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No. 125

Planning, Management and Conduct of Regulatory Safety Review and Assessment for Nuclear Power Plants

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PLANNING, MANAGEMENT AND CONDUCT OF REGULATORY SAFETY REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

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FOREWORD

In recent years, many States have expressed an interest in embarking on nuclear power programmes. A decision to use nuclear energy for electricity production is a significant undertaking for any State. It entails a commitment to the safe, secure and peaceful use of nuclear energy and necessitates the establishment of an adequate governmental, legal and regulatory framework, in addition to other necessary infrastructure elements.

IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety, addresses this issue and establishes the requirements that are considered necessary for ensuring safety while embarking on a nuclear power programme. One of the important aspects addressed in GSR Part 1 (Rev. 1) is the review and assessment of information relating to the safety of the facility by the regulatory body before it grants authorization in the form of a licence to conduct specified activities. The review and assessment process for nuclear facilities and activities is further elaborated in IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety.

This publication supplements the generic guidance provided in GSG-13 with additional information, mainly for States embarking on nuclear power programmes, on the safety review and assessment conducted during the licensing process for the construction, commissioning and operation of a nuclear power plant. Practical guidance is provided to assist the regulatory body in effectively discharging its responsibility to verify the safety of the applicant's proposals before granting a licence.

The IAEA would like to express its appreciation to all the experts who contributed to the development and review of this publication. The IAEA officer responsible for this publication was U. Bezdeguemeli of the Division of Nuclear Installation Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

As the main element of a regulatory framework, a well defined and effectively applied authorization system that encompasses review and assessment activities and inspection activities by the regulatory body is key to the achievement of the highest level of safety throughout the lifetime of a nuclear power plant.

Requirement 25 of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [1], states:

> **"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."**

Action 34 of IAEA Safety Standards Series No. SSG-16 (Rev. 1), Establishing the Safety Infrastructure for a Nuclear Power Programme [2], states:

> "**The regulatory body should plan and conduct all the required licensing and oversight activities during the licensing process, including during siting, construction, commissioning and operation, consistent with the regulatory approach that was selected.**"

Action 38 of SSG-16 (Rev. 1) [2] states that "**The regulatory body should review and assess programmes to be implemented by the operating organization, as appropriate**."

The review and assessment performed by the regulatory body is a critical appraisal of submissions made by an applicant[1], and of inspection outcomes, event reports and/or other reports relevant to the safety of the nuclear installation or relevant activities. The review and assessment process enables the regulatory body to make a decision or a series of decisions on the acceptability in terms of

[1] An applicant is any person or organization applying to a regulatory body for authorization (or approval) to undertake specified activities [3].

safety of the nuclear installation or relevant activities by evaluating compliance with the applicable regulations or safety standards. This helps to ensure that the nuclear installation is designed and will be operated safely and that it will not pose any undue risk to the radiation workers, the general public or the environment. The review and assessment process consists of evaluating the submissions made by the applicant, and other information described above, on all aspects relating to the safety of the nuclear installation or relevant activity. The review and assessment process is also an important tool for the regulatory body to enforce adherence to regulatory requirements and to ensure effective regulatory control for the safety of the nuclear installation.

Since it is one of the main functions of the regulatory body, the review and assessment process is to be well defined by the regulatory body in appropriate internal documents as part of its integrated management system (IMS). The review and assessment process is also to be taken into consideration appropriately in relevant plans and programmes, including those for building the capacities and competences of the regulatory staff needed for the effective and timely conduct of all relevant regulatory duties.

The number of States considering the introduction of nuclear power or expanding their existing nuclear power programme has increased in recent decades. Currently, approximately 30 countries have expressed the intention of developing a nuclear power programme. These countries are in various stages of preparation for embarking on a nuclear power programme, ranging from developing their nuclear safety infrastructure, conducting feasibility studies or identifying potential sites to negotiating with potential suppliers or carrying out construction activities.

Accordingly, the regulatory bodies of these countries have been carrying out the licensing of nuclear power plants or activities in preparation for it. In such cases, the regulatory body's efforts focus on defining the licensing process and on developing their organization, procedures, plans and programmes for the review and assessment and for inspections at different licensing steps, as recommended in SSG-16 (Rev. 1) [2]. One of the main areas of focus is the readiness of the regulatory body to conduct effectively and efficiently the review and assessment of the information and documents that will be submitted by the applicant at the different licensing steps.

Observations by the IAEA from peer review missions and other expert services show that many regulatory bodies of States embarking on a nuclear power programme need practical guidance on the planning, management and conduct of the review and assessment process for the licensing of a nuclear power plant. This publication supports the development and implementation by States of procedures, plans and programmes for the conduct of all relevant regulatory duties during the licensing process in an effective, efficient and timely manner.

Recommendations on the review and assessment process are provided in IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [4]. Appendix III of GSG-13 [4] provides a generic list of topics to be considered in the review and assessment process by the regulatory body throughout the lifetime of a facility or activity. IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [5], provides further recommendations on the integration of review and assessment as a core process in the IMS of the regulatory body. IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations [6], provides guidance on the licensing process for all types of nuclear installation. The recommendations and guidance provided in GSG-13 [4], GSG-12 [5] and SSG-12 [6], however, are generic for all types of nuclear installation but do not cover the practical aspects needed for the effective and efficient conduct of all necessary review and assessment work during the licensing of a nuclear power plant.

1.2. OBJECTIVE

The purpose of this publication is to provide practical and detailed information to the regulatory bodies of States, particularly those embarking on a nuclear power programme, on the planning, management and conduct of the regulatory review and assessment of documents and information submitted by an applicant for the licensing of a nuclear power plant.

This publication provides information on establishing a well defined, well organized and clear regulatory review and assessment process for the safety of nuclear power plants at different licensing steps. The information is elaborated with examples of appropriate global practices based on the experience by some States of performing regulatory review and assessment at different licensing steps. Therefore, this publication aims to supplement and elaborate the recommendations given in SSG-16 (Rev.1) [2], GSG-13 [4], GSG-12 [5] and SSG-12 [6].

Since this publication describes in detail the review and assessment process applied by a regulatory body during the licensing steps of a nuclear power plant, the information can be used by regulatory bodies to develop their relevant internal procedures and other types of internal staff guidance documents as well as relevant plans and programmes.

Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

1.3. SCOPE

This publication focuses on the regulatory review and assessment process and the aspects to be taken into consideration when planning, managing and conducting review and assessment during the licensing of nuclear power plants, particularly for the licensing of the construction, commissioning and operation stages. This publication is intended to be used by regulatory bodies and their technical support organizations (TSOs).

The information provided in this publication reflects the practices adopted by the regulatory bodies of many States in using a project management approach for review and assessment. Using such an approach, the work is carried out by a project team under the leadership of a project manager, and the project team is organized into review groups that are responsible for predefined subjects of the review and assessment process. In this way, the information can be easily adapted by regulatory bodies with different organizational structures. If these assumptions do not hold for national application, the process may be adapted into the established system of review and assessment of the State.

Review and assessment, as an important regulatory process of the IMS of the regulatory body, has the same general approach for safety and security aspects of a nuclear power plant. This guidance can therefore be applied both in general and for the safety–security interface. However, the review and assessment of nuclear security related submissions may vary in scope and nature in certain aspects, for example in terms of different organizational arrangements, the proprietary or confidential nature of the information submitted or different national arrangements for nuclear security management and response. Therefore, this publication does not cover specific aspects of nuclear security.

1.4. STRUCTURE

This publication comprises three sections and ten annexes. Section 1 introduces the publication and provides its background, scope and purpose. Section 2 presents detailed information regarding the main considerations for the preparation, planning and organization of review and assessment as well as the responsibilities of the review and assessment project team. Section 3 consists of seven subsections covering the necessary steps and the details of the review and assessment process. The annexes provide additional information and checklists as examples to support or facilitate project implementation.

2. PREPARATION FOR REVIEW AND ASSESSMENT

2.1. MAIN CONSIDERATIONS FOR REVIEW AND ASSESSMENT

The regulatory body determines a set of applicable regulations and guides to be used as the basis for the review and assessment of the application well in advance to ensure that the applicant provides relevant information with the application. Depending on the regulatory approach, this set may, in addition to national regulations and guides, include IAEA safety standards and regulations and guides from the vendor State and/or a third State that are proposed by the applicant and agreed on by the regulatory body. The regulatory body also considers vendor, international or a third State's industrial codes and standards proposed by the applicant to be used for the review and assessment, and approves, adopts or agrees to them as necessary. The regulatory body needs to be aware of potential inconsistencies in using sets of regulations or industrial codes and standards from different sources and of the time that would be needed to study, comprehend and be ready to implement them.

One of the best approaches that can be implemented by a State embarking on a nuclear power programme is to use the IAEA safety standards as the foundation, supplemented with additional acceptance criteria as appropriate. This set of regulations based on the IAEA safety standards can be complemented by more specific regulations or guides when needed.

IAEA Technical Safety Review (TSR) services[2] are available to Member States for the review of various subject areas against the relevant IAEA safety standards. These reviews may cover, for instance, the review of the national regulations against the IAEA safety standards. There is an IAEA TSR service for the review of the compliance of a proposed nuclear power plant design against the relevant IAEA safety standards. This review is considered to be a valuable contribution to assist the detailed review to be performed by the regulatory body.

For each authorization application, the regulatory body determines the documents that need to be prepared and submitted by the applicant to demonstrate the safety of the proposed nuclear power plant and relevant activities for which the authorization is requested. As stated in para. 4.34 of GSR Part 1 (Rev. 1) [1]:

> "The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make

[2] More information on TSR services is available at https://www.iaea.org/services/review-missions/tsr

available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."

Such guidance on the format and content may be based on the applicant's proposal, on IAEA safety standards or on the regulations of the vendor State. The main application document demonstrating the safety of the nuclear power plant or relevant activities is usually the safety analysis report (SAR), as described in IAEA Safety Standards Series No. SSG-61, Format and Content of the Safety Analysis Report for Nuclear Power Plants [7]. Further recommendations regarding documents to be submitted by the applicant to the regulatory body at different licensing steps are provided in SSG-12 [6], SSG-61 [7] and Ref. [8].

Additional guidance for an application can be useful for ensuring that the quality of the application meets the expectations of the regulatory body. Such guidance addresses the requirements for the approval of licence application documents, such as on the format and revision control of the documents as well as on the quality of information, including figures, drawings and references.

Since the licence application documents may contain security related or protected or proprietary information, the regulatory body establishes an appropriate system for the secure handling of such information in accordance with the relevant national legal framework. Detailed guidance regarding the handling of these documents when there is a need for external support for their review is given in appendix I of GSG-12 [5].

The regulatory body establishes and initiates formal and informal communications with the applicant at an early stage of the project to mutually share as much information as possible in accordance with the relevant national legislation. It is important for the regulatory body to define the language(s) to be used in communications (e.g. in meetings, official letters, technical documents) in accordance with the relevant national legislation or practices. Agreement on the official working language is particularly important when the languages of the vendor State and the recipient State are different. In this case, it is essential to have appropriate arrangements for translation so that the documents and information submitted by the applicant are correctly understood.

The regulatory body may also arrange a dedicated and protected information technology portal to facilitate submission of the licence application and all other relevant documents in electronic format, as well as a virtual reading room to facilitate access by regulatory body reviewers to the material referred to in but not submitted with the application. The dedicated portal could also be used for all regulatory correspondence, such as the submission of the requests for additional information (RAIs) to the applicant.

2.2. PLANNING AND ORGANIZATION FOR REVIEW AND ASSESSMENT

One of the important tasks for the regulatory body of a State embarking on a nuclear power programme is to implement a human resources development plan in the early phases of the nuclear power programme to build in-house capacity for the effective conduct of its regulatory functions over the long term. The size and composition of the regulatory body, the scope of external support used and the involvement of advisory committees will be influenced by the size, scope and maturity of the nuclear programme that the regulatory body regulates. More specific and detailed recommendations regarding the organization and expertise necessary for the effective conduct of regulatory review and assessment are provided in GSG-12 [5] and in Ref. [9].

Not all regulatory bodies might have all necessary competences available in-house, however. In this case, the regulatory body may use external TSOs or external experts inside or outside the country, when appropriate and necessary during the performance of the regulatory review and assessment and for the conduct of inspections that support the review and assessment process. In considering its future tasks and the best use of internal resources, the regulatory body will need to define which activities are to be retained in-house as core activities and which may be outsourced. Hence, the regulatory body needs at least a sufficient number of qualified staff in different technical areas to exercise the role of an 'intelligent customer' in order to retain the ability to determine and manage its requests for advice and to comprehend and act on the advice received from TSOs or external experts. The regulatory body needs an adequate number of staff qualified to specify, monitor, oversee and evaluate the work of the external technical support provider. In other words, to exercise the role of an 'intelligent customer', the regulatory body needs a sufficient number of qualified staff to:

(a) Specify the work of external technical support providers.
(b) Assess the work proposals in the bidding process and then select the most appropriate external technical support providers.
(c) Set the time frame for the completion of tasks.
(d) Provide appropriate and complete information to TSOs or external experts.
(e) Supervise work in accordance with defined procedures, and conduct a technical review of the work whenever necessary.
(f) Facilitate the interaction of external technical support providers with other relevant parties if necessary.
(g) Evaluate, understand and use the outcome provided by external technical support providers and make final regulatory decisions.

Obtaining assistance and advice from external technical support providers does not relieve the regulatory body of its assigned responsibilities. Therefore, the regulatory body needs a sufficient number of qualified staff with adequate core competences to make informed decisions. The necessary arrangements need to 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 technical support, and that the staff of the regulatory body do not inappropriately influence the outcome or advice from the TSO or the external expert.

As mentioned in Section 1.3, a primary assumption of this publication is that the regulatory body manages the review and assessment in the licensing process using a project management approach. In order to ensure its implementation, the regulatory body needs to incorporate the project management approach in its IMS. Employing a formal project management approach and the early training of the staff who will perform the review and assessment with the use of project management tools can facilitate the implementation of the process, and ensure that the goals of the review and assessment project are met in a timely manner.

Review and assessment projects need to be carefully planned, with clearly defined objectives, outcomes and timetables and the allocation of appropriate and sufficient resources. Good planning also helps staff to conduct their assigned project duties in an efficient and effective manner. The project management team develops and uses tools to estimate and monitor the progress of the review and assessment. The project management team also develops different levels of periodic progress reports for the reviewers, the steering committee, the top management[3], the applicant, interested parties and the public. In some cases, the administrative support to assist the regulatory body in planning, measuring, estimating and reporting may be outsourced to a professional project management service provider with experience in complex industrial project management. Additionally, the project plan is reviewed by the project manager periodically to check for changes that may adversely affect the plan's implementation (e.g. changes in staff, scope or schedule).

A review and assessment project has an owner, a steering committee, a project manager, review group leaders and reviewers. The project owner is one of the members of the top management of the regulatory body. The role of the project owner is to support the project manager by monitoring the project and providing the project with adequate resources. In this respect, the project owner is responsible for the approval of the project plan and its updates and for the

[3] The term 'top management' refers to the most senior decision making level of the regulatory body.

successful execution of the project. The project owner is usually the chairperson of the steering committee.

The steering committee usually consists of the internal stakeholders, such as relevant managers of the regulatory body. The role of the steering committee is to support the project manager by directing and monitoring the project, and in this respect, it is responsible for ensuring the provision of adequate resources in a timely manner to the project for its successful execution. The steering committee also reviews the project plan and its updates proposed by the project manager and discusses the challenges encountered by the review group members.

The project manager is appointed by the project owner. The project manager is responsible for drafting the project plan and for the implementation of the project in accordance with the approved plan.

One of the first tasks for the project manager, supported by the appropriate staff[4], is to draft a review and assessment project plan. For drafting the project plan, the project manager may utilize an international project management guide (e.g. Ref. [10]) that can be adopted for the management of the review and assessment project. Areas to be considered in a typical project plan are presented in Annex I. If any of those areas are already documented as a part of the IMS of the regulatory body, it is sufficient to refer to such processes in the project plan.

The project manager reports on the progress of the project to the project owner and the steering committee and maintains contact with the various participants within the regulatory body regarding issues relevant to the project. The project manager may serve as the main project management contact person for the applicant, licensee, advisory bodies, other authorities and external experts. The contact points of the regulatory body are defined in a communication protocol. This communication protocol is included in the IMS of the regulatory body or established as part of the project plan; it highlights the means of internal and external communication as well as the associated roles and responsibilities. The project plan defines the decision making process regarding the project activities if it is not already defined in the IMS of the regulatory body.

It is the responsibility of the project manager to bring any significant need for changes in and/or deviations from the project plan to the attention of the project owner and the steering committee.

The project manager may request the information necessary for establishing the work breakdown, licensing plan and schedule from the applicant in the early stages of the project. Such information may include the schedule for the design, manufacturing, construction, installation and commissioning stages of

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[4] In some States, there is a project management office or unit that standardizes the project related governance processes within the regulatory body and facilitates the sharing of resources, methodologies, tools and techniques.

the nuclear power plant and its main components; configuration baseline freeze points[5] in relation to the phases of regulatory review; planned submission of licence applications; and proposed start date for operation of the facility. The titles and descriptions of the main contents of the documents specified in the regulations and guides that are to be submitted to the regulatory body with each licence application, the document submission schedule and the estimated duration for regulatory review are communicated to the applicant. The project plan includes the review and assessment of the application for each licensing step in accordance with the regulations and guides.

Review groups consisting of a group leader and reviewers are defined in the review and assessment project plan, typically with responsibility for reviewing different topical areas. Ideally, the review groups are established in such a way as to cover the entire spectrum of the topical areas considered. It is therefore beneficial to engage multidisciplinary experts who can cover the relevant topical areas as well as the potential interfaces between them (e.g. interfaces between safety and security). Typical content of an SAR submitted for the licensing of a nuclear power plant [7] is presented in Annex II, and examples of review groups are provided in Annex III. The steering committee agrees on the participation of the staff in the review groups considering their workload in their original section or unit. A need to change the composition of the review group may arise during implementation of the project. In this case, the project manager brings this need to the attention of the steering committee for its agreement. The roles and responsibilities of a review group are defined in a review matrix (see Annex III for examples), which is part of the project plan and clearly identifies the reporting responsibilities for the review and assessment.

The project management team, consisting of the project manager and the review group leaders, is responsible for the preparatory activities, monitoring of the project, dealing with interfaces and developing solutions as cross-cutting issues are encountered.

The project management team first considers the availability of in-house expertise and tools for the review and assessment and then identifies the areas of review and assessment for which external technical support is needed. When the need is approved, the project management team initiates the procurement process to ensure that the external technical support services will be available at the necessary time. The project management team clearly defines the modes of interaction between the external technical support providers and the reviewers. It also determines in advance how the review and assessment output

[5] The application safety case is based on one single frozen configuration baseline to ensure that the plant and systems design with supporting analysis are congruent and traceable, thereby enabling a change management process.

of the external technical support providers will be used by review groups. The project manager also determines the means of information exchange between the external technical support providers and the applicant; direct communication between the two parties is not allowed. Detailed recommendations regarding the effective use of external technical support and important aspects to be taken into account when using an external technical support provider are given in appendix I of GSG-12 [5].

Each review group has a group leader responsible for the coordination of the group's activities. The reviewers report to the group leaders on tasks related to the implementation of the project. In most cases, the group leaders discuss minor issues with their line managers and maintain contact with the various stakeholders, such as TSOs, applicants or other authorities, regarding issues relevant to the project tasks in their area of responsibility. However, major issues are communicated by the main contact person of the regulatory body, as defined in the communication protocol.

The project manager, together with the other members of the project management team, plans the implementation of the project, including the effective allocation of human resources among the project activities, and develops a work schedule for the review and assessment process, which is subject to change as necessary following a formal procedure. The project schedule, which is an important part of the project plan, includes expected timings of submissions, expected duration of the review and assessment process (including RAIs), timings of the use of the external technical support providers, and the time needed for the recording and reporting of project activities and outputs. This plan is shared with reviewers and the steering committee. The schedule and the relevant parts of the project plan are shared with the external technical support providers and the applicant to help them to plan their own activities accordingly. All concerned parties are notified of any changes in the plan and the schedule.

Any inspections or site visits necessary to support the review and assessment activities are also defined in the project plan, including the scope and schedule of the inspections to be implemented, the interface of inspection activities with the project, and inputs coming from the inspection activities to be considered in the review and assessment. Regulatory inspections are usually needed prior to granting a licence to confirm that the arrangements described in the SAR (e.g. an IMS, relevant quality assurance plans and competences) are in place.

The results of inspections conducted at earlier lifetime stages, such as site evaluation, construction and commissioning, may provide important inputs to the decision by the regulatory body to grant a licence and are appropriately considered in the review and assessment.

The project management team establishes a decision making mechanism within the review groups, laying out the means and criteria for escalating issues

from the reviewer to the decision making levels using a graded approach. This mechanism may include the establishment of a safety committee consisting of senior safety experts of the regulatory body to obtain advice on safety significant technical issues. The safety committee may have the authority to bring critical issues to the attention of the top management of the regulatory body or the steering committee if deemed necessary. The safety committee may also be involved in the resolution of professional disagreements between reviewers, group leaders and the project manager. This type of decision making involves the relevant reviewer, the group leader, the project manager and others who need to be part of the decision making process. A formal procedure for the resolution of differing professional opinions helps to foster appropriate decision making. It is important for safety that a mechanism exists that enables dissenting opinions to be heard, duly considered and also appropriately recorded before a final decision is made.

Differences in opinion can also arise between the reviewers in the regulatory body and the applicant's staff concerning the acceptability of a part of the application. To address such situations, it is desirable to create a mechanism for escalating disputed issues to the attention of the management of each organization for its consideration. Ultimately, the regulatory body makes the final decision on the acceptability of the application.

2.3. OTHER CONSIDERATIONS FOR REVIEW AND ASSESSMENT

The project manager ensures that all necessary mechanisms have been established before the review and assessment process commences, either by referencing the relevant documents of the IMS of the regulatory body or by describing the mechanisms in detail within the project plan. The project manager provides for the necessary arrangements to ensure that the project team can fulfil its responsibilities in an effective and timely manner. These arrangements might include the provision of any additional external technical support needed by the reviewers for certain activities.

The project management team provides guidance for the reviewers in advance, which describes the scope of the review and assessment and the procedure to be followed for the conduct of the review and assessment. The guidance defines any interfaces between review sections that the reviewers need to consider, and specifies the outputs and the format of the safety evaluation reports (SERs) (see also Sections 3.2 and 3.6).

The project management team establishes a mechanism to ensure that the regulatory review and assessment process thoroughly covers both the applicable regulatory requirements and the information provided in the application documents. All application documents need to be reviewed and assessed by the

project team with respect to all requirements laid out in the regulatory documents previously determined as the basis for the review and assessment. Utilizing an appropriate database of the applicable regulatory requirements facilitates the monitoring of progress in the review and assessment process.

Since a considerable amount of information will be exchanged during the review and assessment between the applicant, the regulatory body and the TSO, the effective management of documents and records by all parties is essential. A secure electronic file sharing platform with remote access by the applicant, the regulatory body and external technical support providers can facilitate document and information transfer. In this case, to ensure that the official records are complete, a solution to the issue of electronic validation of documents for official recognition needs to be established; alternatively, hard copies of documents submitted through official channels to the regulatory body are to be retained.

It is good practice to ensure that communications between the applicant and the regulatory body are conducted in accordance with an agreed communication protocol and recorded in formal correspondence. Nevertheless, informal interactions such as topical meetings between the applicant's staff and their counterparts in the regulatory body can facilitate mutual understanding and the efficient resolution of issues. Therefore, these also need to be addressed in the communication protocol.

As the review groups conduct their work, they may discover that certain topics require additional explanation or information before a finding can be reached. These topics are flagged as issues for resolution. A categorization system and a screening and approval mechanism for issues provide the project manager with a tool to ensure consistency and clarity of the articulation of issues. The project management team establishes criteria for the categorization of the issues using a graded approach. An example of issue categories is given in Annex IV.

A mechanism is needed to document and track RAIs from the applicant to resolve issues. It is the task of the reviewer to follow up on the response of the applicant to the request, to review and assess the given response, and to conclude the issue officially in accordance with the process defined in the project plan or in the IMS of the regulatory body.

The project manager establishes mechanisms to monitor and report to stakeholders, as applicable, on the progress of the review and assessment process, on the activities of reviewers and on compliance with written procedures. Useful metrics for progress reporting include the percentage of SAR sections under review and/or completed and the number of RAIs raised, responded to and closed.

The main output of the review and assessment process is an SER prepared as a basis for the final decision on the application. The reviewers are responsible for completing the tasks assigned to them within the time stated in the task assignments and for reporting the results of their review and assessment

according to the guidelines specified in the project plan. The review group leaders then prepare their parts of the SER and include the input provided by the TSO. Finally, the project manager compiles the SER to be used as the basis for the decision regarding the authorization.

The use of standard forms for recording activities (e.g. task assignments, minutes of meetings, RAIs) or templates for reporting documents (e.g. reviewer reports, SERs), as applicable, facilitates the management of the review and assessment process. Therefore, all records and reports are prepared using appropriate forms and templates and are checked for grammatical and typographical errors to ensure quality.

For better management of the review and assessment process, it is helpful to use a structured coding system for the application documents, task assignments, RAIs, records and reports to be produced by the members of the project team (e.g. reviewers, group leaders, project manager).

The project manager coordinates the review and assessment activities according to a procedure and follows a work flow chart, which is part of the project plan. The IMS of the regulatory body may provide a flow chart for the review and assessment process. A flow chart of the review and assessment process presented in this publication is provided as an example in Annex V. The project manager also coordinates the review and assessment by external technical support providers and ensures that their activities can be integrated into the review and assessment conducted by the regulatory body, with the assistance of the review group leaders.

The steering committee conducts regular meetings with the project management team to monitor the progress of assigned activities and to understand the difficulties in the implementation of the process. The outcomes of these meetings are documented to monitor the progress of actions to be taken by relevant individuals and/or departments.

The review and assessment process may be assessed periodically by the project management team during its implementation. The regulatory body continually improves the process by diverse means, for example through self-assessment and independent assessment results, management review, feedback mechanisms, non-conformance control, and corrective and preventive actions.

3. REVIEW AND ASSESSMENT PROCESS

3.1. ACCEPTANCE CHECK OF THE APPLICATION

When an application for the licensing of a nuclear power plant has been submitted to the regulatory body, it is officially provided to the assigned project manager in accordance with the defined procedure in the IMS of the regulatory body. The project manager assigns a team to check whether all the necessary application documents have been submitted, and keeps record of the outcome of this check. Examples of documents to be submitted to the regulatory body for any stage of the licensing of a nuclear power plant are presented in SSG-12 [6].

The purpose of the acceptance check is to ensure that the submission contains enough information to initiate the review and assessment process and that it is of adequate quality in accordance with the relevant guidelines. Therefore, at this stage, the team focuses on determining whether resubmission or significant additional information is necessary; it does not evaluate the full sufficiency and accuracy of the information provided by the applicant. The project management team may provide checklists to the reviewers to facilitate the conduct of this acceptance check. Examples of such checklists are provided in Annex VI.

The findings of this acceptance check are recorded and discussed with the project management team as appropriate. Some of these findings (e.g. use of a unit system different from that requested by the regulatory body, illegible tables, figures or charts) may be used as an input to the review and assessment process and for raising RAIs after the process starts.

The results of the acceptance check are reported to the steering committee and top management of the regulatory body, as appropriate. The team advises on whether the application is sufficient to initiate the review and assessment process, noting any missing sections that the applicant has still to submit, or whether a resubmission with a revised version of the application documents is necessary.

If the submission is of adequate quality and contains enough information to initiate the review and assessment process, the regulatory body officially notifies the applicant of the acceptance of the application. In addition, the acceptance notification to the applicant may indicate any missing or incomplete information and the timeline by which the requested information needs to be submitted. The notification may also state that the responsibility for any consequences of submitting inadequate information, such as delays in the review and assessment process, lies with the applicant. If the applicant is requested to resubmit documents, the acceptance checking process is repeated from the beginning for those documents.

The decision to commence the review and assessment process is made by the top management of the regulatory body; this decision triggers the start of the schedule and the allocation of financial resources to the TSO and to the review and assessment process.

3.2. COMMENCING THE REVIEW AND ASSESSMENT

The project manager assigns tasks to the group leaders according to the responsibilities allocated in the project plan. The group leaders then assign these tasks to individual reviewers. Task assignment and coordination between different review disciplines can be effectively managed in the electronic document and task management system of the regulatory body. Another simple, formal way of assigning those tasks to the reviewers is using a predefined hard copy form. An example of such a form is provided in Annex VII. The task assignment provides reviewers with the necessary information regarding the expected scope and depth of their review and assessment based on a graded approach as established in Ref. [11], and lists the records and reports that need to be provided as a result of their review and assessment. Possible aspects for review and assessment in the application documents are provided in Annex VIII, and further recommendations are given in GSG-13 [4] and SSG-12 [6].

The necessary depth of the review and assessment process may vary for each application document or parts or chapters of it according to the relevance to the licensing step. The project management team predefines the depth of review and assessment by applying a graded approach for each application document and parts of it, if applicable, considering several factors, such as the licensing step; the novelty, complexity or previous history of the design; the experience of the applicant; the risk associated with the proposed nuclear power plant; and the safety importance, to ensure that:

(a) All information relevant to the licensing step is sufficiently reviewed and assessed.
(b) Sufficient review and assessment of all information needed to demonstrate the safe operation of the nuclear power plant will be completed by the end of the licensing process.

The scope of the review and assessment process may be influenced by whether the proposed design of the nuclear power plant has been previously licensed or certified by the regulatory body in another State. If a reference plant or design concept is utilized, the regulatory body may seek information from the regulatory body that licensed the reference plant or design and benefit from

its experience and safety evaluation. The regulatory body may also establish close contact with the regulatory body or bodies that have authorized similar plants or designs to facilitate knowledge transfer and to request the regulatory SERs and assessment results. However, the regulatory body needs to recognize that its responsibility for regulating the safety of the nuclear power plant cannot be delegated.

If a reference plant or design is utilized, particular attention is given during the review and assessment to the regulatory requirements and safety assessments regarding prior licensing decisions for the reference plant or design and to any differences between the proposed plant and the reference plant or design, following a graded approach. Special attention is given to:

(a) Regulatory requirements that differ from those applied to the reference plant or design, including industrial codes and standards;
(b) Design changes, including new technologies, that have not been reviewed or approved by the regulatory body in the State of the reference plant or design;
(c) Differences in site characteristics and their expected impacts on the proposed design;
(d) Operating experience gained since the approval or authorization by the regulatory body in the State of the reference plant or design.

Reference [12] provides further information on the use of a reference plant or design concept by States embarking on a nuclear power programme and contains useful guidance in appendix II regarding the use of an experienced regulator's evaluation based on SAR topics.

Depending on the review and assessment tasks assigned to reviewers, the review and assessment output of one reviewer might serve as an input for other reviewers. For example, the output of the review and assessment of the safety analysis section of an application may be used as an input for the review and assessment of the engineered safety features section and emergency preparedness and response section. Similarly, the output of the review and assessment of the site characteristics section may be used as an input for sections concerning the design of structures, systems and components. Such interfaces are predefined and stated in the review matrix (see Annex III) as well as in the relevant sections of the safety review procedures or guidance (if they exist). If further interfaces are identified later, they are discussed in project management team meetings and records are kept of the agreed points concerning those interfaces.

Before the commencement of the review and assessment process, the project management team may organize meetings with the applicant on specific areas to discuss the relevant expectations and findings of the regulatory body

among experts of both parties, accompanied by TSOs and the vendor or designer as necessary. The project management team ensures that these meetings are not used as a forum to make regulatory decisions or take positions but rather to exchange information for further understanding. The organization of similar meetings may also be useful at other stages of the licensing process.

3.3. PERFORMING THE REVIEW AND ASSESSMENT

In accordance with Requirement 26 of GSR Part 1 (Rev. 1) [1], a graded approach to review and assessment can be implemented by conducting the review of each topic in the SAR at different levels according to its safety significance. The four levels discussed below provide an example. Each level contains review and assessment activities that are complementary to preceding levels. Nevertheless, the levels might not necessarily be implemented consecutively if appropriate. It has to be kept in mind that as the level of depth increases, the applicable scope of application documents may broaden.

The first level of review and assessment focuses on understanding the subject under review within the scope of all application documents, and checking the sufficiency of the information provided and compliance with the relevant regulations and guides to identify any general issues. At this level of review, it may be assumed that all information submitted by the applicant is correct. The review and assessment of compliance with the relevant regulations and guides continues throughout all review and assessment levels. At this level, priority is given to preparing the RAIs and providing review and assessment outputs needed by other reviewers. The reviewers raise the RAIs for any missing or insufficient information in accordance with the review and assessment schedule.

The second level of review and assessment focuses on a detailed assessment of the subject to verify the correctness of the information and the justification of the safety arguments provided in various topical areas as appropriate to the licensing step, including the site evaluation, basic safety functions, the design basis of structures, systems and components, the safety analysis and operational aspects. The RAIs at this stage focus on further clarification, justification or correctness of the information provided with the application. The consistency of information given within an application document and across the application documents, such as the assumptions and design data, is reviewed at this level.

The third level of review and assessment aims at making a detailed assessment of certain predefined aspects, such as severe accident management, seismic design, aircraft crash and extreme meteorological conditions, with priority given to site related issues and differences from the reference plant or design, if applicable. This level of review also covers the verification of assumptions

and inputs, including initial and boundary conditions, appropriateness of methodologies, validation and verification of the software used by the applicant, and compliance of results with regulatory requirements and/or acceptance criteria.

The fourth level of review and assessment involves conducting confirmatory calculations, analyses and tests on selected topics in the application. Performing in-depth confirmatory calculations and analyses for all safety topics is not feasible for a regulatory body. Therefore, the project management team decides (usually prior to initiation of the review and assessment process) which topics are to be verified and provides the means for confirmatory calculations. A need for additional confirmatory calculations, analyses and tests can also be identified during the third level of review and assessment. The project management team determines the availability of in-house capabilities to perform these calculations and may also consider procuring the services of external technical support if in-house capabilities are insufficient.

The project management team determines the scope of confirmatory calculations to be performed by taking into consideration the importance to safety of the questions to be resolved, differences from the reference plant or design (if any) and site specific conditions. Confirmatory calculations, except sensitivity analyses, are usually carried out with the same initial and boundary conditions of the provided analyses to ensure comparability of the results. As stated in para. 3.193 of GSG-13 [4]:

"Confirmatory calculations can provide information that can assist [the regulatory body] in:

(a) Identifying weaknesses, if any, in the safety case;
(b) Estimating safety margins or the degree of conservatism in the safety case;
(c) Performing sensitivity analyses and uncertainty analyses in order to verify the authorized party's designation of the risk significance of various structures, systems and components;
(d) Understanding complex process interactions between engineered features and natural features (this is particularly important for radioactive waste disposal facilities);
(e) Verifying that the safety assessment is consistent with current data obtained from research and monitoring;
(f) Gaining further confidence in its own decision making process;
(g) Developing its in-house capacity for the resolution or further clarification of safety issues;
(h) Extending the review and assessment process to include a quantitative evaluation of the design and operation of facilities and activities."

The decision of the project management team to conduct confirmatory calculations will depend on the regulatory approach being followed.

If an additional or revised safety analysis is necessary, the regulatory body requests the applicant to provide it.

3.4. REQUESTS FOR ADDITIONAL INFORMATION

During the review and assessment process, the reviewers may need additional information or further clarification on a subject from the applicant in order to complete their review and assessment. RAIs are made officially in a structured form, and records of the requests and the responses are kept in the recording system of the regulatory body. These records contribute to the final reporting of the review and assessment results.

The project management team establishes a mechanism to communicate such RAIs to the applicant. The responses to RAIs may be in the form of the submission of a revised document with new information added to the text, or the submission of additional information. Responses to RAIs along with any supplementary documentation are submitted in the agreed language of the project. If individual RAIs are sent separately, it is advisable to record them on a form, along with their responses, to facilitate follow-up and record-keeping. An example of an RAI form is provided in Annex IX.

The project management team and the applicant agree on a mechanism to incorporate the information provided in responses to RAIs into the application documents. Practical alternatives include requesting the applicant to adopt a methodology for the continuous update of application documents or to incorporate such new information towards the end of the review and assessment process. The reviewer is responsible for verifying the incorporation of accepted responses into the application documents.

The issuance of RAIs and responses to them have the potential to delay the schedule for completion of the review and assessment process. The project management team establishes with the applicant expected timelines for responses to RAIs and also clarifies that the progress of the review depends on the quality and the timeliness of the applicant's submissions.

It is important that each RAI articulates the request in a clear and unambiguous manner. The RAI includes a rationale for the request, based on the regulations and guides, and an explanatory part for further clarification.

RAIs are made at the earliest possible stage of the review and assessment process to ensure that there will be enough time for the applicant to respond and for the reviewer to process the response. However, the reviewer may raise

follow-up requests if the response is not satisfactory, even at a later stage of the review and assessment process.

To ensure the quality of RAIs, the project management team establishes a screening system. A usual approach is to issue an RAI only if it is approved by the relevant review group leader or the project manager. Multiple levels of screening might be useful for reviews with a broad scope. Such a screening helps to eliminate repetition, enhance comprehensibility and enable appropriate recording and tracking of each RAI to facilitate follow-up. The project management team may choose to notify the applicant of each request as soon as it is approved or to communicate the requests to the applicant in batches.

The project manager or the relevant review group leader screens the RAI for completeness, clarity and reason and returns it to the reviewer for correction if necessary. If an RAI does not seem to be necessary or clear to the project manager or the relevant review group leader, the request is discussed with the reviewer who drafted it. In case of disagreement, the decision making mechanism described in Section 2.2 is employed.

The RAI form is officially communicated to the applicant. For efficiency, RAIs may be shared electronically with the applicant on a secure information technology platform. The project management team retains an original copy in electronic or printed form.

Reviewers or review groups may have meetings with the applicant to clarify any questions regarding the RAI. The reviewer or the review group that issued the RAI is responsible for its follow-up.

Responses to RAIs are provided to the relevant reviewers and filed accordingly. If the response to an RAI is not adequate, the reviewer may prepare a follow-up request or the issue is discussed with the applicant until a resolution is achieved. If there is no agreement between the regulatory body and the applicant on a resolution, the decision making mechanism described in Section 2.2 is employed.

An RAI can be closed positively, meaning that the requested information has been provided. However, the results of the review and assessment of the provided information may still indicate insufficient information, leading to a further follow-up RAI. A link to any previous requests in the record will facilitate management of the history of issue resolution.

Both the applicant and the project management team establish separate databases to manage the RAIs, the responses and the final closures of the issues.

If the applicant has difficulties responding to RAIs in a proper manner, the project management team may organize a reactive regulatory inspection of the IMS (particularly with regard to the safety assessment process), the resources management and the competence management of the applicant and/or the design organization. The inspection process that will complement the regulatory

review and assessment is defined in detail in regulations and guides and in the project plan.

The majority of RAIs are resolved quickly through one or two iterations that supply the missing information and satisfy the reviewer. However, a smaller number of RAIs may emerge for which prompt resolution is not achieved even after several rounds of question and response. Once the majority of RAI responses are received, the project management team may start preparing a draft SER with issues that are still open to share with the steering committee or the decision maker.

The reasons for issues remaining open may include the unavailability of certain key information (e.g. engineering design documents), information that is available but fails to show compliance with requirements, or differences in interpretation between the reviewers and the applicant's staff. In such cases, it is important for the project management team to establish mechanisms to work through and resolve the remaining open issues. The issue resolution mechanisms include regular tracking and review of the status of RAIs and their responses, maintenance of open communication between the reviewers and TSOs on the regulatory side and their counterparts on the applicant side, and referral where appropriate to dispute resolution and escalation to more senior levels of management in cases of differences of professional opinion.

3.5. REVIEWER REPORTS

Reviewers record and report the results of their review and assessment in a formal manner. Two alternative approaches commonly used in some countries are for reviewers to prepare either separate reviewer reports or draft sections of the SER.

In the case of separate reviewer reports, the project management team provides guidance on the format and content of the reports, including on matters such as the language to be used and the protection of sensitive information, to ensure consistency among the reviewer reports. The format of the reviewer report needs to facilitate the drafting of the SER.

Reviewer reports have an approval mechanism through the project manager or the review group leader or another mechanism suitable for the system established for the review and assessment.

External technical support providers may directly contribute to the drafting of the reviewer reports under the supervision of the respective review group leaders, or they may provide standalone reports that are considered as an input to individual reviewer reports.

The approach is defined in the preparatory stages of the review and assessment project so that the reviewers in the regulatory body know whether to include the findings of the external technical support providers in their reports directly or simply to make reference to the relevant parts of the external reports. The external reports supporting the review may also be included as attachments to the reviewer reports. In any case, the regulatory body has the ultimate responsibility for the development and approval of the SER.

A reviewer report includes:

(a) The exact identification of application documents or parts of documents reviewed;
(b) The scope and the objectives of the review and assessment;
(c) The licensing basis, relevant acceptance criteria and provisions;
(d) The review and assessment performed, including the additional information requested from the applicant;
(e) A comparison of provided information against the licensing basis, relevant safety requirements and acceptance criteria, with reference to the review findings of the external technical support provider, if any;
(f) A comparison with a reference plant or design, if applicable;
(g) Independent confirmatory calculations, analyses and tests performed by external technical support providers or the project team itself, if applicable;
(h) Inspection findings regarding the subject under review, if applicable;
(i) A conclusion with respect to the demonstration of safety, with reference to the suggestions of the external technical support provider, if any;
(j) Connections to other technical fields or cross-cutting areas and issues, if any;
(k) Proposed additional requirements and authorization conditions to be met by the applicant after authorization, if any.

3.6. PREPARATION OF THE SAFETY EVALUATION REPORT

The SER highlights the safety objectives and requirements set out by the regulatory body along with its findings as to whether the information submitted by the applicant, including responses to RAIs, is sufficient to demonstrate compliance with the requirements and to demonstrate the safety of the nuclear power plant. Therefore, the SER provides a basis for regulatory decision making on authorization. Additionally, the SER identifies open issues that need further 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 or environmental protection.

The main inputs for the SER are (a) the reviewer reports produced by the reviewers and review group leaders and the technical evaluation reports prepared by the external technical support providers, or (b) the draft SER sections mentioned in Section 3.5 as the second approach for producing the SER. Using this second approach, external technical support providers may directly contribute to the drafting of the SER under the supervision of the respective review group leaders.

The project management team defines in the project plan how the SER is developed on the basis of the input reports. The project management team tracks the status of drafting and completion of individual sections of each SER chapter. These metrics of SER completion, along with indicators related to the status of RAIs, provide important measures for the management of the overall status and progress of the review and assessment project. Such metrics can be extracted from electronic databases or spreadsheets if used.

The type of SER to be produced for the regulatory decision and its 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 States, the SER follows the structure of the application documentation, particularly the SAR, by containing the same chapters. An example of the structure and content for an SER based on this approach is provided in Annex X.

If the SER sections are not drafted directly by the reviewers, a dedicated team assigned by the project manager or by review group leaders prepares the parts of the SER based on reviewer reports.

In any case, the project manager or a team assigned by the project manager compiles those parts of the SER, adds an appropriate summary of the work performed and of the evaluation findings and conclusions, and conducts a review of those parts for consistency, integrity and quality. Finally, the SER is reviewed by the steering committee and approved by the project owner before being submitted to the decision makers.

The SER mainly addresses:

(a) Documents submitted by the applicant;
(b) The basis for the review and assessment;
(c) The review and assessment performed;
(d) Comparison with relevant regulations and guides;
(e) A comparison with a reference plant or design, if applicable;
(f) Independent confirmatory calculations, analyses and tests performed by external technical support providers or the project team itself, if applicable;
(g) A conclusion with respect to the demonstration of safety;

(h) Additional requirements and authorization conditions to be met by the applicant after authorization.

In some States, an executive summary of the SER may be prepared for decision makers as part of the SER or in the form of a separate document. In the latter case, the SER will be an appendix to the statement of safety. The statement of safety presents the main conclusions of the review and assessment and also proposes any specific licence conditions to be imposed during the licensing process.

Depending on the national regulatory structure, the regulatory body may consider communicating the SER to the applicant and the public prior to the final decision making. In some cases, a hearing or consultations with the public are stipulated in national administrative regulations. The international trend is to make the regulatory review and assessment and authorization process more transparent to the stakeholders, interested parties and the public. Conducting stakeholder interactions and public consultations, as well as addressing comments or concerns resulting from them, may be part of the project plan.

In addition, consideration needs to be given to drafting the licence (including the licence conditions) as it is an important legal document for the 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. Records of this decision are kept.

3.7. CLOSURE OF THE REVIEW AND ASSESSMENT PROJECT

Once a review and assessment project has been finalized, the implementation and results of the project are reviewed against the project plan (e.g. objective, timetable, resources used), feedback is shared, and any follow-up actions by the regulatory body (e.g. to oversee the licence conditions) are agreed upon. A closure meeting with the project team is often held to communicate these results.

The project manager also requests feedback from the applicant in the final stage of the project on such things as communication between the regulatory body and the applicant, meeting practices, processing of submissions within the regulatory body, good practices applied during the project, areas for improvement and lessons learned. Feedback can also be requested from other interested parties and relevant authorities.

The project manager collates the summary of the project, the feedback received and lessons learned, as well as commendable practices from the project's execution, into a project closure report. The report is submitted for approval in

accordance with the procedures defined in the IMS of the regulatory body and then distributed internally to the relevant staff and managers.

After the project is closed, the project manager archives all material related to the project and decides whether such items as the distribution list of emails and the electronic workspace are maintained or terminated. However, the project related documents need to be easily retrievable for future reference after the closure of the project.

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Annex I

EXAMPLE OF THE STRUCTURE AND CONTENT OF A PROJECT PLAN FOR A REGULATORY REVIEW AND ASSESSMENT

The following is an example of the structure and content of the project plan for a regulatory review and assessment to be conducted for the licensing of a nuclear power plant [I–1]:

(1) Background
    (a) Targets of review and assessment, application of regulations and guides
    (b) Feedback from other similar projects for project planning (such as benchmarking from other countries)
(2) Project work breakdown and phases of the project
    (a) Project scope
    (b) Work breakdown and project phases
    (c) Roles and responsibilities
(3) Project management
    (a) Project schedules and resource planning
    (b) Project kick-off
    (c) Project meetings
    (d) Project steering, control, documentation and archiving
    (e) Project related inspections
    (f) Project communication plan
        (i) Communication principles within the review and assessment project
        (ii) Internal communication
        (iii) External communication
    (g) Project closure
(4) Project quality management
    (a) Regulatory body's integrated management system procedures
    (b) Regulatory internal review and decision making
    (c) Document management within the project
    (d) Output records and reports
    (e) Forms and templates to be used
    (f) Procedures for main processes such as review and assessment or inspections

(5) Project monitoring and controlling
    (a) Tracking, reviewing and regulating the progress and performance of the project at regular intervals
    (b) Identifying any changes to the plan necessary to eliminate identified problems encountered during the implementation of the project
    (c) Initiating the corresponding changes based on the findings of (5b)
    (d) Management review
    (e) Non-conformance control and feedback mechanisms
    (f) Independent and self-assessment
(6) Project risk management plan
    (a) Risk identification
    (b) Risk register
    (c) Risk mitigation
    (d) Risk reviews
(7) Project finance management
    (a) Licensing fees
    (b) Expenditures (e.g. software, external support services)
(8) Project stakeholders
    (a) Applicant
    (b) Vendors, design organizations
    (c) Interested parties (domestic, international)
    (d) National and international cooperation
        (i) Bilateral cooperation between regulatory bodies
        (ii) Multilateral cooperation among regulatory bodies
        (iii) Project activities within international organizations

REFERENCE TO ANNEX I

[I–1] PROJECT MANAGEMENT INSTITUTE, A Guide to the Project Management Body of Knowledge (PMBOK Guide), 5th edn, PMI, Newtown Square, PA (2013).

Annex II

CONTENT OF A TYPICAL SAFETY ANALYSIS REPORT FOR A NUCLEAR POWER PLANT

IAEA Safety Standards Series No. SSG-61, Format and Content of the Safety Analysis Report for Nuclear Power Plants [II–1], provides the following chapter structure for the safety analysis report, which is to be submitted as part of the licensing application. Detailed guidance regarding the information to be included in each chapter is provided in SSG-61 [II–1].

- Chapter 1: Introduction and general considerations
- Chapter 2: Site characteristics
- Chapter 3: Safety objectives and design rules for structures, systems and components
- Chapter 4: Reactor
- Chapter 5: Reactor coolant system and associated systems
- Chapter 6: Engineered safety features
- Chapter 7: Instrumentation and control
- Chapter 8: Electrical power
- Chapter 9: Auxiliary systems and civil structures
- Chapter 10: Steam and power conversion systems
- Chapter 11: Management of radioactive waste
- Chapter 12: Radiation protection
- Chapter 13: Conduct of operations
- Chapter 14: Plant construction and commissioning
- Chapter 15: Safety analysis
- Chapter 16: Operational limits and conditions for safe operation
- Chapter 17: Management for safety
- Chapter 18: Human factors engineering
- Chapter 19: Emergency preparedness and response
- Chapter 20: Environmental aspects
- Chapter 21: Decommissioning and end of life aspects

REFERENCE TO ANNEX II

[II–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Format and Content of the Safety Analysis Report for Nuclear Power Plants, IAEA Safety Standards Series No. SSG-61, IAEA, Vienna (2021).

Annex III

EXAMPLES OF REVIEW GROUPS AND RELEVANT REVIEW MATRICES IN REVIEW AND ASSESSMENT PROJECTS BY DIFFERENT REGULATORY BODIES

III–1. INTRODUCTION

Tables III–1, III–2 and III–3 provide examples of review matrices for three different cases of review groups based on three different regulatory bodies following different regulatory approaches: Case A, Case B and Case C.

A review matrix is generated according to the roles and responsibilities in the review and assessment project. Usually each chapter of the safety analysis report (SAR) is assigned to a leading review group (indicated by 'L' for 'lead' in the review matrices). Other groups may support the lead review group by providing input either to the whole SAR chapter or to only some sections of the SAR chapter (indicated by 'S' in the review matrices).

III–2. REVIEW GROUPS FOR CASE A

The following lists the review groups for Case A and their abbreviations. The abbreviations are used in the review matrix for Case A (see Table III–1).

— Safety functions, safety analysis, safety systems, design basis (DB)
— Probabilistic risk assessment (probabilistic safety assessment) (PRA)
— Mechanical and manufacturing (M&M)
— Radiation and environmental safety (RAD)
— Civil, fire protection (CIV)
— Electrical systems – automation (ES-I&C)
— Nuclear waste management (NW)
— Leadership and management of safety; management systems, quality management, organizations, safety culture, operations (MAN)
— Security arrangements (SEC)
— Project management team (project manager, project engineer(s), project assistant(s)) (PM)
— Nuclear safeguards arrangements (SG)
— Plant functions, auxiliary systems, layout (PFA)

TABLE III–1. EXAMPLE OF A REVIEW MATRIX FOR CASE A

SAR chapter	DB	PRA	M&M	RAD	CIV	ES-I&C	NW	MAN	SEC	PM	SG	PFA
1: Introduction and general considerations	S	S	S	S	S	S	S	S	S	L	S	S
2: Site characteristics	S	S		S	L		S	S	S	S	S	S
3: Safety objectives and design rules for structures, systems and components	L	S	S	S	S	S	S		S	S		S
4: Reactor	L	S	S	S		S						S
5: Reactor coolant system and associated systems	S	S	L	S		S				S		S
6: Engineered safety features	L	S	S	S	S	S			S	S		S
7: Instrumentation and control	S	S		S		L			S			S
8: Electrical power	S	S				L			S	S		S
9: Auxiliary systems and civil structures	S	S	S	S	S	S	S			S		L
10: Steam and power conversion systems	S	S	S	S	S	S				S		L
11: Management of radioactive waste				S	S	S	L			S	S	S
12: Radiation protection	S	S		L	S	S				S		S
13: Conduct of operations	S	S		S		S	S	L	S	S	S	S
14: Plant construction and commissioning	S		S	S	S	S	S	S	S	L	S	S
15: Safety analysis	L	S		S	S	S		S				S
16: Operational limits and conditions for safe operation	S			S		S		L		S		
17: Management for safety								L	S	S		
18: Human factors engineering	S	S	S	S	S	S	S	L	S	S		S
19: Emergency preparedness and response	S	S	S	L	S	S	S	S	S	S		S
20: Environmental aspects	S		S	L	S	S	S					S
21: Decommissioning and end of life aspects	S		S	S	S	S	L	S	S	S		S

Note: L — lead; S — support.

III–3. REVIEW GROUPS FOR CASE B

The following lists the review groups for Case B and their abbreviations. The abbreviations are used in the review matrix for Case B (see Table III–2).

— Site
— Management systems (MS)
— Systems engineering, including fire safety (SE)
— Probabilistic safety assessment (PSA)
— Radiation protection and emergency preparedness, including waste safety (RP)
— Electrical systems (ES)
— Instrumentation and control (I&C)
— Structural systems (SS)
— Nuclear security and safeguards (NSS)
— Personnel training and qualification (PTQ)

TABLE III–2. EXAMPLE OF A REVIEW MATRIX FOR CASE B

SAR chapter	Site	MS	SE	PSA	RP	ES	I&C	SS	NSS	PTQ
1: Introduction and general considerations Sections[a] 1.4, 1.5, 1.6			**S**	**L**						
2: Site characteristics	**L**									
3: Safety objectives and design rules for structures, systems and components Sections 3.3, 3.4, 3.5 Section 3.7 Section 3.8			**L**			**S**	**S**	**S**		
4: Reactor Section 4.5			**L**		**S**		**S** **S**			
5: Reactor coolant system and associated systems			**L**	**S**	**S**		**S**			
6: Engineered safety features Section 6.2			**L**	**S**	**S**	**S**	**S** **S**	**S**		
7: Instrumentation and control			**S**	**S**		**S**	**L**			
8: Electrical power						**L**	**S**			
9: Auxiliary systems and civil structures			**S**			**S**	**S**	**L**		
10: Steam and power conversion systems			**L**	**S**	**S**	**S**				
11: Management of radioactive waste			**S**		**L**		**S**			
12: Radiation protection					**L**					
13: Conduct of operations Section 13.5									**S**	**L**
14: Plant construction and commissioning			**S**		**S**	**S**	**S**	**L**		
15: Safety analysis Section 15.6			**L**	**S** **S**	**S**					
16: Operational limits and conditions for safe operation				**L**						
17: Management for safety		**L**								
18: Human factors engineering							**S**			**L**
19: Emergency preparedness and response					**L**					
20: Environmental aspects					**L**					
21: Decommissioning and end of life aspects					**L**			**S**		

Note: L — lead; S — support.

[a] Section numbers correspond to the structure provided in IAEA Safety Standards Series No. SSG-61, Format and Content of the Safety Analysis Report for Nuclear Power Plants, IAEA, Vienna (2021).

III–4. REVIEW GROUPS FOR CASE C

The following lists the review groups for Case C and their abbreviations. The abbreviations are used in the review matrix for Case C (see Table III–3).

— Mechanical and materials (MAM)
— Civil structures and site evaluation (CAS)
— Fuel neutronics and reactor physics (FAR)
— Electrical and instrumentation (EAI)
— Radiation and waste safety (RAW)
— Plant systems (PLS)
— Probabilistic safety assessment (PSA)
— Deterministic safety assessment (DSA)
— Conduct of operation and management system (CAM)
— Nuclear security (NUS)

TABLE III-3. EXAMPLE OF A REVIEW MATRIX FOR CASE C

SAR chapter	MAM	CAS	FAR	EAI	RAW	PLS	PSA	DSA	CAM	NUS
1: Introduction and general considerations	S	S	S	S	S	L	S	S	S	S
2: Site characteristics		L			S		S			S
3: Safety objectives and design rules for structures, systems and components	L	S	S	S		S	S	S		S
4: Reactor	S		L				S	S		
5: Reactor coolant system and associated systems	L					S		S		
6: Engineered safety features	S					L		S		
7: Instrumentation and control				L						S
8: Electrical power				L						S
9: Auxiliary systems and civil structures	S			S	S	L				
10: Steam and power conversion systems	S					L				
11: Management of radioactive waste		S			L			S		
12: Radiation protection					L	S				
13: Conduct of operations									L	S
14: Plant construction and commissioning						S			L	
15: Safety analysis	S			S		S	S	L		
16: Operational limits and conditions for safe operation			S	S	S	L	S	S	S	
17: Management for safety		S							L	S
18: Human factors engineering				L			S			S
19: Emergency preparedness and response						S	S	S	L	
20: Environmental aspects		S			L					
21: Decommissioning and end of life aspects	S	S	S	S	L	S				S

Note: L — lead; S — support.

Annex IV

AN EXAMPLE OF ISSUE CATEGORIZATION

During the review and assessment process, identified mistakes need to be corrected and topics requiring additional explanation or information to reach a finding are flagged as ‘issues for resolution’. The following can be used by the project management team to establish criteria for the categorization of issues using a graded approach.

— Category 1: Missing information. This indicates that the information needed to perform the review and assessment on a subject does not exist in the application. It means that review and assessment of the subject can only be performed after the necessary information has been provided by the applicant.
— Category 2: Insufficient information. This indicates that the information provided on a subject is not sufficient to finalize the review and assessment, and additional information or clarification is needed. This category may also be considered as a subset of the previous category.
— Category 3: Non-conformance. This indicates that the provided information does not conform to the relevant regulatory requirements and requires resolution of the non-conformance. This category may further be divided into two subcategories where the resolution of the non-conformance is:
    - Subcategory 3a: Considered as a prerequisite to authorization, or
    - Subcategory 3b: Not considered as a prerequisite to authorization.
— Category 4: Editorial mistakes. This necessitates correction of the mistakes. This category may also include mistranslations that would lead to ambiguity of the text or diagrams and figures that are not legible. Instead of preparing a formal request, a list of the issues in this category may be used to communicate this type of finding to the applicant.

Annex V

EXAMPLE OF A FLOW CHART FOR THE REVIEW AND ASSESSMENT PROCESS DURING A LICENSING PROCESS

Figure V–1 shows a flow chart for a typical review and assessment conducted during a licensing process for nuclear installations, particularly for nuclear power plants.

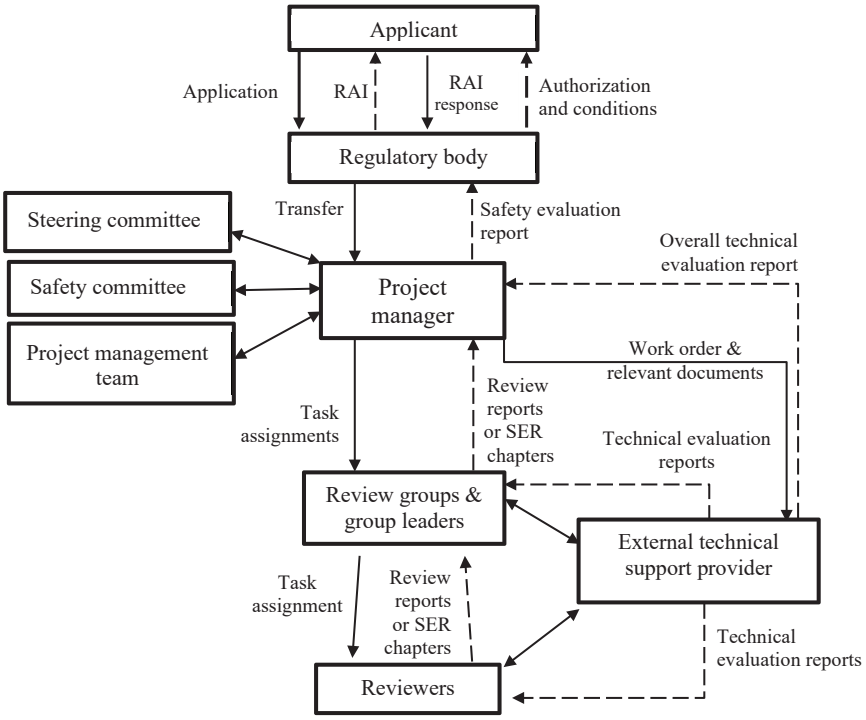

FIG. V–1. An example of a flow chart for the review and assessment process; RAI — request for additional information; SER — safety evaluation report.

Annex VI

ITEMS TO BE CONSIDERED DURING THE ACCEPTANCE CHECK OF THE APPLICATION

The following items are usually considered when conducting an acceptance check of the documents submitted by the applicant.

(a) With regard to formatting:
- If the pages and sections in each document have been numbered correctly;
- If abbreviations and definitions used in each document are explained or provided;
- If a table of contents and a list of tables and figures are included, and whether they are consistent with the text;
- If proper referencing has been applied and whether the referenced material has been provided or not;
- If each document has approval signatures;
- If units of measurement are used consistently (e.g. metric (SI) or imperial);
- If drawings and figures are legible;
- Other formatting that ensures the quality of the application.

(b) With regard to content:
- Whether the information requested in content requirements has been provided or not (not in terms of the level of detail of the content);
- Whether the quality of the language used in the application documents is sufficient to facilitate understanding;
- Any other content requirements concerning the review and assessment.

An example of a checklist to assist with the acceptance check is provided below.

Example of a Checklist for the Acceptance Check of the Application

Name of the document:			
Code of the document:			
1. Printed copy		✓	Explanation
1.	Number of printed copies is as requested		
2.	Classification of document is stated		
3.	Document is approved by the applicant		
4.	Document has a revision number		
5.	Print quality is satisfactory		
6.	Paper quality is satisfactory		
7.	Non-text items (e.g. graphs, drawings) are readable		
8.	Language of the document is as agreed and understandable		
9.	All pages are numbered		
	Any other format requirements		
2. Electronic copy		✓	Explanation
1.	Copy is properly authenticated		
2.	Files and folders are named properly		
3.	Format of the main text is as prescribed (e.g. font, size, spacing)		
4.	Page margins are as prescribed		
5.	Headers and footers contain the prescribed information		
6.	Non-text items (e.g. figures, graphs) are readable		
7.	Maps have adequate resolution		
8.	Drawings are given in prescribed format		
	Any other requirements for electronic copies		
3. Content control over electronic copies		✓	Explanation
1.	Language of the document is as agreed and understandable		
2.	Correct terminology is used (e.g. IAEA)		
3.	SI units of measurement are used		
4.	References are provided		
5.	Document is consistent with the relevant guide in terms of headings, etc.		
	Any other requirement that needs to be controlled		

Controlled by	**Reviewed by**	**Approved by**
Date, name and signature	Date, name and signature	Date, name and signature

Annex VII

EXAMPLE OF A TASK ASSIGNMENT FORM

The following form can be used to assign review and assessment tasks to the reviewers of each review group.

A. Task			
Code		**Date**	
	Assignment date		
	Expected finishing date		
B. Task assigned to			
Name of staff or review group		**Date**	**Signature**
1.			
2.			
3.			
C. Type of assignment			
☐ Control of adequacy of application ☐ Review and assessment ☐ Verification of information		☐ Verification calculation ☐ Sensitivity analysis ☐ Other	
D. Description of task and its scope			
Clear definition of the task assigned to the reviewers or groups and the scope of the task			
E. Reference documents			
A list of names and codes of documents that are the basis for the assignment 1. 2. 3.			
F. Expected output of the task			
Clear description of records and reports that need to be filed as an output of the assignment 1. 2. 3.			
G. Reasons for late or non-completion of the assignment, if applicable			
Problems contributing to late or non-completion of the assignment and proposed solutions, if applicable 1. 2. 3.			
Assigned by		**Approved by**	
Date, name and signature		Date, name and signature	

Annex VIII

AREAS FOR REVIEW AND ASSESSMENT IN THE APPLICATION DOCUMENTS

The following aspects may be reviewed and assessed in the application documents, with due consideration to the scope and content of the application and the licensing step:

- Compliance of documents with the relevant format and content requirements, if these exist.
- Consistency of the referenced regulations in application documents with the licensing basis.
- Consistency of information provided.
- Sufficient description of the installation and its layout.
- Suitability of the site and potential effects of the nuclear installation on the public and the environment.
- Adequacy of the site characterization and relevant design parameters.
- Sufficient and proper utilization of main design principles (e.g. defence in depth, redundancy, diversity, physical separation, fail-safe approach).
- Sufficient presentation and discussion of structures, systems and components (SSCs).
- Safety, seismic and quality classifications of SSCs.
- Safety functions of SSCs, appropriateness of these functions and capabilities of SSCs to perform these functions.
- Environmental qualification of SSCs and equipment qualification programme.
- Operational modes and operating limits and conditions.
- Adequacy of the established integrated management system.
- Compliance with the regulatory requirements and acceptance criteria.
- Adequacy of plans and programmes, such as monitoring programmes, and their consistency with the safety analysis report.
- Appropriateness of methods and tools used for any analysis.
- Information regarding verification and validation of the software used in analyses.
- Experimental tests carried out to validate the software used in analyses or equipment or system qualification. The regulatory body may also conduct its own experimental tests (or use a technical support organization) for new safety features to verify and validate analysis methods used.

— Appropriateness of assumptions, initial and boundary conditions of any analysis.
— Completeness and consistency of initiating events and their categorization for accident analyses, determination of limiting cases.
— Adequacy of the scope, outputs and results of analyses to demonstrate safety.

Annex IX

PREPARING A FORM FOR A REQUEST FOR ADDITIONAL INFORMATION

The project manager develops a form to file a request for additional information (RAI) that includes information as applicable to the system of the regulatory body. Some examples of information that might be useful are listed below:

(a) A unique code for each RAI;
(b) Category of issue (see Annex IV);
(c) Date the RAI was raised;
(d) Date the response to the RAI is expected;
(e) Reviewer that raised the RAI;
(f) A title that represents the RAI;
(g) The exact location of the text for which the RAI was raised;
(h) The request in a clear and understandable statement;
(i) Rationale for the RAI and further explanation, including reference to the relevant regulatory requirement, if needed.

The project manager also considers developing a form for how the response is provided. Such a form may include:

(1) Date of response;
(2) The response;
(3) A separate field for any amendments to the application documents with the exact location in the text of where this change will be implemented, if the response requires an amendment to be made to the application documents;
(4) List of appendices that are cited in the response;
(5) Appendices.

The last record that is kept on the RAI is the result of review and assessment performed on the information provided and the decision on the closure of the RAI.

By exchanging RAIs with the applicant in electronic form, it is possible to have only one form in which all relevant records are kept, including the request, the response, the review and assessment of the response and the final decision on the closure of the RAI. An example of a form for this approach is provided below.

Example of an Electronic Form for a Request for Additional Information (RAI)

1. Identification of RAI			
1.1. RAI code		**1.2. Category of issue**	
1.3. Date of RAI		**1.4. Expected date of response**	
1.5. Review group			
1.6. Title of RAI	Brief but concise title for the RAI		
1.7. Document/ area	Title of the document for which the additional information is requested, including its code and revision number The exact location of the text in the document for which the RAI is raised (e.g. lowest level heading, paragraph number)		

2. RAI
2.1. RAI The reviewer provides a description of the RAI as the first paragraph, detailed and clear enough to avoid further iterations. Additional clarification and supporting information may be provided in subsequent paragraphs for further substantiation of the issue.
2.2. Rationale The reason or justification for the RAI, referencing relevant articles of regulations or acceptance criteria, etc.

3. Applicant's response to the RAI	
3.1. Date of response	
3.2. Response The applicant provides a detailed and clear response to the RAI to avoid further iterations. The response may include explanations, discussions, information on tables, charts, etc, provided as appendices to the response to substantiate the discussions. If an amendment is needed to the main text, the amendment is presented in a separate section below.	
3.3. Amendment In this section, any amendment to be made to application documents is presented in full by the applicant, including the exact location that clearly identifies which part of the text is being amended.	
3.4. Appendices An itemized list of references that are used in the response, if applicable, is provided here. The applicant needs to provide these documents separately in addition to this form.	

4. Review and assessment of response	
4.1. Date of receipt of response	
4.2. Review Results of evaluations on additional information provided, including suggested conclusions of RAIs, are provided by the reviewer.	
4.3. Date of decision	
4.4. Decision The final decision on the RAI by the project manager is included here.	

Annex X

EXAMPLE OF THE CONTENT OF A SAFETY EVALUATION REPORT

The following provides an example of the structure and content of a safety evaluation report that is to be prepared by the reviewers.

Executive summary

Table of contents

List of tables

List of figures

1. Introduction
    - 1.1. General
    - 1.2. Regulatory basis for review and assessment
    - 1.3. Objective and scope of the application
2. Relevant inspections to complement the review and assessment
    - 2.1. Inspections performed
    - 2.2. Evaluation and results
3. Review and assessment activities
    - 3.1. Open issues, if any, from previous stages
    - 3.2. Adequacy review of the application
    - 3.3. Review and assessment
        - 3.3.1. Review of the Advisory Committee, if any
        - 3.3.2. Relevant IAEA review or mission reports, if any
        - 3.3.3. Review and assessment by the external technical support provider
        - 3.3.4. Review and assessment by the regulatory body
    - 3.4. Issues encountered in the review and assessment process
4. Review and assessment of submission document No. 1
    - 4.1. Introduction
    - 4.2. Chapter 1 of document No. 1
        - 4.2.1. Information provided
        - 4.2.2. Relevant provisions and criteria
        - 4.2.3. Assessment
        - 4.2.4. Conclusion
    - 4.3. Chapter 2 of document No. 1

4.3.1. Information provided
4.3.2. Relevant provisions and criteria
4.3.3. Assessment
4.3.4. Conclusion

…

5. Review and assessment of submission document No. 2
5.1. Introduction
5.2. Chapter 1 of document No. 2
5.2.1. Information provided
5.2.2. Relevant provisions and criteria
5.2.3. Assessment
5.2.4. Conclusion

…

X. General evaluation and conclusion (including open items for action at a later stage and proposed licence conditions)

References

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Establishing a well defined, well organized and clear regulatory review and assessment process at each licensing step is key to achieving the highest level of safety throughout the lifetime of a nuclear power plant. Reflecting a project management approach adopted in many States, this publication provides practical guidance for the planning, management and conduct of the review and assessment by regulatory bodies of applications for authorization. It is intended for the managers and staff of regulatory bodies of States, particularly those embarking on a nuclear power programme, who are involved in the regulatory review and assessment process.

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