



L12.- Safety Assessment Review Process (I)

International Atomic Energy Agency



Objectives

- ✓ *What is the regulatory review?*
- ✓ *Regulatory requirements for regulatory review;*
- ✓ *Objective and importance of the regulatory review process;*
- ✓ *Management of the review process*





Introduction

- The regulatory decision making process may involve one or several regulatory bodies and may also be scrutinized by the public and other interested parties.
- The credibility of the process is enhanced if the regulatory body takes a coordinated approach in order for interested parties to observe that regulatory decisions are based on a careful and comprehensive examination of the safety case that has been prepared by the operator and submitted to the regulatory body for approval.
- Some important elements of the process of regulatory review of safety assessment for facilities and activities using radiation sources are discussed in the following sections.



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- ✓ ***Management of the review process***





Regulatory review

The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process:

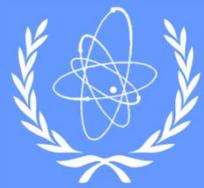
- *Initial review,*
- *Subsequent reviews,*
- *Reviews of changes to safety related aspects of the facility or activity,*
- *Reviews of operating experience, or*
- *Reviews of long term operation, life extension, decommissioning or release from regulatory control.*

The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.



Regulatory Body review process functions

- To establish regulations and issue guidance;
- To issue, amend or revoke authorizations;
- To review and evaluate safety assessments submitted by operators;
- To disseminate information to other governmental bodies and to the public;
- To carry out inspections with or without advance notification and to enforce regulatory requirements;
- To provide for independent radiological monitoring around facilities;
- To provide for emergency arrangements.



General Considerations

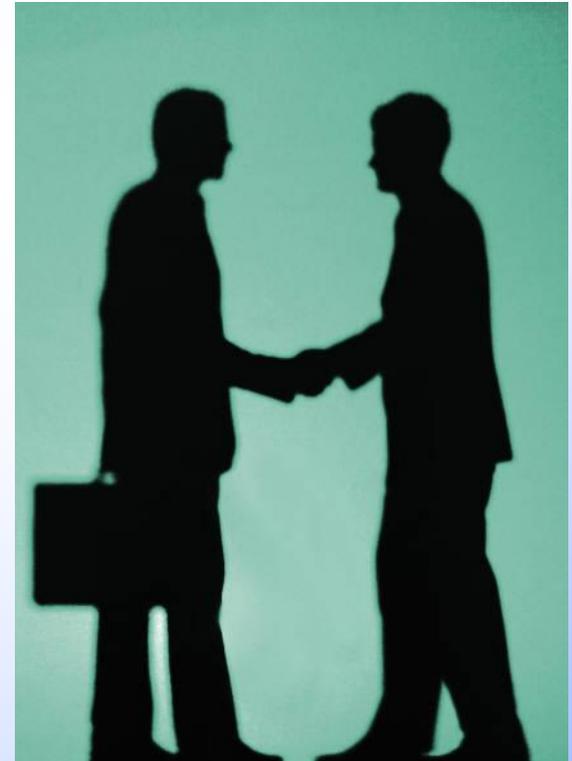
- Role of the regulator well defined and documented.
- Independent review process.
- Openness and transparency.
- Well defined and structured regulatory review process.
- Interested parties involvement framework.
- Experienced and multidisciplinary regulatory review team.
- Clearly defined regulatory requirements against which the acceptability of the assessment finding will be judged.





Regulatory Authority/Licensee interface

- Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship, shall be fostered.
- An effective interface between both parties also contributes to confidence building in other stakeholders.





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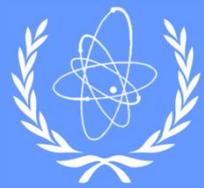




Regulatory Requirements

The completeness and quality of safety assessment cases often depend on the clarity of regulatory requirements, expectations and approach





Review and assessment of information relevant to safety

Requirement 25: Review and assessment of information relevant to safety

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

IAEA Safety Standards
for protecting people and the environment

Governmental, Legal
and Regulatory
Framework for Safety

General Safety Requirements Part 1
No. GSR Part 1





Review and assessment of information relevant to safety

The regulatory body shall acquire an understanding of the design of the facility or equipment, the concepts on which the safety of the design is based and the operating principles proposed by the applicant, to satisfy itself that, among other factors:

- *The available information demonstrates the safety of the facility or the proposed activity and the optimization of protection.*
- *The information provided in the applicant's submissions is accurate and is sufficient to permit confirmation of compliance with regulatory requirements.*
- *Operational and technical provisions, and in particular any novel provision, have been proved or qualified by experience or testing, or both, and will enable the required level of safety to be achieved.*



Review and assessment of information relevant to safety

- The regulatory body shall assess all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable.
- Any proposed modification that might significantly affect the safety of a facility or activity shall be subject to a review and assessment by the regulatory body.

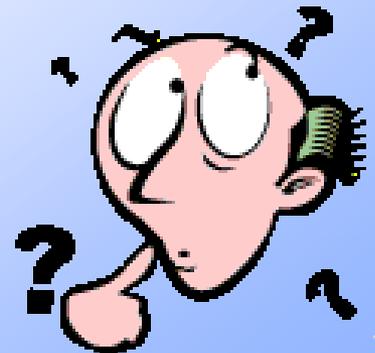




Review and assessment of information relevant to safety

In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:

- 1. The regulatory requirements;*
- 2. The nature and categorization of the associated hazards;*
- 3. The site conditions and the operating environment;*
- 4. The basic design of the facility or the conduct of the activity as relevant to safety;*
- 5. The records provided by the authorized party or its suppliers;*
- 6. Best practices;*
- 7. The applicable management system;*





Review and assessment of information relevant to safety

In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:

8. *The competence and skills necessary for operating the facility or conducting the activity;*
9. *Arrangements for protection (of workers, the public, patients and the environment);*
10. *Arrangements for preparedness for, and response to, emergencies;*
11. *Security Arrangements;*
12. *The relevance of applying the concept of defence in depth to take into account inherent uncertainties*



Review and assessment of information relevant to safety

In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:

14. *Arrangements for the management of radioactive sources and radioactive waste;*
15. *Relevant research and development plans or programmes relating to the demonstration of safety;*
16. *Feedback of operating experience nationally and internationally, and especially of relevant operating experience from similar facilities and activities;*
17. *Information compiled in regulatory inspections;*
18. *Information from research findings;*
19. *Arrangements for the termination of operations.*





Review and assessment of information relevant to safety

- For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner.
- Risks that are not related to radiation may arise in the operation of facilities or the conduct of activities.
- The regulatory body shall record the results and decisions deriving from reviews and assessments.

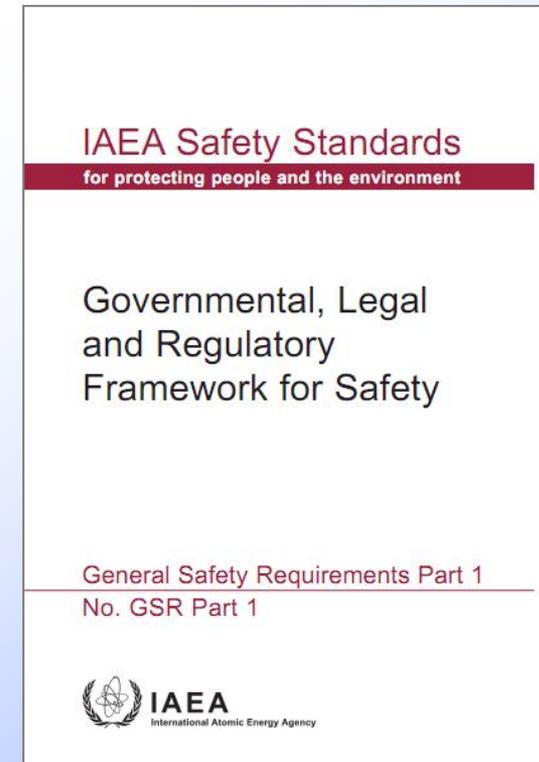




Graded approach to review and assessment of a facility or an activity

Requirement 26: Graded approach to review and assessment of a facility or an activity

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





Types of regulatory requirement

✓ Regulatory limits.

- Radiological and non-radiological
- Dose/risk constraints
- Intervention criteria

✓ Technical requirements.

- Safety indicators
- Defense in depth, passive safety etc.
- Safety assessment approach, methodology
- Scenarios analysis etc.

✓ Managerial requirements.





OBJECTIVE

- ✓ *What is the regulatory review?*
- ✓ *Regulatory requirements for regulatory review;*
- ✓ *Objective and importance of the regulatory review process;*
- ✓ *Management of the review process*





Goal of the regulatory review process

The overall goal of the regulatory review is to verify that the facility or activity will not cause an unacceptable adverse impact on human health or safety, or on the environment, both now and in the future.





Objectives of the regulatory review process

To achieve this goal, the regulatory review process will typically have the following objectives:

- Determining whether the safety assessment has been conducted in an acceptable manner;
- Verifying that the results of the safety assessment and the assumptions comply, or are in accordance with the regulatory requirements and expectations;
- Ensuring that relevant measures and contingencies to mitigate unlikely potential effects have been identified and considered.



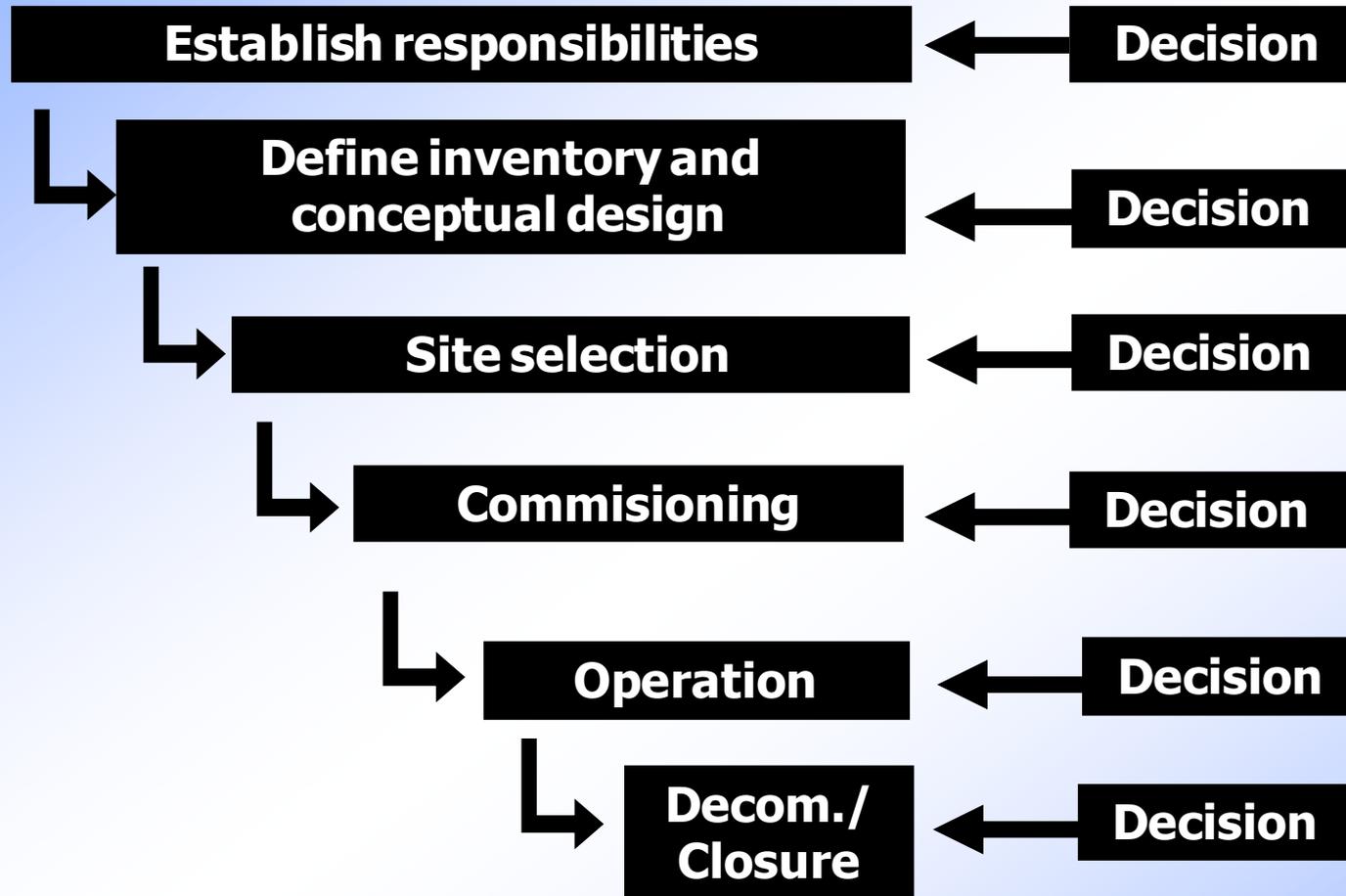
Objectives of the regulatory review process

Account should be taken of the status of the facility and the associated context for the safety assessment.





Stepwise process



This slide shows a possible stepwise process for the safety assessment that can be applied to any facility or activity.

The regulatory review should be applied to any of these stages.



Objectives of the regulatory review process



- ✓ *Determining whether issues required by the regulatory body to be addressed by the operator have been clearly identified.*
- ✓ *Identifying any unresolved issues and to verify that plans for resolving these issues have been developed.*
- ✓ *Ensuring that follow-up and monitoring programs are identified and adequate.*
- ✓ *Supporting the decision making process.*



Objectives of the regulatory review process

In order to facilitate the assessment against the primary objectives of the regulatory review, it is common for a number of secondary objectives to be specified:

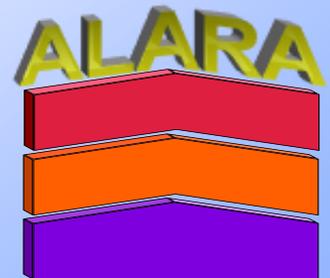
- Has been developed within an appropriate context?.
- Is sufficiently complete?.
- Is sufficiently transparent in its presentation of data and information?.
- Has been prepared by competent personnel applying a suitable management system that provides confidence in the quality of the operator's safety assessment?.

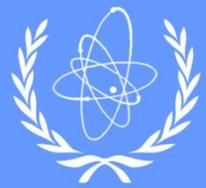


Objectives of the regulatory review process

Cont...

- Is based on appropriate assumptions and makes use of adequate assessment techniques?.
- Demonstrates an adequate understanding of the facility or activity?.
- Clearly describes how the identification, establishment, justification and optimization of safety measures, limits, controls and conditions were performed and that adequate defence in depth is provided?.
- Clearly identifies the uncertainties and addresses them adequately?.
- Provides an adequate assessment and supporting justification that protection is optimized and risks are as low as reasonably achievable (ALARA)?





Objectives of the regulatory review process

- ✓ Appropriately applies the graded approach to the requirements applied to the safety assessment for the facility or activity?.
- ✓ Addresses all relevant factors of the management system to be applied for the siting, construction, commissioning, operation, decommissioning or closure of the facility, as appropriate?.





Objectives of the regulatory review process

- ✓ Provides for adequate planning of emergency preparedness measures?.
- ✓ Provides for adequate planning of surveillance and maintenance measures?.
- ✓ Demonstrates that good engineering practices with adequate defence in depth have been used in developing the design of the facility or activity?.
- ✓ Defines a programme for future development of the safety assessment for the facility or activity?.





Defining the objectives of the regulatory review process

When defining the objectives and scope of the review, relevant points that should be considered include the following:

- ✓ *The important safety issues for the site (if applicable);*
- ✓ *The extent of the safety information provided by the operator, and the resources available to the regulatory body to evaluate the information;*
- ✓ *Whether the review will consider only radiological impacts on humans or will consider other impacts as well;*
- ✓ *Whether the review will consider impacts on the public, on workers and on non-human species in addition to the overall impact of the facility on the environment;*
- ✓ *Which parts of the safety assessment documentation should be the focus of the review;*
- ✓ *The use to be made of the results of regulatory review;*



Importance of the regulatory review

- ✓ The regulatory review process constitutes a key component of the decision making process.
- ✓ It is crucial to public acceptance
- ✓ *The quality of the review process enhances confidence in:*
 - ✓ *The credibility of the regulator.*
 - ✓ *The regulatory process.*
 - ✓ *The review findings and the regulatory decision.*

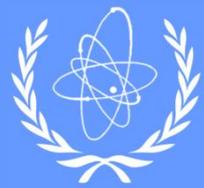




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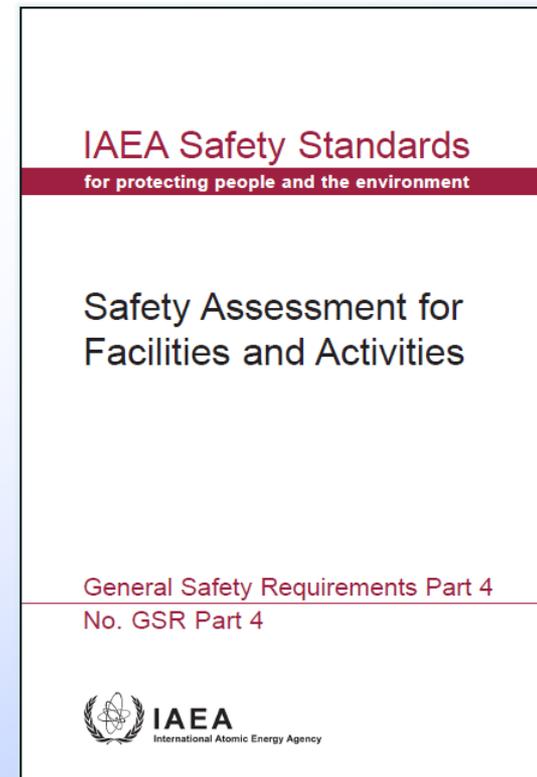
Management of the review process

- ✓ The review of a safety assessment should be treated as a project in itself, to which the standard principles of good project management apply.
- ✓ Depending on the scale of the review, it may be necessary to establish a dedicated team of personnel to conduct the review.
- ✓ The regulatory review may be conducted by the regulatory body with or without support from external organizations, but the results of the review are the responsibility of the regulatory body, which should take ‘ownership’ and “responsibility” of the results.



Management of the review process

- ✓ The regulatory body should establish clear and consistent regulatory requirements, guidance and expectations on safety assessments early in the process.
- ✓ The regulatory review process should be free from conflicting interests, and the team of reviewers should not allow themselves to become unduly influenced during the review process by internal and external considerations that are outside the scope and terms of reference of the review.





Management of the review process

- ✓ The regulatory body should have in place well established and documented procedures for the review process.
- ✓ The regulatory review process should be structured and traceable with clearly defined roles and responsibilities and decision making processes.





Management of the review process



- The regulatory body should have personnel with expertise and hands-on experience in safety assessment of the practice that is intended to be reviewed.
- Should have either in house expertise or should have access to specialists in all the necessary disciplines involved in such assessment.



Management of the review process



- ✓ The regulatory review should be conducted using a level of resources that is commensurate with the level of complexity of the safety assessment and the potential risks associated with the facility or activity under consideration.
- ✓ Communication between the operator and the regulatory body should be maintained throughout the regulatory review processes.



Management of the review process

- ✓ The regulatory review process should include a framework for consultation with interested parties with well defined consultation steps, rules of procedure and decision making processes.
- ✓ The credibility of this process can be enhanced by including means for discussion of progress and the outcome of the review process within this framework.





Management of the review process

- ✓ In the review process it should be ensured that the rationale and judgments as to whether or not the arguments presented in the safety assessment are adequately supported by the underlying science and technology; whether those arguments are in accordance with regulatory requirements and expectations should be documented.





Management of the review process

- ✓ Definition of the objectives and scope of the review as well as identification of all national and international regulations, guidance and recommendations that apply to the development of the safety assessment;
- ✓ Development of a review plan that identifies the review tasks and addresses other relevant topics;





Management of the review process

- ✓ Identification of the responsibilities of review team members and ensuring that they receive adequate training and guidance in the review methods;
- ✓ Co-ordination of the conduct of the review tasks, and ensuring sufficient communication between review team members;

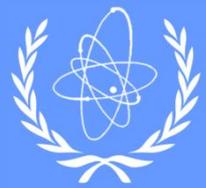




Management of the review process

- ✓ Assembling a review team of competent personnel possessing the necessary expertise and experience to undertake the review;
- ✓ Definition of a project schedule and allocation of resources for the conduct of project tasks, including consideration of the conduct of the review if resources become limited at a later stage;





Management of the review process



- ✓ Identification at an early stage of the review of any areas of regulatory guidance that are important to regulatory decision making but that may be unclear or could be interpreted in different ways;



- ✓ Establishment of a formal process to identify problems whose resolution is required by the operator, and a mechanism for monitoring other considerations and resolution of problems;

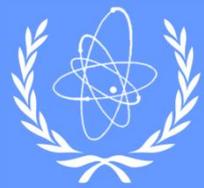


Management of the review process



- ✓ Co-ordination of communication with the operator of the facility, and with other interested parties during the review process;
- ✓ Review and integration of documents generated in the review process;
- ✓ Synthesis, documentation and communication of the findings from the review.





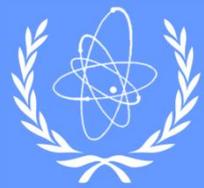
Management of the review process



- ✓ The review procedures applied should allow the regulatory body to verify that the review of the safety assessment has been performed by competent people, and has been recorded in a traceable and auditable manner.



- ✓ Project specific procedures should include structured approaches for documenting review results.



Management of the review process

- ✓ Project specific procedures should include structured approaches for:
 - *Documenting review comments,*
 - *Specifying required competence,*
 - *Specifying responsibilities and tasks in the review,*
 - *Recording the status of review comments, and*
 - *Dealing with instances where differing or opposing views or review comments on the safety assessment arise.*





Management of the review process

- ✓ Further procedures may be necessary if the review includes tasks such as audits or independent calculations performed by the regulatory body.
- ✓ For each regulatory review, a review plan will be necessary to guide the procedural and technical aspects of the review.
- ✓ Conflict resolution process.
- ✓ Technical guidance should include the criteria against which to judge specific aspects of the safety assessment.





Management of the review process



- ✓ Final step: synthesis, documentation and communication of review findings.
- ✓ Interaction with implementers and interested parties.
 - ✓ *The earlier the better.*
 - ✓ *The more active the better.*
 - ✓ *Maintain proper collegial attitudes.*

