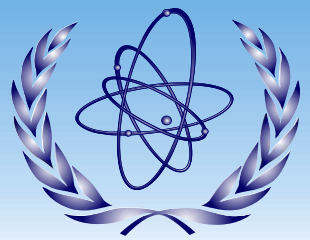

International Atomic Energy Agency

Safety Review and Assessment by the Regulatory Body

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Regulatory Activities Section

Nuclear Safety and Security Department

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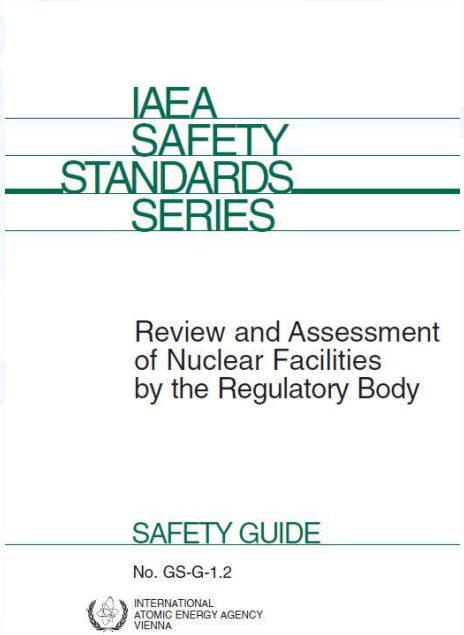
- Responsibilities of the Regulatory Body regarding review and assessment
- Objectives of the regulatory review and assessment
- Management of review and assessment
- Verification of the safety analysis



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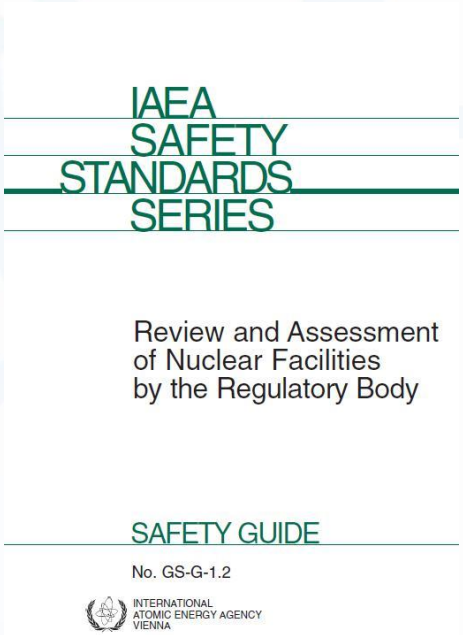


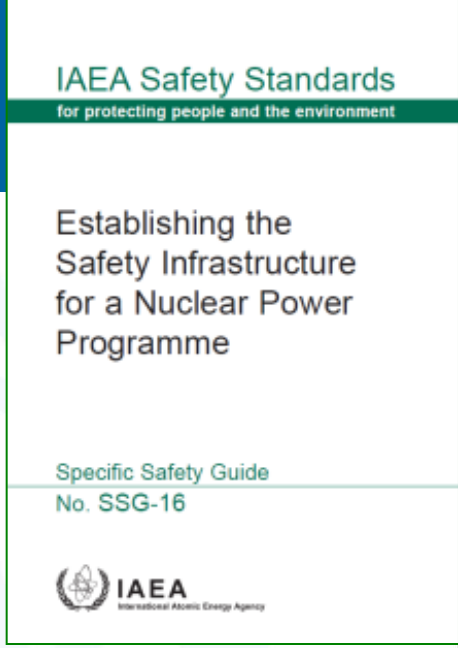
Responsibility for Review and Assessment

- **GSR Part1- 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.

Regulatory Body SSG-16



Action 38.

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

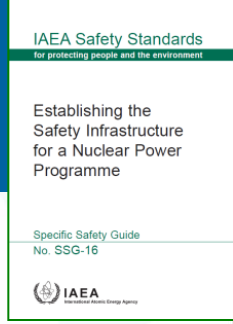
Action 84.

The regulatory body should review and assess the operating organization's programme on safety management.

Action 97.

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

Regulatory Body SSG-16



Action 164.

The regulatory body 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.

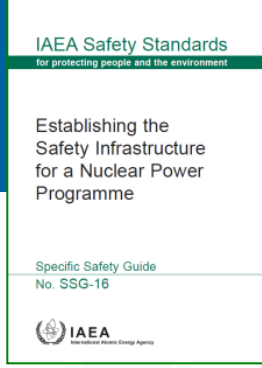
Action 182.

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.

Regulatory Body SSG-16



Action 111.

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

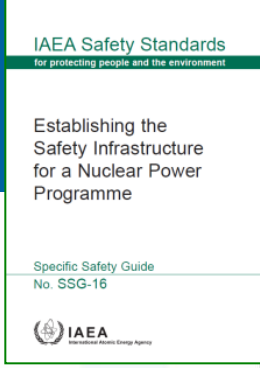
Action 115.

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.

Regulatory Body 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.

- Responsibilities of the Regulatory Body regarding review and assessment
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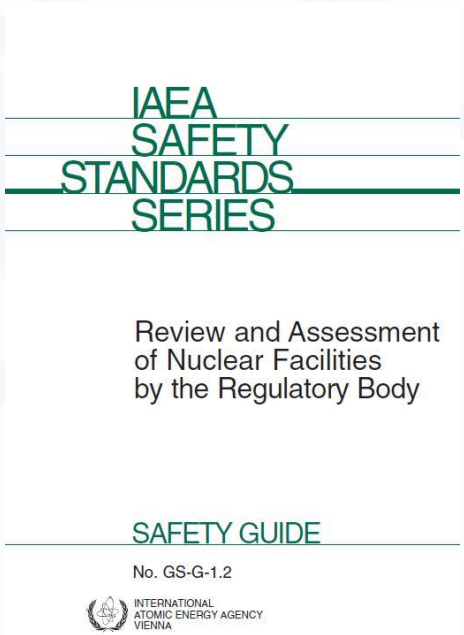
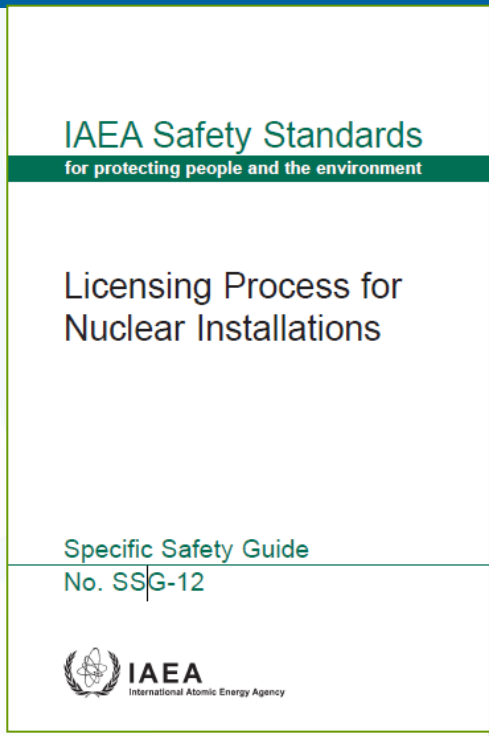


Objectives of the regulatory review and assessment

The basic objective of the review and assessment is to determine whether the operator's submissions demonstrate that the facility complies throughout its life cycle with the safety objectives, safety principles and safety criteria stipulated or approved by the regulatory body.

Stages of the authorization process subjected to the review and assessment by the regulatory body

- The site evaluation
- Design, manufacture and installation/construction
- Commissioning
- Operation
- Decommissioning & Release from regulatory control



Objectives of the regulatory review and assessment

The specific objectives of the review and assessment are to determine whether

- ✓ the information contained in the operator's submissions is sufficient to enable verification of compliance with regulatory requirements;
- ✓ the applicant has the ability and resources to discharge its obligations;
- ✓ the site chosen is suitable for the proposed facility, account being taken of the interaction between the site and the facility;
- ✓ proposals and commitments of the applicant in respect of design, construction, installation, commissioning, operation and decommissioning meet the relevant regulatory requirements;
- ✓ the commissioning test programme is complete and contains a well defined set of operational limits, test acceptance criteria, conditions and procedures;
- ✓ the operational limits and conditions are consistent with the regulatory requirements, the operational characteristics of the facility, and the state of knowledge and operational experience;
- ✓ ……, etc.

Relevant IAEA Safety Guides

More specific and detailed guidance regarding the documents and information should be submitted by 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) Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body GS-G-1.3

4) Format and Content of the Safety Analysis Report for Nuclear Power Plants GS-G-4.1

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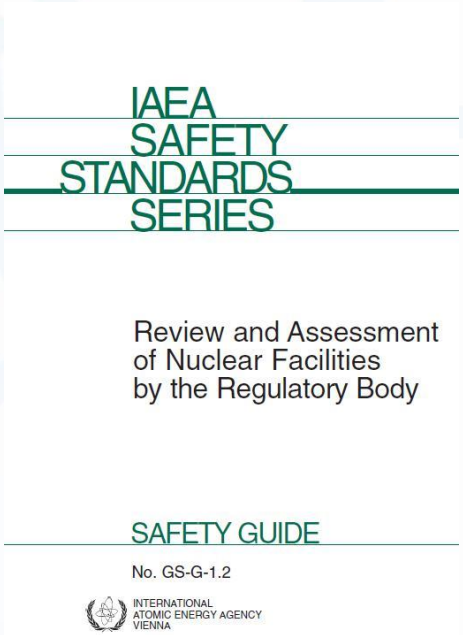


Management of review and assessment

Managerial responsibilities to be assigned to a single individual or organizational unit:

- ✓Planning and directing the review and assessment process;
- ✓Preparing the procedures to be followed in accordance with the management system;
- ✓Keeping a log to record the name of the sender and that of the recipient for all documents sent or received; the follow-up action necessary and the outcome of this action;
- ✓Monitoring the progress of documents submitted by the operator and the progress of the review and assessment process against the tentative programme agreed by the licensee and the regulatory body (if there is such a programme);

Review and assessment plan

The plan should cover:

- Definition of the scope of the review and assessment process (performance of a step by step review and assessment procedure to determine whether the applicable safety objectives and regulatory requirements have been met for each aspect or topic);
- Specification of the purpose and technical bases for the review and assessment process (these could be considered acceptance criteria);
- Identification of the additional information necessary for the review and assessment;
- Identification of resources to be used;
- Decisions on the acceptability of the operator's safety arguments or the need for further submissions.

Organization and Resources

- Enough resources should be provided to the regulatory body for an effective conduct of regulatory review and assessment.
- More specific and detailed guidance regarding the organization and expertise necessary for an effective conduct of regulatory review and assessment are provided in the IAEA Safety Guide, “Organization and Staffing of the Regulatory Body for Nuclear Facilities GS-G-1.1”.
- Consultants and advisory bodies can be used as external support during the regulatory review and assessment.

  However, the regulatory body should have sufficient number of permanent staff with the competence to manage the work of external consultants and to evaluate the quality and results of their work. The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body’s responsibility for making decisions and recommendations shall not be delegated.

Records of the Regulatory Body'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.

✓This documentation should also summarize the review and assessment performed and should present a clear conclusion about the safety of the activity authorized.

✓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.

✓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.

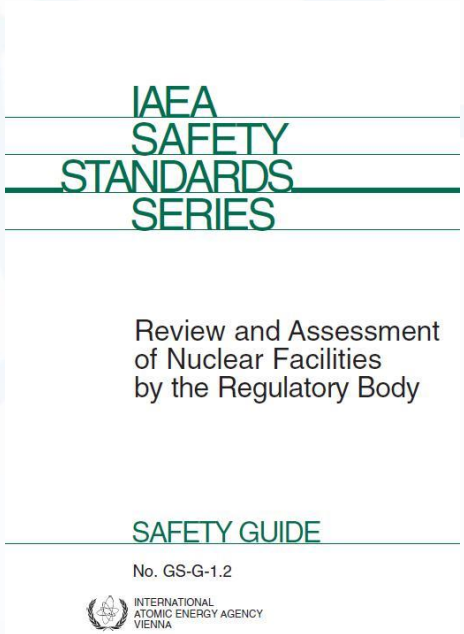
Monitoring of the review and assessment process

- 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.

- This system should cover, among other things:

- Regulations and guides;
- Procedures for assessment within the regulatory body;
- Procedures for contact with the operator;
- Availability of suitable staff for review and assessment;
- Procedures for using consultants and advisory committees in the process;
- Procedures for commissioning and evaluating research initiated by the RB;
- Records of documentation;
- Production, recording and dissemination of the results of reviews and assessments.

- Responsibilities of the Regulatory Body regarding review and assessment
- Objectives of the regulatory review and assessment
- Management of review and assessment
- **Verification of the safety analysis**



Verification of the safety analysis

- It should be the responsibility of the regulatory body to determine whether the submissions of the licensee have provided a sufficiently complete, detailed and accurate demonstration of this.
- The general aim of the regulatory review of the safety analysis, whether deterministic or probabilistic, is to verify that the safety measures are sufficient to provide adequate assurance for each identified safety barrier.
- The regulatory body may find it useful to perform its own analyses (audit calculations, etc.) or research. Any input of this nature by the regulatory body should in no way compromise or diminish the operator's responsibility for the safety of the facility.

Verification of the safety analysis

Main verification areas:

- Structures, systems and components
- Organization and management of the operator/licensee
- Radiological consequences in normal conditions
- Safety analysis of fault conditions
- Identification of PIEs
- Analysis of PIEs
- Operational safety performance

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.

…Thank you for your attention

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International Atomic Energy Agency