and assessment of the operator's analysis, and should check whether these have been taken into account.
  - Regulatory review and assessment should include a check that any data, modeling or computer codes used in making calculations in relation to either the performance of equipment under the conditions indicated by the analysis or any radiological consequences are based on sufficiently well founded knowledge and understanding, and that an adequate degree of conservatism has been included.

(III.d) Verification of the Safety Analysis

- **Analysis of PIEs (cont'd)**
  - As a complement to the deterministic approach, the regulatory body should require an evaluation of the risks arising from the facility. A common method providing such an evaluation is probabilistic safety assessment(PSA).
  - The regulatory body should review and assess the PSA in order to gain confidence that it has been carried out according to an acceptable standard so that the results can be used as input to the regulatory decision making process.
  - The insights gained from PSA should be considered with those from other analyses in making a decision on the acceptability of the safety of a facility.

(III.e) Inspection for Review and Assessment

- **Regulatory inspections for review and assessment**
  - **Although a fundamental feature of the review and assessment process is the documentary verification of the information provided by the operator, the regulatory body should also verify claims in the documentation by inspections of the facility.**
  - **The regulatory body should have the right to visit, or to designate others to visit on their behalf, the operator's site and, if necessary, to visit contractors' establishments with the knowledge of the operator. Such visits may provide a good opportunity to access the adequacy and effectiveness of the management systems of the operator, the manufacturers and the suppliers.**

(III.f) Bases for Regulatory Decision

- **Regulatory decision after the review and assessment**
  - **At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either:**
    - **The granting of an authorization which, if appropriate, imposes conditions or limitations; or**
    - **The refusal of such an authorization.**
  - **The regulatory body should recognize the bases for such decisions including:**
    - **The extent to which the safety objectives and regulatory requirements have been met;**
    - **The acceptability on the depth and detail of submissions;**
    - **The confidence in the conclusions reached by the analysis.**

(III.g) Documentation of Review and Assessment

- **Documentation of the review and assessment by the regulatory body**
  - **The documentation should summarize the review and assessment performed and should present a clear conclusion about the safety of the facility authorized. Typically, the following topics should be covered:**
    - **Reference to the documentation submitted by the operator;**
    - **The bases for the evaluation;**
    - **The evaluation performed;**
    - **Comparison with requirements, regulations and guides;**
    - **Comparison with another similar (reference) facility;**
    - **Independent analysis performed by the regulatory body;**
    - **Conclusions with respect to safety;**
    - **Additional requirements to be fulfilled by the operator.**

Summary

Summary

- **Part I. Introduction**
  - **IAEA safety standards and guided related to the development of the review and assessment process are introduced.**
  - **The review and assessment process should be developed, implemented and continuously improved as a part of a management system of the regulatory body.**
  - **The process is carried out under controlled condition by using management system documents like procedures.**

Summary

- **Part II. Development of the Process**
  - **Key elements that constitute the review and assessment process are explained.**
  - **The details of the process, including objectives, responsibilities, work flow and administrative control, resource control, and monitoring and audit, should be identified, established, and described in the MS procedures for the review and assessment.**

Summary

- **Part III. Performance of the Process**
  - **General aspects and information that should be carefully considered to perform effectively and efficiently the review and assessment process, are discussed.**
  - **These considerations should be appropriately incorporated in the procedures for the process or in the detailed technical guidance on specific topics of the review and assessment.**