

DOCUMENTATION FOR REVIEW AND ASSESSMENT

Venue, Date

Name of the Expert
Regulatory Activities Section
Nuclear Safety and Security Department



IAEA

International Atomic Energy Agency

Learning Objectives

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

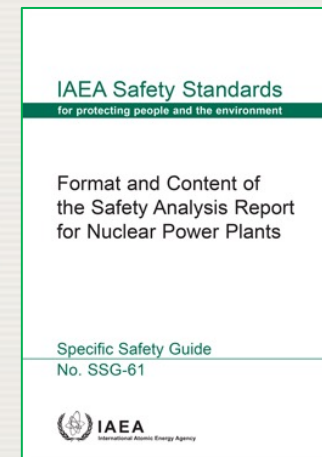
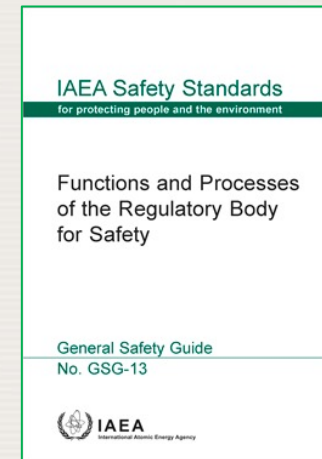
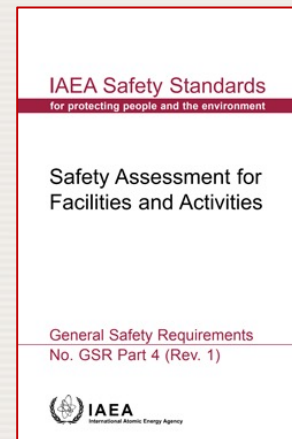
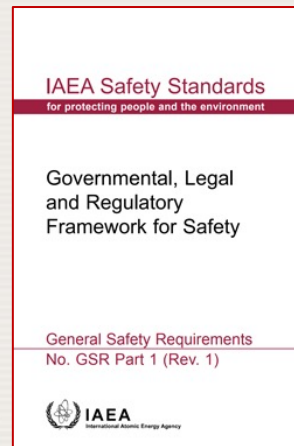
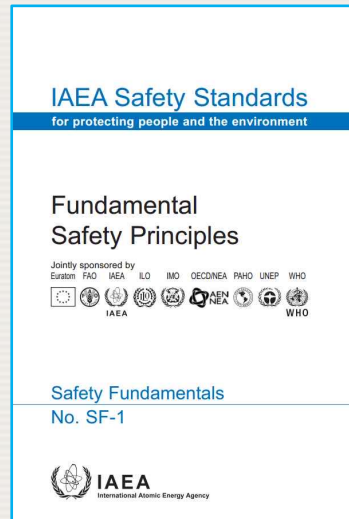
- Relevant IAEA Standards describing documents related to review and assessment,
- Documents produced by the applicant related to Review and Assessment, and
- Documents of regulatory body related to review and assessment.

Content

- Reference IAEA Safety Standards
- Documents produced by the Applicant/Licensee
- Documents produced by the Regulatory Body

- **Reference IAEA Safety Standards**
- Documents produced by the Applicant/Licensee
- Documents produced by the Regulatory Body

Reference IAEA Safety Standards

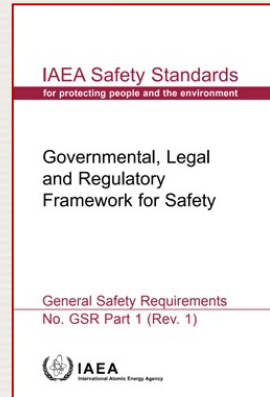


Reference IAEA Safety Standards

The Need for Safety Analysis Reports

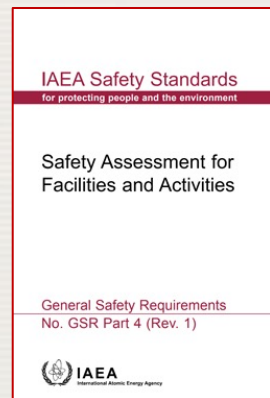
GSR Part 1, Requirement 24: Demonstration of safety for the authorization

“Prior to granting of an authorization, the applicant shall submit a safety assessment associated with facilities and activities in line with the guidance issued by the regulatory body on format and content of the documents to be submitted by the applicant for an authorization.”



GSR Part 4, Requirement 20: Documentation of safety report

“The results and findings of safety assessment shall be documented.”

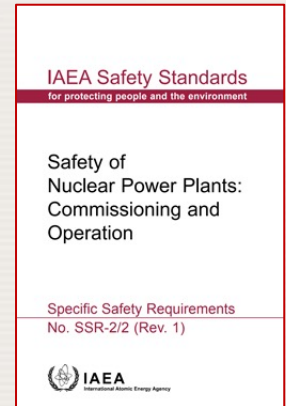


Reference IAEA Safety Standards

The Need for Safety Analysis Reports

SSR 2/2, Requirement 10: Safety Assessment

*“Comprehensive **deterministic safety assessments and probabilistic safety assessments** shall be carried out throughout the design process for a nuclear power plant to ensure that all safety requirements on the design of the plant are met throughout all stages of the lifetime of the plant, and to confirm that the design, as delivered, meets requirements for manufacture and for construction, and as built, as operated and as modified.”*



- Reference IAEA Safety Standards
- **Documents produced by the Applicant**
- Documents produced by the Regulatory Body

Documents Produced by the Applicant

“SSG-12, 2.38 (a) *The applicant or licensee should prepare and submit a comprehensive application to the regulatory body that demonstrates that priority is given to safety; that is, that the level of safety is as high as reasonably achievable and that safety will be maintained at the site for the entire lifetime of the nuclear installation.*”

- Various types of **documents** will need to be prepared by the applicant/licensee in discharging its responsibilities **with respect to the safety** of the facility or the activity.
- Some of these documents will also form **part of the formal submission** to the regulatory body for review and assessment.

Documents Produced by the Applicant

- Other documents to keep the regulatory body fully informed of the conditions prevailing at the facility or for the activity include **routine reports** periodically submitted to the regulatory body, and **specific reports of events**.
- Another type of documentation is **internal reports** that the applicant/licensee produces, which should be made available upon request to the regulatory body. These include reports such as: dose records, quality records from contractors, internal audits.

Documents Produced by the Applicant

Examples of documents to be submitted to the regulatory body by the Applicant/Licensee;

- A descriptive construction report
- A site evaluation report
- Report on the environmental impact assessment
- The management and organization
- A preliminary safety analysis report (PSAR)
- Commissioning programmes and reports
- Physical protection plans
- Fire protection plans
- Maintenance and periodic testing programmes
- Emergency preparedness and response plans

Documents Produced by the Applicant

GSG-13

- A well-engineered facility or activity will not achieve the **required level of safety** if it is not properly built, operated and managed.
- Review and assessment by the regulatory body should therefore include consideration of the applicant/licensee's organization, management, procedures and safety culture , which may affect the operation of the facility or conduct of the activity.
- The applicant/licensee should be able **to demonstrate** that there is a documented and effective **management system** in place that gives safety the highest priority.

Documents Produced by the Applicant

GSG-13

The documentation submitted should cover all aspects of the applicant/licensee's management and organizational procedures and systems that have a bearing on safety, such as:

- The development of operational limits and conditions;
- The production and revision of safety documentation;
- The planning and monitoring of maintenance, inspection and testing;
- Control of contractors (see GSG 13 Appendix III) ;
- The procedures for the control and justification of changes to the applicant/licensee's management and organizational procedures and systems that could have an impact on safety;
- Feedback of operating experience.

Documents Produced by the Applicant

GSG-13

The information to be provided by the applicant/licensee is set out in Appendix III, under the headings:

- The Physical Nature of the Facility and its Environment
- Infrastructure Aspects
- Safety Analysis
- The applicant/licencee and the Management System
- Operational Procedures
- Equipment Qualification
- Management of Ageing
- Applicant/licencee's Safety Performance
- Experience from Other Facilities and Research Findings

Documents Produced by the Applicant

- One of the main documents that need to be submitted by the applicant is the **Safety Analyses Report (SAR)** of the facility.
- SAR may differ depending on type of the facility, but the purpose of it remains the same, demonstrating that the facility is designed to appropriate safety standards and the facility can be operated safely.
- SAR should reflect the current condition of the facility, i.e., if the facility is already built, it should contain as built information.
- Guidance on format and content of a SAR for NPP is given in **SSG 61**
- Detailed guidance is also provided for contents of each chapter of a SAR
- The regulatory body should determine the expected format and content of SAR and communicate with the applicant in advance.

Documents Produced by the Applicant

- **Periodic or progress reporting** may be required from the applicant/licencee at set times or upon the completion of specific activities over the lifetime of the facility, which may include;
 - Progress of site studies and/or construction,
 - Results of the pre-operational and operational environmental monitoring programmes, radiation protection programme, etc.,
 - Result of commissioning tests,
 - Periodic operation reports,
 - Operational records of in-service inspections, personnel training, personnel radiation monitoring, radioactive waste management, effluent discharges, etc.
 - Records and reports of periodic safety reviews

Documents Produced by the Applicant

- The regulatory body should require the applicant reporting of any **event considered significant to safety** which includes the event, the findings of the investigation and proposals for corrective action
- The regulatory body should also require the applicant reporting of any **changes and modifications** in the design or **major non-conformances** that may affect safety, or **major design deficiencies** identified during commissioning or operation.

- Reference IAEA Safety Standards
- Documents produced by the Applicant/Operating Organization
- **Documents produced by the Regulatory Body**

Documents Produced by the Regulatory Body

- The documents produced by the regulatory body as part of review and assessment form the important basis on which the facility is authorized.
- Documents produced by the Regulatory Body may be categorized according to the main functions of the regulatory body described in GSR Part - 1 Rev 1, including review and assessment and inspections.
- These documents should be maintained by the regulatory body under its **management system** and revised when the decision basis changes in response to changes in the facility.

Documents Produced by the Regulatory Body

- The Management System documentation will include procedures for review and assessment. Some of these procedures are:
 - Procedures for review and assessment;
 - Procedures for interaction with the operator;
 - Procedures for using consultants and advisory committees in the process;
 - Procedures for control of records and documentation so that they are stored in an easily retrievable form;
 - Production, recording and dissemination of the results of reviews and assessments
- The **records and reports of the review and assessment**, produced by various experts from the regulatory body and external experts if applicable, amount to the major part of the documentation of regulatory body regarding authorization of facilities.

Documents Produced by the Regulatory Body

- **Reviewers** need to be required to **record and report the results** of their review and assessment in a formal manner. This reports may be in the form of separate **reviewer reports** or **draft sections of the Safety Evaluation Report**, depending on the approach of the regulatory body.
- In either case, guidance on the **format and content of reporting**, including matters such as language to be used and protection of sensitive information, need to be provided to the reviewers to ensure the consistency among the information documented.
- In case of separate **reviewer reports**, the format of the reviewer report needs to facilitate drafting of the safety evaluation report.
- **Reviewer reports** need to go through an approval mechanism suitable for the system established for the review and assessment by the regulatory body.

Documents Produced by the Regulatory Body

- External technical support **may** directly **contribute to** drafting the **reviewer reports** under the supervision of the respective reviewers, or they **may provide standalone reports** which are considered as an input to individual reviewer reports.
- The content of the reviewer reports should be in parallel with the SER, content of which will be introduced later, only in a limited scope on the subject of the review and assessment.
- The basis for the regulatory decisions should be recorded and documented in an appropriate form, which is usually the SER.
- The regulatory body has to maintain its **ultimate responsibility** for the development and approval of the safety evaluation report.

Documents Produced by the Regulatory Body

- It should be possible to access the **bases of previous decisions** so as to achieve consistency and to facilitate any reassessment made necessary by new information.
- **The SER highlights the** safety objectives and requirements laid out by the regulatory body along with its **findings** of whether the information submitted by the applicant, including RAI responses, is sufficient to demonstrate compliance with the requirements and to demonstrate the safety of the facility.
- Additionally, the SER identifies **open issues** that require later follow-up as well as any proposed **licence conditions**.
- The SER may also include issues that relate to other governmental or regulatory bodies on aspects such as emergency preparedness, nuclear security, environmental protection, etc..

Documents Produced by the Regulatory Body

- The **main inputs** of the SER are the **reviewer findings**, either in reviewer report form or in the draft SER sections, and the review findings of the external technical support.
- The type of SER to be **produced for the regulatory decision**, their format and content will be decided considering the national legal and regulatory framework, particularly the decision-making process and regulatory approach being followed.
- In most of the member states, the SER follows the structure of the application documentation, particularly safety analysis report, by containing the same chapters.

Documents Produced by the Regulatory Body

- The SER need to be complemented with an **executive summary**, to be reviewed for consistency, integrity and quality, and to be approved by the proper management prior to the submission to the decision making makers.
- The SER mainly addresses:
 - Documents submitted by the applicant;
 - Basis for the review and assessment;
 - The review and assessment performed;
 - Comparison with reference plant, if applicable;
 - Independent confirmatory calculations, analysis and tests by external technical support or regulatory body team itself;
 - Conclusion with respect to demonstration of safety, and
 - Additional requirements and conditions to be met by the applicant after the authorization.

Documents Produced by the Regulatory Body

- Depending on the national regulatory system, the regulatory body may consider **communicating the SER with the applicant and/or public** prior to final decision making. In some cases, applicant and/or public hearing/consultation(s) is stipulated in national administrative regulations.
- In addition, consideration needs to be given to drafting **the licence and the licence conditions** which is an important legal document for licensing process, equivalent to a regulation.
- **A formal decision on granting the licence** needs to be taken by the proper authority in accordance with the nuclear legislation and the records of the decision are kept.

Thank you for your
kind attention!

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