IAEA SAFETY STANDARDS SERIES

Review and Assessment of Nuclear Facilities by the Regulatory Body

SAFETY GUIDE

No. GS-G-1.2

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ATOMIC ENERGY AGENCY
VIENNA

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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REVIEW AND ASSESSMENT OF NUCLEAR FACILITIES BY THE REGULATORY BODY

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world''.

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FOREWORD

by Mohamed ElBaradei
Director General

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of nuclear energy.

The following bodies oversee the development of safety standards: the Commission on Safety Standards (CSS); the Nuclear Safety Standards Committee (NUSSC); the Radiation Safety Standards Committee (RASSC); the Transport Safety Standards Committee (TRANSSC); and the Waste Safety Standards Committee (WASSC). Member States are widely represented on these committees.

In order to ensure the broadest international consensus, safety standards are also submitted to all Member States for comment before approval by the IAEA Board of Governors (for Safety Fundamentals and Safety Requirements) or, on behalf of the Director General, by the Publications Committee (for Safety Guides).

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA for its assistance in connection with the siting, design, construction, commissioning, operation or decommissioning of a nuclear facility or any other activities will be required to follow those parts of the safety standards that pertain to the activities to be covered by the agreement. However, it should be recalled that the final decisions and legal responsibilities in any licensing procedures rest with the States.

Although the safety standards establish an essential basis for safety, the incorporation of more detailed requirements, in accordance with national practice, may also be necessary. Moreover, there will generally be special aspects that need to be assessed on a case by case basis.

The physical protection of fissile and radioactive materials and of nuclear power plants as a whole is mentioned where appropriate but is not treated in detail; obligations of States in this respect should be addressed on the basis of the relevant instruments and publications developed under the auspices of the IAEA. Non-radiological aspects of industrial safety and environmental protection are also not explicitly considered; it is recognized that States should fulfil their international undertakings and obligations in relation to these.

The requirements and recommendations set forth in the IAEA safety standards might not be fully satisfied by some facilities built to earlier standards. Decisions on the way in which the safety standards are applied to such facilities will be taken by individual States.

The attention of States is drawn to the fact that the safety standards of the IAEA, while not legally binding, are developed with the aim of ensuring that the peaceful uses of nuclear energy and of radioactive materials are undertaken in a manner that enables States to meet their obligations under generally accepted principles of international law and rules such as those relating to environmental protection. According to one such general principle, the territory of a State must not be used in such a way as to cause damage in another State. States thus have an obligation of diligence and standard of care.

Civil nuclear activities conducted within the jurisdiction of States are, as any other activities, subject to obligations to which States may subscribe under international conventions, in addition to generally accepted principles of international law. States are expected to adopt within their national legal systems such legislation (including regulations) and other standards and measures as may be necessary to fulfil all of their international obligations effectively.

EDITORIAL NOTE

An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.

The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.

The English version of the text is the authoritative version.

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. The achievement and maintenance of a high level of safety in the siting, design, construction, commissioning, operation and decommissioning of nuclear facilities, and in the closure of waste disposal facilities, requires a sound legal and governmental infrastructure, including a regulatory body with well defined responsibilities and functions. Review and assessment of submissions on safety from the operator of a nuclear facility are among the principal functions of such a regulatory body.

1.2. The IAEA Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1] sets out the requirements for such an infrastructure. These include requirements in respect of the establishment of an independent regulatory body for nuclear facilities and the responsibilities and functions to be assigned to it.

1.3. Four interrelated IAEA Safety Guides provide recommendations for satisfying the requirements concerning particular responsibilities and functions of the regulatory body in the regulation of nuclear facilities. The present Safety Guide addresses regulatory review and assessment; three related Safety Guides cover, respectively, the organization and staffing of the regulatory body [2], regulatory inspection and enforcement [3], and documentation relating to the regulatory process [4].

OBJECTIVE

1.4. The purpose of this Safety Guide is to provide recommendations for regulatory bodies on reviewing and assessing the various safety related submissions made by the operator of a nuclear facility at different stages (siting, design, construction, commissioning, operation and decommissioning or closure) in the facility's lifetime to determine whether the facility complies with the applicable safety objectives and requirements[1].

[1] Throughout this publication, the term 'safety objectives' is used to mean 'safety objectives, safety principles and safety criteria'.

SCOPE

1.5. This Safety Guide covers the review and assessment of submissions in relation to the safety of nuclear facilities such as: enrichment and fuel manufacturing plants; nuclear power plants; other reactors such as research reactors and critical assemblies; spent fuel reprocessing plants; and facilities for radioactive waste management, such as treatment, storage and disposal facilities. This Safety Guide also covers issues relating to the decommissioning of nuclear facilities, the closure of waste disposal facilities and site rehabilitation.

STRUCTURE

1.6. Objectives, management, planning and organizational matters relating to the review and assessment process are presented in Section 2. Section 3 deals with the bases for decision making and conduct of the review and assessment process. Section 4 covers aspects relating to the assessment of this process. The Appendix provides a generic list of topics to be covered in the review and assessment process.

2. REVIEW AND ASSESSMENT PROCESS

OBJECTIVES OF REVIEW AND ASSESSMENT

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

2.2. The specific objectives of the review and assessment will depend on the stage of the lifetime of the facility. Examples of these specific objectives include the following:

(a) To determine whether an operator has the ability and resources (in particular, the funding arrangements for decommissioning) to discharge its obligations associated with any authorization granted for any stage of the lifetime of the facility.
(b) To determine whether the site chosen is suitable for the proposed facility, account being taken of the interaction between the site and the facility and of anticipated changes to the environment of the site during the proposed period of commissioning and operation; and to recommend to the appropriate authorities requirements in respect of the site surroundings that may be considered necessary by the regulatory body.

(c) Before manufacture, construction, installation, commissioning, operation and decommissioning or closure: to determine whether proposals and commitments of the operator in respect of design, operation and decommissioning or post-closure meet the regulatory body's requirements, and to apply any further conditions or requirements that may be considered necessary by the regulatory body.

(d) To determine whether the commissioning test programme is complete and contains a well defined set of operational limits, test acceptance criteria, conditions and procedures; whether the commissioning tests can be safely conducted; and whether the test results are adequate for confirming the adequacy of all safety related features of the facility.

(e) To determine whether the operator uses an appropriate safety management system that meets the regulatory body's requirements.

(f) To determine whether the operational limits and conditions are consistent with the regulatory body's requirements, the operational characteristics of the facility, and the state of knowledge and operational experience; and to determine whether an adequate level of safety is being maintained.

(g) To determine whether the operator's personnel meet the regulatory requirements, in terms of both number and competence.

(h) To determine whether proposed modifications to the facility, at whichever stage in its lifetime, have been conceived and their implementation planned so that safety is not compromised.

(i) To evaluate safety reviews performed by the operator.

(j) To determine whether the operator's plans and commitments in respect of decommissioning meet the requirements of the regulatory body.

(k) To determine whether the operator's plans and commitments in respect of the closure and post-closure stages for a disposal facility meet the requirements of the regulatory body.

(l) To determine, if relevant, whether the performance indicators proposed by the operator are appropriate.

(m) To determine whether the programme proposed by the operator for confirmation of performance is acceptable (this is particularly important for waste disposal facilities).

(n) To determine whether any additional requirements (or licence conditions) have been fulfilled by the operator.

MANAGEMENT OF REVIEW AND ASSESSMENT

2.3. Management within the regulatory body of the review and assessment process is an important part of the process. Consideration should be given to assigning

managerial responsibility to a single individual or organizational unit. The management of review and assessment should include responsibility for:

(a) Planning and directing the review and assessment process;
(b) Preparing the procedures to be followed in accordance with the overall quality management programme;
(c) Co-ordinating all information exchange between the regulatory body and the operator;
(d) For all documents sent or received, keeping a log to record the name of the sender and that of the recipient, the follow-up action necessary and the outcome of this action;
(e) Monitoring the progress of documents submitted by the operator and the progress of the review and assessment process against the tentative programme agreed by the operator and the regulatory body (if there is such a programme);
(f) Making the necessary arrangements whenever different parts of the regulatory body need to combine their expertise to make a decision in a timely manner;
(g) Making arrangements for co-ordination between review and assessment activities and inspection activities, as appropriate;
(h) Making arrangements for liaison with consultants, advisory committees or any other relevant organizations as appropriate, whenever these are called upon;
(i) Facilitating consultation nationally with other regulatory bodies and governmental departments, where appropriate;
(j) Collating and disseminating the overall findings of the regulatory body following the completion of the review and assessment process;
(k) Planning for public consultation during the review process, as appropriate;
(l) Planning for any hearing process at the end of the review and assessment process, as appropriate;
(m) Qualification and training of the personnel engaged in the review and assessment process.

2.4. The IAEA Safety Requirements publication on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1] establishes the following requirements. “A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator’s technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:

(1) The available information demonstrates the safety of the facility or proposed activity;
(2) The information contained in the operator's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and
(3) The technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety" (Ref. [1], para. 5.9.)

2.5. The review and assessment of nuclear facilities necessitate considerable amounts of work and resources, and appropriate plans should be made for these. The regulatory body should develop a programme to review and assess information provided by the operator (see Ref. [4], paras 4.2–4.8) or collected during its own inspections [3]. The co-operation of the operator should be obtained to ensure that review and assessment can be carried out in an effective and informed manner. In addition, information from other sources (such as incident reports from other States) which have a bearing on the safety of facilities should be reviewed and assessed.

SCHEDULING OF SUBMISSIONS

2.6. The regulatory body should indicate to the operator the period of time that is considered necessary for the review and assessment process so as to facilitate the process and to minimize delays in the granting of any necessary authorizations. It is appropriate to reach agreement on an indicative schedule. In scheduling a review and assessment programme, the regulatory body should allow for the fact that the information initially submitted by the operator may be incomplete. In such cases, it will take time to obtain adequate information so that review and assessment in full can be initiated. In addition, important issues may arise, necessitating additional studies and leading to delays. Such factors may lead to large variations in the time necessary for review and assessment in a given stage of the lifetime of the facility. The operator should submit any additional information sought by the regulatory body within the stipulated time. The regulatory body should expend its best efforts to complete its review and assessment process in accordance with the agreed schedule, but this objective should in no way compromise the regulatory body's responsibilities.

DIFFERENT STAGES OF THE AUTHORIZATION PROCESS

2.7. The authorization process (see Ref. [4], Appendix) is a continuing process which may start before the planning and feasibility study for the site and continue

through decommissioning or closure of the nuclear facilities until release from regulatory control. This section outlines the areas in which review and assessment should be concentrated. It is not sufficient to review and assess these areas in isolation; all relevant areas from previous decision points should be considered at each stage in the authorization process in order to ensure that the acceptability of the operator's submissions has not been compromised. A listing of the topics that should be considered in the review and assessment process throughout the lifetime of a facility is given in the Appendix.

2.8. As a practical matter, review and assessment of each area may start at an earlier stage and continue into subsequent stages. Also, depending on the arrangements made at the national level and the nature of the facility, review and assessment of some areas may be combined. Since this Safety Guide covers a wide range of types of facility, it is not possible to provide details of specific areas that should be subject to review and assessment at each stage of the lifetime of facilities of each type. However, this section provides a general overview of major areas for review and assessment; the degree to which the respective areas should be considered will depend on the nature of the facility and the risks associated with it.

Site evaluation

2.9. In considering an application for siting, the regulatory body will tend to concentrate on the characteristics of the site and, as appropriate, the interaction between the proposed facility and the site. Site evaluation for many facilities is initially determined by processes not greatly influenced by highly prescriptive criteria. However, general requirements concerning remoteness, local population density and transport arrangements will apply. For waste disposal sites, geological and hydrogeological considerations will be major factors in site evaluation. It is likely that for such sites the regulatory body may be involved in the formulation of site selection criteria and in the process of determining the suitability of a site (see Refs [5–7]).

2.10. In all cases, the site of the facility should be qualified by review and assessment to determine the potential interaction between the proposed facility and the site and to assess the suitability of the site from the point of view of safety. This site review and assessment may be performed in parallel with the design review and assessment or may, as in some States, be performed at an earlier stage. Areas of review and assessment which are of particular significance are the implications of the local environment, natural and human made, for the facility's safety and the demands that the facility would make on the local infrastructure.

2.11. For waste disposal facilities, the geological barrier is an important element of the very long term assurance necessary. The arguments to be made will depend on an understanding of the natural environment. Such an understanding is unlikely to be complete at this stage and should be reinforced and confirmed in the construction and operational stages to provide the technical basis and gain the public confidence necessary. The process of review and assessment of the site qualification could take many decades and indeed may last into a period of institutional control following closure of the facility.

Design, construction, manufacture and installation

2.12. Before authorization of construction of the facility, review and assessment will be concentrated on the operator's approach to safety and safety standards, and how these have been applied in developing the design. Features such as the physical layout and the construction of the facility and the key process elements should be carefully considered, and their effects on the safety of the facility throughout its lifetime should be assessed at the design stage. In addition, before authorizing construction, the regulatory body should review and assess the operator's arrangements for the control of activities in construction, manufacture and installation. Once construction has started, many features of the design can be changed only with great difficulty. An outline plan for decommissioning, covering issues such as strategies to be used, radiation doses to be expected and amounts of waste to be produced, should be prepared by the operator at the design stage. The plan should be subject to review and assessment by the regulatory body.

2.13. Review and assessment of the design should continue during construction, manufacture and installation as the details become finalized. Changes to the authorized design at this stage should be analysed by the operator and reported to the regulatory body, which should carry out the necessary review and assessment.

Commissioning

2.14. Commissioning can be considered in two stages: inactive, before fissile and radioactive material is introduced, and active, after fissile and radioactive material has been introduced. Clearly, radiological risks arise only after the second stage has been started. Commissioning should be carried out in accordance with programmes which have been reviewed and assessed by the regulatory body, which should determine whether the as-built facility meets its requirements.

2.15. The inactive stage of commissioning is aimed at ensuring that the facility has been constructed, manufactured and installed correctly and in accordance with the

design documentation. If deviations from this documentation have occurred, they should be recorded, and it should be shown that the safety analysis has not been compromised. The results of inactive commissioning should also confirm the operational features of the facility and should lead to the development of detailed instructions for operators, which should be confirmed during the active stage.

2.16. Active commissioning with the introduction of fissile and radioactive material is a major step in the authorization process. The review and assessment should take into consideration: the final or as-built design of the facility as a whole; the commissioning programme and its progress; the organizational structure; the qualifications of operating personnel; emergency preparedness; the preliminary operational limits and conditions; and the preliminary operating procedures. Whenever there are deviations from the design parameters, these should be analysed by the operator and reported to the regulatory body, which should carry out the necessary review and assessment.

2.17. As the active commissioning processes move closer to completion, review and assessment should be concentrated on how the facility is operated and maintained, and on the procedures for controlling and monitoring operation and responding to deviations or other occurrences. Before authorizing routine operation, the regulatory body should review and assess the consistency of the results of commissioning tests. If the regulatory body finds inconsistencies in these results, it should assess any corrections of non-conformances and modifications to the design and operational procedures that were made as a result of the commissioning. The regulatory body should review and assess any proposed changes to the limits and conditions.

Operation

2.18. For routine operation the regulatory body should require that the operator report regularly on adherence to safety objectives and compliance with specified regulatory requirements, and on efforts made to enhance safety. The regulatory body should review and assess the reports and should perform inspections to confirm compliance with regulatory requirements and to confirm that the facility is able to continue in operation.

2.19. While the need for reassessment may arise in a number of ways (see para. 2.25), systematic safety reassessments, termed periodic safety reviews (PSRs), should be carried out by the operator at intervals to review the cumulative effects of ageing of the facility and of modifications, and the implications of operating experience and

technical developments. The nature of this review and the interval between reviews will depend on the nature of the facility and the potential magnitudes of the risks it presents. The objective of the reviews should be to assess the facility against current regulatory requirements and practices and to determine whether adequate arrangements are in place to maintain its safety. When a review shows that the facility does not meet current regulatory requirements, the significance of the shortcomings should be assessed and possible ways of meeting the requirements should be considered. The PSR should enable the regulatory body to judge whether it is acceptable for the facility to continue to be operated until the next PSR is carried out.

2.20. During the operation of the facility, the outline plan for decommissioning should be updated by the operator from time to time and reviewed by the regulatory body in the light of operational experience, new or revised regulatory requirements and technological developments.

Decommissioning

2.21. Decommissioning of a nuclear facility, such that regulatory controls may be removed, includes decontamination and the dismantling and/or removal of radioactive materials, radioactive waste, components and structures. Decommissioning comprises: the preparation and approval of a detailed decommissioning plan; the actual decommissioning activities; and the management of waste arising from these activities. Just before the permanent shutdown of the facility, a detailed plan should be prepared for authorization or approval by the regulatory body. The decommissioning plan should be reviewed and assessed in order to ensure that decommissioning can be accomplished safely with a progressive and systematic reduction in radiological hazards. In those cases for which it is proposed to defer decommissioning in whole or in part, it should be shown that there will be no undue burden on future generations. The management of waste from decommissioning should be a significant feature of decommissioning plans. Large amounts of waste may be generated over short time periods, and the waste may vary greatly in type and activity. In the review and assessment of the decommissioning plans, it should be ensured that such waste can be managed safely.

Closure of a waste disposal facility

2.22. To enable a disposal facility to proceed beyond the operational stage to closure, ancillary facilities should be decommissioned and the facility should be appropriately sealed. Detailed proposals for closure and for assessment of the

safety of the facility in the long term should be reviewed and assessed by the regulatory body. Particular consideration should be given to detailed information, including relevant operating records, on: the radionuclide content and physical properties of the waste and its packaging; geological and hydrogeological conditions; the performance of the facility's design (including backfill materials, engineered structures and the sealing arrangements); aspects of monitoring and retrievability; and the migration of radionuclides and potential pathways.

2.23. If institutional control after closure of a waste disposal facility is deemed necessary, the arrangements for future control, including continuing environmental monitoring programmes, should be subject to review and assessment by the regulatory body.

Release from regulatory control

2.24. Before an operator can be allowed to relinquish the authorization, it should be ensured that all responsibilities and liabilities that pertain under the authorization have been satisfactorily discharged and that there is no reasonable possibility that any future requirement will be made on the operator. The operator should provide evidence of this and, in particular, should demonstrate that the rehabilitated site will not pose unacceptable radiological risks in comparison with radiological conditions that prevailed before the facility was built. The regulatory body should review and assess this evidence and should determine whether it adequately closes the issues.

Reassessments

2.25. Throughout the lifetime of a facility, it may be necessary for the operator to make a reassessment of its safety (or of an aspect of it). This reassessment could be at the initiative of the operator or at the request of the regulatory body. The need for reassessment may arise owing to:

— Experience relevant to safety that has been gained at the facility, at similar facilities and at other relevant nuclear and non-nuclear facilities;
— Information from relevant tests and from research and development programmes, and new knowledge of technical matters;
— Proposed modifications to the facility or to the way in which it is to be managed and operated; and
— Changes in the regulatory framework, regulations and guides.

ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Organization

2.26. Review and assessment are principal functions of the regulatory body. The size and composition of the regulatory body, the number of consultants used and the use of advisory committees should reflect the number and the size, nature and stage in the lifetime of the facilities that it regulates. The Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities [2] gives recommendations on the general approach to the organization of review and assessment, and the qualifications, abilities and training necessary for personnel engaged in these functions.

Consultants

2.27. Paragraph 4.3 of Ref. [1] establishes requirements in respect of the use of consultants to assist the regulatory body in, among other things, the review and assessment process. Additional considerations in relation to consultants are presented in Ref. [2], paras 3.28–3.29.

2.28. In using consultants, the regulatory body should carefully define the terms of reference for the review and assessment. The regulatory body should ensure that consultants have a clear understanding of its safety objectives. The regulatory body should have permanent staff with the competence to manage the work of consultants and to evaluate the quality and results of their work. "The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated." (Ref. [1], para. 4.4.)

Advisory bodies

2.29. The functions and organization of advisory bodies are discussed in para. 4.9 of Ref. [1] and paras 3.30–3.32 of Ref. [2]. Careful consideration should be given to the establishment of one or more such bodies to provide assistance in the review and assessment process of the regulatory body.

EXTERNAL RELATIONSHIPS

Relationship with the operator

2.30. The regulatory body and the operator should establish formal relations based on independence and mutual respect. Proper channels of communication between the operator and the regulatory body should be established. The operator, with its responsibility for the safety of the facility, may be the only organization among those involved in the manufacture, construction, installation, operation and safety analysis of the facility that will have direct relations with the regulatory body. In this case, the operator should represent all its contractors in formal dealings with the regulatory body, including the submission of documents and attendance at meetings.

2.31. The operator should submit its documentation early enough to allow the regulatory body to proceed in a timely manner with its review and assessment. The regulatory body may issue general guidance on meeting requirements for documentation. The regulatory body should have regular contacts with the operator in order to provide detailed guidance, including guidance on the type and content of, and timing for, documentation to be presented by the operator.

2.32. In all stages of the authorization process, the operator and the regulatory body should continue to hold meetings to discuss topics such as the bases for proposed changes, in advance of making formal submissions, or to discuss matters already under consideration. A formal programme of meetings at different levels of management may be established between the regulatory body and the operator, in order to promote good relations and to afford the possibility of announcing possible changes or initiatives, thus facilitating future planning. Written records should be kept of such meetings, and of any decisions or agreements reached.

Relationship with the operator's contractors

2.33 Much of the information needed by the regulatory body to perform its review and assessment may be prepared for the operator by its contractors. These contractors may be involved in design, manufacture, construction, installation, maintenance or safety analysis, and may themselves have subcontractors. It should be the responsibility of the operator to make arrangements with its contractors to ensure the availability of all necessary information and to keep the regulatory body fully apprised of new information and of any revisions to information submitted previously that may be relevant to the review and assessment process. The regulatory body may seek or may permit the participation of contractors in meetings between the regulatory body and the operator in order to clarify issues concerning safety and to

facilitate the exchange of information. As review and assessment progress, it may be necessary for the regulatory body, with the knowledge of the operator, to have direct contact with a contractor. These contacts should not diminish the responsibility of the operator for the safety of the facility.

Relationship with other governmental bodies

2.34. In addition to the regulatory body, other governmental bodies may participate in the regulatory process in accordance with national legislation, regulations and practices. The regulatory body should establish and maintain liaison throughout the lifetime of the facility with other governmental bodies as appropriate; and it should develop and, where practicable, formalize working procedures with such bodies, whether at the national, regional or local level. Areas of the review and assessment in which such bodies might participate should be identified. These bodies may include:

— Environmental protection authorities;
— Authorities responsible for public liability issues;
— Authorities for physical protection and/or safeguards;
— Authorities for planning the use of water resources and land;
— Authorities responsible for public and occupational health and safety;
— Fire protection authorities;
— Transport authorities;
— Law enforcement bodies;
— Bodies with responsibilities for civil engineering structures and buildings, and electrical and mechanical equipment;
— Other bodies with responsibilities for emergency preparedness;
— Other bodies with responsibilities for limits on releases of radioactive effluents.
— Other regulatory authorities, particularly those performing similar functions.

2.35. The nature of the relation between the operator and other governmental bodies should be determined by national laws, regulations and practices.

Relationship with regulatory bodies of other States and international bodies

2.36. “The safety of facilities and activities is of international concern. Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation.” (Ref. [1], para. 4.11.)

2.37. There may be specific technical areas in which the regulatory body can obtain information for use in the review and assessment process. Exchange of information will be particularly useful whenever regulatory bodies of other States have experience in authorizing similar facilities; it should be considered whether to set up a group of such regulatory bodies. Sources of information and expertise include international bodies such as the IAEA.

2.38. Specific reasons for a regulatory body to seek information include:

(1) Gaining knowledge of a novel facility to be introduced of which other States have experience;
(2) Adding to the database of operating experience with specific facilities;
(3) Gaining knowledge of different methods of analysis, such as methods using computer codes;
(4) Gaining knowledge of different approaches to review and assessment;
(5) Gaining knowledge of the management of the review and assessment process;
(6) Gaining knowledge of the operator's contractors in another State;
(7) Obtaining information on facilities in other States which, owing to their proximity, may have an influence on neighbouring States.

2.39. Information may be exchanged by means of meetings, transfer of documents and visits by experts, but none of these should in any way relieve the national regulatory body of its responsibilities for making decisions and recommendations.

3. PERFORMANCE OF THE REVIEW AND ASSESSMENT PROCESS

GENERAL

3.1. The review and assessment process is a critical appraisal, performed by the regulatory body, of information submitted by the operator to demonstrate the safety of the facility. Review and assessment are undertaken in order to enable the regulatory body to make a decision or series of decisions on the acceptability of the facility in terms of safety. The process consists of examining the operator's submissions on all aspects relating to the safety of the facility. It should include consideration of both normal operation and failures, and events, including human errors, that have the potential for causing the exposure of workers or the public or radiological hazards to the environment. This safety analysis should be as complete

as possible, and one of the initial tasks of the review and assessment is to confirm its completeness. The review and assessment process should include checks on the site and elsewhere to validate the claims made in the submissions. Operators often have external peer reviews conducted at their facilities by national or international organizations. The results of such reviews could provide the regulatory body with additional insights into the activities of the operator.

INTERNAL GUIDANCE

3.2. The regulatory body should provide internal guidance on the procedures to be followed in the review and assessment process and guidance on the safety objectives to be met. Detailed guidance on specific topics for review and assessment should also be provided, as necessary. Consideration should be given to the extent to which the regulatory body's internal guidance may be made available to operators and the public.

REVIEW AND ASSESSMENT PLAN

3.3. "The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout." (Ref. [1], para. 5.10.)

3.4. For regulatory efficiency, the findings of the preliminary review should be prioritized on the basis of their potential implication for the overall safety assessment of the facility and associated hold points in the authorization process. For regulatory effectiveness, the review and assessment efforts should usually be focused more on those aspects of site evaluation, design or operation which involve untested (innovative) features.

3.5. For more important submissions by the operator (such as the safety analysis report) it may be useful for the regulatory body to perform an acceptance review of the documentation. As a result of this acceptance review, an application or submission that is grossly deficient in certain areas may be returned to the operator for correction and resubmittal.

3.6. In carrying out a review and assessment of an operator's submission, the regulatory body should employ a systematic plan to provide assurance that all topics

significant to safety will be covered and that operators of similar facilities will be treated equally. This plan should include a series of procedures that the regulatory body will follow for all aspects and topics covered by the submission in order to identify those items for which applicable safety objectives and requirements have been met and those for which they have not. An outline for such a plan might be as follows:

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

3.7. In practice, the scope and depth of the review and assessment will depend on several factors such as novelty, complexity, previous history, the experience of the operator and the associated risk[2]. The areas on which regulatory review and assessment should be concentrated at different stages can be considered in broad terms. For example, while the site qualification stage is a significant stage for all facilities, it is particularly important for waste disposal facilities.

3.8. A major feature of the operator's submission will be its analysis of normal and fault conditions[3]. However, the importance of the other aspects of the safety submission should be recognized: the safety of a facility is based on sound engineering and good management, and safety analysis is a confirmation of the adequacy of these and not a substitute for them. The value of safety analysis is in extending knowledge and understanding of the facility and its behaviour and in identifying shortcomings in areas in which safety can be improved.

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[2] Note that for the purposes of this publication the term 'risk' is used in the general sense of a qualitative combination of the frequency and the consequences of a type of event.

[3] Throughout this publication the term 'fault conditions' is used to denote all situations in which there is a deviation from the normal operational envelope or from reference conditions resulting from postulated initiating events.

DOCUMENTATION TO BE SUBMITTED BY THE OPERATOR

Responsibilities of the operator

3.9. The operator should be responsible for submitting documentation in support of its application for authorization. At each stage of the authorization process the operator should be required to demonstrate to the satisfaction of the regulatory body that the facility can be sited, designed, constructed, commissioned, operated, decommissioned or closed without giving rise to undue radiological risks to workers, the public or the environment. The nature of this information and the types of documents containing the information will depend on the nature of the facility and the risks it presents as well as on the applicable national requirements.

3.10. At all stages the operator should be able to demonstrate that it is in control of the facility and has adequate organization, management, procedures and resources to discharge its obligations and, as appropriate, its liabilities. The totality of the documentation which the operator uses in making this demonstration, some of which may not be in the initial formal submission, should cover all appropriate topics (see Appendix), depending on the stage of the authorization process and the nature of the facility.

3.11. "Any modification to safety related aspects of a facility or activity (or having an indirect but significant influence on safety related aspects) shall be subject to review and assessment, with the potential magnitude and nature of the associated hazard being taken into account." (Ref. [1], para. 5.11.)

Records of the operator's submissions

3.12. The formal exchange of information through agreed channels of communication is a fundamental element of the review and assessment process. Information exchanges that may occur between the regulatory body and other concerned parties (including other governmental bodies, the operator and its contractors, advisory committees, consultants and, as appropriate, members of the public) should be in written form and should be formally recorded upon receipt and stored in a manner that allows easy retrieval. Certain formal documentation will be required by the laws and regulations of the State or by the requirements of the regulatory body. This documentation should be provided in a timely manner by the operator.

3.13. Other formal submissions will be made in response to specific requests from the regulatory body or at the initiative of the operator. The records of official meetings

and hearings may also constitute means for formal exchanges of information and should also be suitably recorded and stored.

Proprietary information and confidentiality

3.14. Certain information provided by the operator or its contractors should be considered confidential because of its proprietary nature, for security reasons or because of the right of individuals to privacy, in accordance with national law and regulations. Such confidential information should be made available as necessary without restriction, to the regulatory body; that is, to its staff, consultants and advisory committees as well as to any other governmental bodies involved in the review and assessment process. Those to whom such information is entrusted should be advised of its confidential nature and should be obliged, consistently with national law and regulations, to protect its confidentiality.

BASES FOR DECISIONS

3.15. "The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either:

(1) The granting of an authorization which, if appropriate, imposes conditions or limitations on the operator's subsequent activities; or
(2) The refusal of such an authorization.

The regulatory body shall formally record the basis for these decisions." (Ref. [1], para 5.5.)

3.16. The purpose of the review and assessment of the documented information submitted by the operator is to enable the regulatory body to make a decision or a series of decisions on the safety of the facility and its associated activities.

3.17. Decisions relating to safety should be made on the basis of the review and assessment of the operator's submissions, the studies and evaluations performed independently by the regulatory body itself, and the safety objectives and specific requirements established by the regulatory body. These safety objectives (see footnote 1) and regulatory requirements will themselves be founded on current knowledge as represented by technological developments in all pertinent fields. Decisions of the regulatory body should reflect professional judgement by technically competent

persons on the basis of regulatory requirements and operational experience throughout the review and assessment process.

3.18. The regulatory body should request any necessary additional information and should be prepared to suspend or terminate its review and assessment if, in its judgement, such action is justified because of deficiencies in the information provided. The regulatory body should require that the documentation submitted for review and assessment be prepared subject to a proper and effective quality assurance system and should be appropriately reviewed.

3.19. At many stages during the review and assessment process, decisions will be taken on the acceptability of various aspects of the facility. The nature of these decisions will vary during the lifetime of the facility, and some will be directly associated with stages of the regulatory authorization process. The regulatory body should recognize the basis for such decisions, in which a number of factors should be taken into account. Important among these are:

(a) The extent to which the safety objectives and regulatory requirements have been met;
(b) The acceptability of the depth and detail of the operator's submission, in view of the nature of the facility and the magnitudes of the risks it presents;
(c) The state of knowledge concerning particular processes or effects;
(d) The confidence in the conclusions reached on the basis of the analysis.

3.20. These factors are an integral part of the review and assessment process and should be given special consideration in the documentation produced by the regulatory body. The decisions on acceptability are taken against a background of safety objectives, precedents and judgements, the basis for which should be clearly understood. The decision on the safety of the facility, for example, will always be taken in the light of a requirement to meet certain obligations. These will include, for example, operational limits and conditions and obligations in respect of the maintenance programme and the frequency of in-service inspection or acceptance criteria for radioactive waste.

BASES FOR REVIEW AND ASSESSMENT

Safety objectives and requirements

3.21. At all stages of the authorization process, the regulatory body should have a clear understanding of the safety objectives and regulatory requirements that will be

used in the review and assessment. The safety objectives and regulatory requirements should be communicated to the operator for guidance in preparing its documentation.

3.22. Safety objectives and regulatory requirements should specify safety goals for levels of performance in the protection to be achieved at the facility. The regulatory body should refrain from prescribing specific designs, safety management systems or operational procedures.

3.23. The regulatory body may develop safety objectives and requirements itself or it may adopt objectives and requirements that have been developed and issued by international organizations or by regulatory bodies in other States. If these objectives and requirements are to be adopted, a good understanding of their basis, use and effectiveness in other States should be acquired by means of appropriate contact with the relevant bodies. They should be adopted as necessary for specific purposes.

3.24. In formulating the content and structure of the safety objectives and requirements to be used in its review and assessment process, the regulatory body should consider a broad range of sources, including:

(a) National laws and regulations;
(b) Advice obtained from consultants, dedicated support organizations and advisory bodies associated with the regulatory body;
(c) Standards and guidance on nuclear, radiation, transport and radioactive waste safety as well as information issued by national and international organizations;
(d) Requirements and experience in other relevant industries;
(e) Technical results and experience from research and development;
(f) Expertise and requirements used by others involved in reviewing and assessing similar facilities in respect of technologies or safety.

Public consultation is a part of the process for the establishment of safety objectives and regulatory requirements in some States.

3.25. The safety objectives and regulatory requirements should cover, among other things:

— Prevention of faults rather than mitigation of their consequences;
— Application of the principle of defence in depth;
— Meeting the single failure criterion for safety related systems;
— Requirements for redundancy, diversity and separation;

— Preference for a passive system over an active or operator based system for prevention and protection;
— Criteria relating to human factors and the human–machine interface;
— Dose limits and dose constraints (both occupational and public), amount of discharges to the environment and ALARA considerations;
— Criteria for assessing radiological risks to workers and the public;
— Minimization and management of waste generated, including the future decommissioning stage;
— Emergency preparedness.

Regulations and guides

3.26. "The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales." (Ref. [1], para. 5.25.) In developing regulations and guides, recommendations issued by international bodies such as the IAEA and those used in other States will provide a useful reference source and should be considered.

3.27. Regulations (mandatory) should be developed on a generic basis or on the basis of facility type and should provide for more detailed requirements to be incorporated into individual authorizations. In some States such mandatory requirements are incorporated into conditions attached to the licence (Ref. [4], paras 5.11–5.21).

3.28. "Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator." (Ref. [1], para. 5.27.)

3.29. The regulatory body should require at all times reasonably practicable improvements in the safety of facilities and to this end should periodically review its regulations and guides against scientific and technological advances. The extent to which regulations and guides should be revised will depend on their level of detail. If safety goals and general guidance only are given, less frequent revision will be necessary. If legal requirements are changed, this may necessitate changes to regulations and guides.

3.30. The regulatory body might not have, in advance, detailed safety objectives and requirements covering all the areas that are subject to review and assessment since,

even with a fairly comprehensive set of safety objectives and requirements, some aspects of safety may not be covered. The regulatory body should evaluate the acceptability of the proposals put forward by an operator case by case against general principles. Consideration of the proposals may lead to the production of additional regulations and guides or in the modification of existing ones.

3.31. In some instances, the operator may propose an alternative approach to that suggested in a guide to achieving a safety objective. In such a case, the operator should be required to demonstrate that its proposed approach will provide an equivalent level of safety. Further details on regulations, guides and licence conditions are provided in Ref. [4].

Comparison with regulations, guides and industrial standards

3.32. The regulatory body should establish which requirements, regulations, guides and industrial standards are applicable to the facility in question and should determine the requirements to be placed on the operator. Where no such requirements, regulations, guides and industrial standards exist, the regulatory body should consider developing them. In carrying out its review and assessment, the regulatory body should use the applicable requirements as a reference in deciding on the acceptability of an operator's submissions.

3.33. In many cases, the applicable regulations, guides and industrial standards may not adequately cover the full range of facilities or may not have the level of detail that should be considered in making a decision on acceptability. The regulatory body should produce non-mandatory guidelines. These guidelines should be made available to the operator so that it is aware of the requirements and guides against which it will be judged. The guidelines should cover, among other things, the applicable requirements in terms of engineering principles and operational and managerial aspects.

Reference (generic) submissions

3.34. Whenever submissions for a particular type of facility (or parts thereof) may be repeated many times, it may be appropriate for an operator (or in some cases a contractor, which may be in another State) to provide a submission for a 'reference facility' or a 'generic facility'. A reference facility is a designated existing facility of a type that is to be constructed in various other locations as well, whereas a generic facility is a type of facility which is to be constructed with relatively minor modifications in various locations. If the national approach provides for reference or generic submissions to be considered, the regulatory body should apply the same

rigour in its review as for other submissions. However, since not all the aspects that should necessarily be considered in the process (as discussed previously) can be dealt with on the basis of such a submission, the regulatory body cannot grant an authorization in the same manner as for a single, specific facility.

3.35. It would be inappropriate to give full authorization on the basis of the reference facility or generic facility, since safety depends on such factors as siting related, managerial and operational aspects which will only become apparent when a specific operator requests authorization in respect of a specific site. The authorization should be limited to the generic design, the submission of which should be followed by supplementary submissions by the operator in respect of the specific facility.

3.36. Provided that the review and assessment by the regulatory body have been completed satisfactorily and the regulatory body has authorized the generic facility, the reference facility or the design, the operator should then have to make only a limited submission for each particular facility. This limited submission should be concentrated on those aspects in which the particular facility under consideration differs from the reference facility or the generic facility, and in particular on those features that are particular to the chosen location or site. In providing a limited submission for a particular facility, the operator should clearly indicate which aspects of the reference submission or generic submission will differ for the particular facility and should provide an explanation of why the other aspects of this submission will not be affected. In addition, the regulatory body, in its comments on the generic facility or reference facility, may identify particular aspects that should be addressed in the specific submission.

3.37. Even if a similar design or a similar facility has been authorized in another State, the regulatory body should still perform its own independent review and assessment. It may take into account the review and assessment made by the other State, and also new experience and knowledge that have been gained since that review and assessment. It should also take into account the differences in safety objectives and requirements between the States. The regulatory bodies of the States concerned should establish close contact in order to facilitate the review and assessment process.

Audit calculations

3.38. The regulatory body may decide to perform a limited number of audit calculations to check that the operator has justified a particular aspect of safety correctly, for specific purposes such as:

(a) Identifying weaknesses, if any, in the operator's safety case;

(b) Estimating safety margins or the degree of conservatism in the operator's safety case;
(c) Performing sensitivity analyses and uncertainty analyses in order to verify the operator's designation of the risk significance of various structures, systems and components (SSCs);
(d) Understanding complex process couplings between engineered and natural systems (this is particularly important for waste facilities);
(e) Verifying that the safety assessment has been maintained 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; and
(h) Extending, on a quantitative basis, the task of reviewing and assessing the design and operation of facilities.

3.39. However, it is neither cost effective nor appropriate for the regulatory body to conduct a complete set of calculations for every submission in the licensing process. Performing audit calculations is very resource intensive and, if routinely practised, could lead to an abrogation of responsibility by the operator.

VERIFICATION OF THE SAFETY ANALYSIS

General

3.40. Much effort that the regulatory body will need to expend in the review and assessment process will be concentrated on the performance of a step by step review and assessment procedure to determine whether the applicable safety objectives and requirements for each aspect or topic have been met. This stage of the process consists in examining the submissions from the operator on its managerial arrangements, engineered systems and operational procedures and on the safety analysis for the facilities. This safety analysis should cover both normal and fault conditions in order to demonstrate that the safety of the facility meets the safety objectives and requirements of the regulatory body. It should be the responsibility of the regulatory body to determine whether these submissions have provided a sufficiently complete, detailed and accurate demonstration of this. In carrying out the review and assessment, the regulatory body may find it useful to perform its own analyses or research. Any input of this nature by the regulatory body should in no way compromise or diminish the operator's responsibility for the safety of the facility. The following sections deal with major aspects of such verification; further details of topics for these aspects are set out in the Appendix.

3.41. In carrying out its review and assessment, the regulatory body should determine whether the operator has defined criteria which meet the safety objectives and requirements relating to:

(1) Engineering design;
(2) Operational and managerial aspects; and
(3) Normal operation and fault conditions.

3.42. The general aim of the regulatory review of the safety analysis report, whether deterministic or probabilistic, is to verify that for each identified barrier to the release of radioactive material the safety measures are sufficient to provide adequate assurance at the following levels:

— Prevention of failure of the barrier itself and prevention of failure of related systems in normal operation and in fault conditions;
— Monitoring of any parameter significant to the integrity of the barrier, to allow the initiation of either manual or automatic actions in order to prevent any evolution towards an unsafe condition;
— Safety action to prevent or limit the release of radioactive material if the barrier has failed;
— For certain applications and depending on the associated risk, the mitigation of consequences.

Structures, systems and components

3.43. From this analysis, the requirements on the SSCs and operations can be derived and compared with the provisions made by the operator. The review and assessment by the regulatory body should ensure that the operator has used the safety analysis to determine the requirements on the SSCs and that the requirements will be met by the equipment and in operational procedures. Specific features that should be subject to review and assessment include:

(a) Safety functions and classification of SSCs;
(b) Quality of engineered features in terms of good engineering practice or as set out in the regulatory requirements;
(c) Control of the facility in normal operation and in fault conditions, with account taken of automatic systems, the human–machine interface and operating instructions;
(d) Quality assurance covering SSCs and operational aspects such as the training, qualification and experience of the operator's personnel and the safety management system.

Organization and management

3.44. A well engineered facility may not achieve the required level of safety if it is not managed well. Review and assessment by the regulatory body should therefore include consideration of the operator's organization, management, procedures and safety culture, which affect nuclear, radiation, transport and radioactive waste safety and the operation of the facility. The operator should demonstrate by documentary means that there is an effective safety management system in place which gives nuclear safety the highest priority.

3.45. Specific aspects which should be subject to review and assessment include the following:

(1) Whether the operator's safety policy emanates from senior management and shows commitment at a high level to regulatory requirements and states the means by which these will be met.
(2) Whether the operator's organization is such that it can achieve the aims and objectives in its safety policy. In particular, the following should be addressed:
   — Adequate control of activities at the facility
   — Fostering co-operation between staff members and between staff and managers,
   — A satisfactory system for communication both up and down the managerial chain and between the managers,
   — Systems to ensure that the staff are competent for the positions assigned to them.
(3) Whether the operator has systems in place to ensure adequate planning of work and suitable performance standards, so that staff and managers know what is expected of them in order to achieve the aims and objectives of the safety policy.
(4) Whether the operator has systems in place to review and to audit periodically all the evidence on its performance, including consideration of operational events and other matters important to safety, in order to determine whether it is adequately achieving its aims and objectives, and to consider and make improvements where necessary.
(5) Whether the operator has systems in place to ensure that it acquires and retains adequate capability within its organization to understand the nature, substance and detail of the advice given to it by contractors and is able to judge the soundness of that advice.

3.46. The review and assessment by the regulatory body should cover all aspects of the operator's managerial and organizational procedures and systems which have a

bearing on nuclear safety, such as: feedback of operational safety experience; the development of operational limits and conditions; the planning and monitoring of maintenance, inspection and testing; the production and revision of safety documentation; and the control of contractors (see the Appendix for further details). The regulatory body should also review and assess the operator's procedures for the control and justification of changes to the operator's managerial and organizational procedures and systems which could have an impact on nuclear safety.

Operational safety performance

3.47. The regulatory body should review reports submitted periodically by the operating organization, in compliance with established requirements, so as to monitor the operational safety performance of the facility. Additionally, reports on safety significant events should be thoroughly reviewed by the regulatory body. The regulatory body should ensure that an effective system for the feedback of operational safety experience is in place, that no safety related event will go undetected and that corrective measures will be adopted to prevent the recurrence of safety related events. If the severity of the event warrants it, the regulatory body may conduct or arrange for an independent investigation, usually by a team with appropriately selected areas of expertise, to confirm that the event was adequately investigated, the root causes were correctly identified, and the corrective and remedial actions taken were adequate. The regulatory body's review should cover the identification of lessons to be learned and the sharing of safety related information.

Radiological consequences in normal conditions

3.48. The assessment of routine operation is directed towards the determination of occupational radiation doses and radioactive discharges. These consequences will be compared with those safety objectives, requirements and limits approved by the regulatory body, including applying the 'as low as reasonably achievable' (ALARA) principle. In the regulatory review and assessment of the operator's submission, it should be determined whether the submission meets these objectives and requirements. In the review and assessment, particular attention should be devoted to a number of factors that influence the potential radiological consequences for workers, the public and the environment in routine operation, which include:

(1) Sources and inventory;
(2) The occupational radiation protection programme and other matters relating to radiation protection;
(3) Radiation protection of the public, with all pathways of exposure taken into account;

(4) Radioactive waste management;
(5) Discharge, dilution and dispersion of radioactive effluents.

3.49. In considering these items, the regulatory body should satisfy itself that radiation doses to workers and the public and radioactive releases to the environment are acceptable. Specifically, review and assessment should ensure that:

(1) The operational limits and conditions and the bases for these have been determined;
(2) The potential radiological consequences at the upper limits of this range have been considered;
(3) It has been demonstrated that arrangements (including operating procedures) which apply the ALARA principle are in place.

3.50. The regulatory body should at all times require reasonably achievable improvements to be made in the design or operating procedures of the facility with the aim of reducing potential radiological consequences.

Safety analysis of fault conditions

3.51. The consideration of fault conditions strongly influences the design limits for the safety systems and for most SSCs needed for the operation of the facility [8]. It will also strongly influence the operational instructions and procedures that operating personnel should follow. In addition, the potential radiological consequences for workers, the public and the environment of fault conditions may be much more severe than those in routine operation. For this reason, the major part of the review and assessment effort should be directed to the safety analysis of fault conditions provided by the operator. It should be performed in accordance with the potential magnitude and nature of the risks associated with the particular facility. Safety analysis can be considered to consist of two major steps:

(1) Identification of postulated initiating events (PIEs) and their frequencies;
(2) Evaluation of how these PIEs develop and their consequences.

3.52. For post-closure performance assessment of the waste disposal facilities, consideration should be given to all significant features, events and processes that may affect the performance of the facility. A complete list of features, events and processes should be developed and criteria (with technical bases) for screening the features, events and processes should be clearly defined. Scenarios to be considered for performance assessment should logically follow from the features, events and processes selected for consideration.

Identification of PIEs

3.53. The identification of the PIEs which should be taken into account in the safety analysis is the first step in the review and assessment process. The method used should be systematic and auditable. Moreover, as complete as possible a listing of PIEs should be provided. An important feature of the review and assessment process should be considering whether the operator's method of identification meets these requirements and whether the operator's list of PIEs is acceptable as the basis for the safety analysis.

3.54. PIEs can be grouped in various ways. One commonly used method is to separate them into:

(a) External hazards, which are outside the control of the operator and may result from natural or human made causes such as a seismic event, an aircraft crash or an explosion of flammable liquid gas in transport.
(b) Internal faults that result from inherent failures of the facility, such as mechanical or electrical failures or loss of services.
(c) Internal hazards such as fire or spillage of corrosive material resulting from failures of systems that are within the operator's control but are not directly considered in the review and assessment process.

Consideration should also be given to human errors, which may be initiators in their own right or may exacerbate a fault.

3.55. It is usual to classify the PIEs relating to internal faults according to the initiating frequencies of the PIEs and their potential consequences. The purpose of such a classification is to help decide on the type and level of analysis that should be undertaken. The regulatory body should decide on which type of classification of PIEs it requires the operator to provide information so that it can decide whether its safety objectives and requirements have been met. The nature of the facility and the potential magnitudes of the risks it presents will influence these requirements, as well as the depth and level of detail of the subsequent analysis.

3.56. A typical PIE classification, based on initiating frequency, would be used to determine the following:

(a) PIEs that are of high likelihood, which should be analysed to show that the facility has a robust tolerance for them owing to the provision of safety systems or an inherent behaviour tending (i) to restore a safe state, (ii) to prevent the release of radioactive material or (iii) to limit any such release to an acceptably low level.

(b) PIEs that are of low likelihood but that have severe potential consequences such that the facility should have safety systems in place to prevent the release of radioactive material or to limit any release to an acceptable level.

PIEs which do not fall into these two groups should also be analysed to determine whether in totality they make an unacceptable contribution to the total risk, whether the PIEs in the classes defined are at a threshold for the rapid escalation of consequences (cliff edge effects), and whether the emergency arrangements are adequate.

Analysis of PIEs

3.57. The regulatory body should determine the type of analytical considerations and assumptions that will apply in its review and assessment of the operator's analysis, and should check whether these have been taken into account. For those PIEs that may affect the design and provision of safety systems, or may affect the requirements for engineering SSCs, sufficient safety margins may be required in the analysis to meet the requirement of demonstrating that the safety of the facility is robust. This part of the safety analysis should be coupled with consideration of the engineering and operational practices. The regulatory body, as part of its review and assessment, should ensure that all claims made in the safety analysis for the performance of such systems are met in practice. Similarly, the engineering systems should be qualified to meet the functional requirements for which they were designed: for all situations and at all times, with ageing and environmental conditions taken into account.

3.58. The analyses of fault conditions and long term safety should usually be performed by using computer codes. Regulatory review and assessment should include a check that any data, modelling or computer codes used in making calculations in relation to either the performance of equipment under the conditions indicated by the analysis or any radiological consequences are based on sufficiently well founded knowledge and understanding, and that an adequate degree of conservatism has been included. As part of its review and assessment, the regulatory body should ensure that the computer codes are based on well understood principles. Computer codes should be validated against experience or experiment to confirm that the coding has been done accurately and the input data have been correctly assigned. In many cases the codes will already have been used widely both nationally and internationally, and thus it will be possible to consider their verification and validity on a generic basis. However, checks should be made to ensure that the code has not been corrupted by modifications and is being used in an appropriate manner.

3.59. As a complement to the deterministic approach, the regulatory body should require an evaluation of the risks arising from the facility. A common method of

providing such an evaluation is for the operator to perform a probabilistic safety assessment[4] (PSA). Probabilistic safety assessment provides a comprehensive, structured approach to identifying failure scenarios and the corresponding damages to the facility, and, as a last step, to deriving numerical estimates of the risks to workers, the public and the environment. Likewise, PSA offers a systematic approach to determining whether the reliability and independence of safety systems are adequate for checking defence in depth provisions [9] and assessing whether the risks are ALARA. It is usual in such analyses to make less conservative assumptions and to consider best estimate values.

3.60. The regulatory body should review and assess the PSA in order to gain confidence that it has been carried out according to an acceptable standard so that the results can be used as input to the regulatory decision making process. For additional details on the capabilities and limitations of the methods of PSA, see Ref. [10]. In the review and assessment, it should be considered: whether the data used in estimating frequencies and probabilities are sufficiently well founded; whether the treatment of supporting systems, dependent failures and human intervention is appropriate; whether the bounding of PIEs into groups for analysis, if used, is sound; whether the identification of failure scenarios is comprehensive; and whether the analyses of the facility's response and consequences are acceptable. In some circumstances it may be appropriate to estimate the risk in a more qualitative manner using principles based on good operational or engineering practices, and for disposal facilities on the consideration of long term natural phenomena. The PSA should include a consideration of the sensitivity of the results to uncertainties in data and modelling and of the importance of individual events in the progression of the failure scenarios.

3.61. The insights gained from PSA should be considered together with those from other analyses in making a decision on the acceptability of the safety of a facility. An important aspect of PSA is that, apart from giving an estimate of risks, it also provides information on whether the design is balanced, on the interaction between design features of the facility, and on where there are weaknesses. These additional aspects should be given due consideration by a regulatory body reviewing a PSA.

3.62. It has been emphasized previously that in the regulatory review and assessment it should be verified that the claims made in the operator's submissions are accurate. In the consideration of the safety analysis, these checks should cover the manner in

[4] For waste disposal facilities, probabilistic risk assessment (PRA) is a more commonly used term.

which operations are carried out, the range of normal operational modes, the availability of standby equipment and personnel, and the performance of major items of equipment. These checks should also ensure that the identification of faults and hazards has been accurate, since some possibilities of common mode effects or causes — those due to internal hazards, for example — may not be apparent until the physical layout is observed. The layout may also limit the degree of operator intervention if systems are difficult to access owing to their position. In considering this aspect, the fact that access by the operator may be necessary because of another fault condition should be taken into account.

REGULATORY INSPECTION FOR REVIEW AND ASSESSMENT

3.63. Although a fundamental feature of the review and assessment process is the consideration by the regulatory body of the documentation provided by the operator, the regulatory body should also verify claims made in the documentation, as a necessary part of the process, by means of and inspections of the facility. Such verification should be carried out by specialists at all stages of the authorization process. These inspections will also allow the regulatory body to supplement the information and data needed for review and assessment. Additionally, the regulatory body will be able to extend its practical understanding of managerial, engineering and operational aspects involved and foster links with specialists in the operating organization. Where the operator fulfils some central functions away from the facility, the regulatory body should also visit the relevant parts of the operating organization. The staff of the regulatory body who carry out review and assessment shall have the right to visit, or to designate others to visit on their behalf, the operator's site and, if necessary, to visit contractors' establishments with the knowledge of the operator. Such visits may provide a good opportunity to access the adequacy and effectiveness of the quality assurance systems of the operator, the manufacturers and the suppliers.

3.64. It may be useful for the operator to arrange for those preparing, or involved in, complex submissions to make presentation(s) to key regulatory assessors highlighting the main technical issues raised and the analytical techniques used in the submissions.

RECORDS OF THE REGULATORY BODY'S REVIEW AND ASSESSMENT

3.65. The review and assessment process will invariably involve the production of reports by various experts in the regulatory body and by any consultants employed. A document control system should be set up for keeping records of the process so as to allow such documents and records to be readily retrieved. It should be possible to

access the bases for previous decisions so as to achieve consistency and to facilitate any reassessment made necessary by new information.

DOCUMENTATION PRODUCED BY THE REGULATORY BODY

3.66. Review and assessment should result in a decision on the acceptability of the safety of the facility which may be connected to a stage in the authorization process. The basis for the decision should be recorded and documented in an appropriate form. This documentation should summarize the review and assessment performed and should present a clear conclusion about the safety of the activity authorized (Ref. [4], paras 5.3–5.5). Typically, the following topics should be covered:

— Reference to the documentation submitted by the operator;
— The basis for the evaluation;
— The evaluation performed;
— Comparison with regulatory requirements, regulations and guides;
— Comparison with another similar (reference) facility where appropriate;
— Independent analysis performed by the regulatory body's staff, or by consultants or dedicated support organizations on its behalf;
— Conclusions with respect to safety;
— Additional requirements to be fulfilled by the operator.

RESEARCH AND DEVELOPMENT INITIATED BY THE REGULATORY BODY

3.67. The regulatory body may find that there are aspects of regulated facilities which are insufficiently understood. This may apply to existing or to future facilities. These aspects may involve, among other things, modelling techniques, processes or fault progression. The regulatory body should encourage the operator (or operators, if similar facilities exist or are planned) to carry out the necessary research and development work to extend understanding of safety related issues. The regulatory body should not accept a safety submission which is not supported by sufficient technical arguments and, if necessary, it should require from the operator a justification of the assumptions made and data used by means of additional studies.

3.68. The regulatory body may decide to initiate research and development work where it considers that there is a need for additional studies beyond those undertaken by the operator. There may also be situations in which the regulatory body requires independent research and development work so that it can apply suitable critical considerations in its review and assessment. For example, if the operator offers a

novel solution to a technical problem, in the form of either hardware or analysis, the regulatory body may conduct or contract independent research, or produce an independent interpretation of research findings, to validate and verify the approach. To ensure that the research and development work is carried out independently of the operator, the regulatory body should consider taking steps to ensure that sources of technical support are maintained which do not have direct contacts with the operator, in view of the fact that the operator itself may also be using outside organizations.

4. MONITORING OF THE REVIEW AND ASSESSMENT PROCESS

4.1. The regulatory body should ensure that the findings and decisions of the review and assessment process are subjected to a suitable process of peer review conforming to the national practices of the State and the overall quality assurance system of the regulatory body. The regulatory body should document the findings of its review and assessment and should make them available to the operator and others in accordance with national practice. Further information is provided in Ref. [4].

4.2. The regulatory body should have a system to audit, review and monitor all aspects of its review and assessment process so as to ensure that it is being carried out in a suitable and efficient manner and that any changes to the process necessitated by advances in knowledge or improvements in methods or for similar reasons are implemented. This system should cover, among other things:

(a) Regulations and guides;
(b) Procedures for assessment within the regulatory body;
(c) Procedures for contact with the operator;
(d) Availability of suitable staff for review and assessment;
(e) Procedures for using consultants and advisory committees in the process;
(f) Procedures for commissioning and evaluating research initiated by the regulatory body;
(g) Records of documentation;
(h) Production, recording and dissemination of the results of reviews and assessments.

Appendix

TOPICS TO BE COVERED BY REVIEW AND ASSESSMENT

A.1. This appendix provides a generic list of topics that should be considered in the review and assessment process throughout the lifetime of the facility, from site selection to decommissioning or closure. Each topic has been itemized; however, addressing all items does not necessarily mean that every aspect of safety has been fully covered. Also, depending on the facility and on the particular stage of the facility's lifetime, some topics will be more important than others, and the degree of detail necessary in the review and assessment may vary.

THE PHYSICAL NATURE OF THE FACILITY AND ITS ENVIRONMENT

A.2. The following information on the facility and on the processes conducted should be provided by the operator at various stages and used as a basis for review and assessment:

(a) A detailed description of the facility, supported by drawings of the layout, the systems and the equipment;
(b) Information on the functional capability of the facility, its systems and major items of equipment (including waste management systems and radiation protection systems and equipment);
(c) The findings of tests which validate the functional capability;
(d) The results of inspections of components;
(e) Maintenance records;
(f) A description of the present physical condition of SSCs on the basis of inspections or tests;
(g) A description of the support facilities available both on and off the site, including maintenance and repair shops;
(h) Geological, hydrogeological and meteorological conditions; and
(i) A description of off-site characteristics, including population densities, land use, industrial developments (including pipelines) and transport arrangements (such as airports, roads and railways).

INFRASTRUCTURAL ASPECTS

A.3. Throughout the lifetime of any facility, the operator will have to propose and implement arrangements for waste management. The regulatory body should review

and assess proposals for on-site treatment and storage of radioactive waste to ensure that the characteristics of the processed waste and the waste packages are compatible with the national strategy for radioactive waste, the applicable waste acceptance requirements for subsequent steps in waste management and regulatory requirements. Specifically, the regulatory body should satisfy itself that the waste or waste packages:

— Are properly characterized and compatible with the anticipated nature and duration of storage pending disposal;
— Can be subjected to regular surveillance; and
— Can be retrieved for further steps in predisposal waste management.

A.4. Adequate arrangements should be made for the transport of radioactive material and waste and equipment both on and off the site. The regulatory body should review and assess these arrangements and should satisfy itself that all national and regulatory requirements have been met.

SAFETY ANALYSIS

A.5. Throughout the lifetime of the facility, the regulatory body should review and assess the information on the facility provided by the operator, and in particular information covering:

(a) A compilation of the safety analysis and its assumptions;
(b) SSCs important to safety;
(c) Limits and permitted operational states;
(d) Anticipated operational occurrences;
(e) PIEs for the safety analyses:
    — External hazards (floods, seismic events, aircraft crashes, explosions of gas or liquid)
    — Internal faults (mechanical or electrical failures)
    — Internal hazards (fires, spillages of corrosive material);
(f) List of features, events and processes:
    — List of barriers with their relative contributions
    — A description of how requirements for defence in depth are met
    — Anticipated activities for confirmation of performance;
(g) Analytical methods and computer codes used in the safety analysis and the verification and validation of such codes;
(h) Radioactive releases and radiation exposures in normal operation and fault conditions;

(i) The operator's safety criteria for analyses of operator actions, common cause events, cross-link effects, the single failure criterion, redundancy, diversity and separation.

A.6. The impacts of the facility on its surroundings should be assessed. Social and economic issues, land use issues, technical issues such as detailed considerations of geology and hydrogeology, transport routes for the facility and protection of the environment should be taken into account in such an assessment. Both the anticipated impacts and the consequences of fault conditions, which are the subject of safety analysis, should be considered.

THE OPERATING ORGANIZATION AND THE MANAGEMENT SYSTEM

A.7. At all stages of the facility's lifetime, the operator should demonstrate that:

(a) It will be in control of the facility;
(b) It has an adequate safety management system to be able to manage and control the facility;
(c) It has resources available to meet its obligations and liabilities in connection with an authorization.

It should be noted that for some facilities (notably waste disposal facilities) this demonstration may need to apply to an extended period, perhaps covering several generations, over which control should be maintained.

A.8. The information that the operators should provide to the regulatory body for review and assessment should include:

(1) Details of the structure of the operating organization, showing that it has adequate control over the activities of its own staff and its contractors;
(2) A demonstration of the adequacy of resources in terms of appropriately trained and experienced staff, ensuring in-house expertise;
(3) A demonstration of the adequacy of the procedures for controlling changes to the organizational structure and resources;
(4) The specification and documentation of the duties of staff, demonstrating the integration of responsibilities for safety into their duties;
(5) A demonstration of the provision of, or access to, a high level of expertise in safety to carry out safety and engineering analysis and to perform associated audit and review functions;

(6) A demonstration of the adequacy of the provisions for financing continuing liabilities and decommissioning; and
(7) Any proposals for the use of contractors.

A.9. The operator should demonstrate an overall system for the management of safety whereby all activities are controlled so as to provide an assurance that requirements for quality assurance, safety and protection of the environment will be met. This will include having operational procedures in place.

A.10. The operator should demonstrate that it has:

(a) A mechanism for setting operating targets and safety targets;
(b) A policy which states that demands of safety takes precedence over those of production;
(c) Documented roles and responsibilities for individuals and groups;
(d) Procedures for the control of modifications to the facility;
(e) Procedures for the feedback of operational experience to the staff, including experience relating to organizational and management failures;
(f) Mechanisms for maintaining the configuration of the facility and its documentation;
(g) Formal arrangements for employing and controlling contractors;
(h) Staff training facilities and programmes;
(i) A quality assurance programme and regular quality assurance audits with independent assessors;
(j) A system for ensuring compliance with regulatory requirements;
(k) Comprehensive, readily retrievable and auditable records of baseline information and operational and maintenance history;
(l) Staffing levels for the operation of the facility that take account of absences, shift working and overtime restrictions;
(m) Qualified staff available and on duty at all times;
(n) Systematic and validated methods for the selection of staff, including testing for aptitude, knowledge and skills;
(o) Programmes for initial, refresher and upgrade training, including the use of simulators;
(p) Training in safety culture, particularly for managers;
(q) Programmes for the feedback of operational experience relating to failures in human performance;
(r) Guidelines on fitness for duty in relation to hours of work, health and substance abuse;
(s) Competence requirements for operating, maintenance, and technical and managerial staff;

(t) A system for consideration of the human–machine interface and its design and for the analysis of human information needs and task workload for the control room and other work stations.

OPERATIONAL PROCEDURES

A.11. The operator should demonstrate that it has produced or obtained:

(1) Formal approval and documentation for all safety related procedures;
(2) A formal system for modification of a procedure;
(3) Understanding and acceptance of the procedures by management and on-site staff;
(4) Verification that the procedures are followed;
(5) Procedures that are adequate in comparison with international good practice;
(6) Arrangements for regular review and if necessary revision of the procedures;
(7) Clear procedures in which principles relating to human factors have been taken into account;
(8) Procedures which comply with the assumptions and findings of the safety analysis and with experience from design and operation; and
(9) Adequate emergency operating procedures.

EQUIPMENT QUALIFICATION

A.12. The operator should provide:

(a) A list of equipment covered by the equipment qualification programme and a list of control procedures;
(b) A qualification report and other supporting documents (such as equipment qualification specifications and a qualification plan);
(c) Verification that the installed equipment matches the qualification requirements;
(d) Documentation of procedures to maintain qualification over the lifetime of the installed equipment;
(e) Information on mechanisms for ensuring compliance with these procedures;
(f) Documentation of a maintenance, testing and inspection programme and a procedure for providing feedback from it to ensure that ageing degradation of qualified equipment remains insignificant;
(g) Documentation of an analysis of the effects of equipment failure on the qualification of equipment not covered by the equipment qualification programme;

(h) A list of appropriate corrective actions to maintain equipment qualification;
(i) Information on means of protection of qualified equipment from adverse environmental conditions;
(j) Information on the physical integrity and functionality of qualified equipment;
(k) Records of all qualification measures taken over the installed lifetime of equipment.

MANAGEMENT OF AGEING

A.13. The operator should provide a programme for the management of ageing of equipment that covers:

(1) Documented methods and criteria for identifying SSCs covered by the ageing management programme;
(2) A list of SSCs covered by the ageing management programme and records which provide information for use in the management of ageing;
(3) An evaluation and documentation of potential ageing related degradation that may affect the safety functions of SSCs;
(4) Details of the extent of understanding of the dominant mechanisms of ageing for SSCs;
(5) Details of the programme for the timely detection and mitigation of ageing processes and/or ageing effects;
(6) Acceptance criteria and required safety margins for SSCs;
(7) Awareness of the physical condition of SSCs, including actual safety margins.

OPERATOR'S SAFETY PERFORMANCE

A.14. The operating organization should provide details of:

(1) The system used for identifying and classifying safety related incidents;
(2) The arrangements made for root cause analysis of incidents, the lessons learned and the follow-up measures taken;
(3) Methods for selecting and recording safety related operational data, including those for maintenance, testing and inspection;
(4) Trend analyses of safety related operational data;
(5) Feedback of safety related operational data into the operating regime, including records and reports of incidents and accidents;
(6) Analyses of safety performance indicators such as:

— Frequency of unplanned shutdowns of operation
— Frequency of selected safety system actuations and demands
— Frequency of safety system failures
— Unavailability of safety systems
— Annual individual and collective occupational radiation doses
— Trends in causes of failures (operator errors, equipment faults, administrative matters, control matters)
— Backlog of outstanding maintenance
— Extent of repeat maintenance
— Extent of corrective maintenance including repair and replacement
— Frequency of unplanned operator actions in relation to safety and their success rate
— Amounts of radioactive waste generated
— Quantities of radioactive waste in storage;

(7) Records of radiation doses to persons on the site;
(8) Records of off-site contamination and data from radiation monitoring for the site;
(9) Records of quantities and relevant characteristics of radioactive waste generated and stored in the facility;
(10) Records of the quantities of radioactive effluents discharged.

EXPERIENCE FROM OTHER FACILITIES AND RESEARCH FINDINGS

A.15. The operator should provide information on its arrangements for:

(a) Feedback of experience relevant to safety from similar facilities and from other nuclear and non-nuclear facilities;
(b) Assessing this experience and taking action on the basis of it;
(c) Determining the need for research and development;
(d) Obtaining information on the findings of relevant research programmes;
(e) Assessing research information and taking action on the basis of it.

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GLOSSARY

assessment. The process, and the result, of analysing systematically the hazards associated with sources and practices, and associated protection and safety measures, aimed at quantifying performance measures for comparison with criteria.

authorization. The granting by a regulatory body or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification, registration, etc.

closure. Administrative and technical actions directed at a repository at the end of its operating lifetime — e.g. covering of the disposed waste (for a near surface repository) or backfilling and/or sealing (for a geological repository and the passages leading to it) — and termination and completion of activities in any associated structures.

commissioning. The process during which systems and components of facilities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria.

decommissioning. Administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility (except for a repository which is closed and not decommissioned).

inspection. An examination, observation, measurement or test undertaken to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competence.

licence. A legal document issued by the regulatory body granting authorization to perform specified activities related to a facility or activity.

operational limits and conditions. A set of rules setting forth parameter limits, the functional capability and the performance levels of equipment and personnel approved by the regulatory body for safe operation of an authorized facility.

operator (operating organization). Any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia,

private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc.

postulated initiating event (PIE). An event identified during design as capable of leading to anticipated operational occurrences or accident conditions. The primary causes of postulated initiating events may be credible equipment failures and operator errors (both within and external to the facility), human-induced or natural events.

regulatory body. An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety.

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