DS473(V3)

Date: 7 July 2015

IAEA SAFETY STANDARDS

for protecting people and the environment

STEP 8: Soliciting comments by Member States

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

DRAFT GENERAL SAFETY GUIDE

GSG XXX (DS473)

IAEA
International Atomic Energy Agency

Contents

1. INTRODUCTION

BACKGROUND

1.1. Regulation is essential to ensure safety for all facilities and activities that give rise to radiation risks for people[1] and the environment. The existence of a legally based, independent, fully resourced, and technically competent regulatory body is a fundamental element outlined in Principle 2 of the IAEA's Fundamental Safety Principles, SF-1 [1]. This principle is reinforced and further defined as a requirement in the Safety Requirements on Governmental, Legal and Regulatory Framework for Safety, GSR Part 1 (Rev.1) [2]. Some of the content of this Requirements document is also included in the Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 3 [3], though the latter document does not develop additional requirements.

1.2. The Safety Fundamentals cover all facilities and activities and, similarly, GSR Part 1 (Rev.1) [2] is not restricted in its coverage. This Safety Guide will maintain the approach by providing guidance on safety regulation applicable to all facilities and activities[2], and in so doing promote a more consistent approach to the regulation of radiation risks. This is particularly important for Regulatory Bodies having responsibilities covering a range of facilities and activities that give rise to radiation risks or when interfaces are needed between various Regulatory Authorities, in order to facilitate co-ordination and co-operation.

1.3. This Safety Guides supersedes the following Safety Guides: Review and Assessment of Nuclear Facilities by the Regulatory Body (GS-G-1.2); Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body (GS-G-1.3); Documentation for Use in Regulating Nuclear Facilities (GS-G-1.4); Regulatory Control of Radiation Sources (GS-G-1.5) (part of); Licensing Process for Nuclear Installations (SSG-12) (part of) and Release of Sites from Regulatory Control upon Termination of Practices (WS-G-5.1) (the regulatory component only).

1.4. Many of this set of existing Safety Guides, were over ten years old and needed to be reviewed, and in some cases only covered a subset of the facilities and activities. To be able to include such a wide range of facilities and activities in a single safety guide it is necessary to apply a graded approach so that the degree of regulatory control and requirements varies in an appropriate manner.

1.5. This Safety Guide covers the technical aspects of a regulatory body's main functions as defined by GSR Part 1 (Rev.1) [2], and their interaction, as well as the associated processes.

---

[1] People, includes workers and the public [1]

[2] Facilities and activities, a general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other activity or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources.

1.6. Corresponding supporting functions are necessary to ensure that the main functions can be performed efficiently and effectively, supported by processes in the frame of an integrated management system. Also, the regulatory body should manage its organizational structure and staffing to support carrying out responsibilities and functions, in accordance with a graded approach. These aspects are covered in a companion Safety Guide, Organization, Management and Staffing of a Regulatory Body, DS472 [4]. It is strongly recommended that the two Safety Guides are treated as complementary guidance.

1.7. The information in these Safety Guides is intended to be mainly used by Regulatory Bodies but can be also useful for governments who are developing a regulatory framework for radiation and nuclear safety. It will also assist authorized parties and others dealing with radioactive materials in understanding regulatory procedures, processes and expectations.

OBJECTIVE

1.8. The objective of this Safety Guide is to provide practical guidance and recommendations on the regulatory body's main functions and the associated processes to implement those functions. The main functions to be addressed in this Safety Guide are those described in GSR Part 1 (Rev.1) [2] and GSR Part 7 [11] and include:

- development of regulations and guides;
- notification and authorization, including licensing procedures;
- regulatory review and assessment;
- regulatory inspection;
- enforcement;
- communication and consultation with interested parties;
- Emergency preparedness and response.

1.9. The main functions interact; for example, regulations and guides set out the regulatory requirements to be used in review and assessment, during the authorization process, in carrying out inspections, and when determining enforcement actions. Similarly, the findings of review and assessment guide the inspection approach and inspection provides areas for review and assessment. Both review and assessment and inspection may influence the development of regulations and guides. This Safety guide addresses these interactions.

1.10. As noted above, there are several supporting functions that are necessary to ensure that the main functions can be performed efficiently and effectively; these include:

- administrative support, including human resources, finance, management of relevant documents and records, equipment purchasing and control etc.;
- legal assistance;
- research and development processes;
- arrangements for contracting external expert support, where needed;
- establishment of advisory committees;
- organization of international links and co-operation.

These support functions and the associated processes are described in [4].

SCOPE

1.11. The Safety Guide covers the regulatory functions, and how they are discharged, during all the phases of the lifecycle of a facility or activity from initial design through to the release from regulatory control by means of processes. However, in line with the graded approach, the regulatory control and recommendations described will not be applicable to all facilities and activities and will differ according to the lifecycle stage: even where applicable, the depth and scope will vary.

1.12. The scope of this Safety Guide is limited to the regulation of safety and does not extend to nuclear security. The regulation of safety and nuclear security should be carried out in such a way that safety measures and nuclear security measures are designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security. The essential elements of an effective nuclear security regime are given in the Nuclear Security Fundamentals [17]. Guidance on addressing nuclear security aspects can be found in the Nuclear Security Series publications: Nuclear security recommendations on physical protection of nuclear material and nuclear facilities [5] and supporting guidance, and Nuclear Security Recommendations on Radioactive Material and Associated Facilities, [6] and supporting guidance.

TERMINOLOGY

1.13. The terminology used by organisations involved in operating facilities and conducting activities and their regulation, has evolved over many years and specific usages have become attached to specific facilities and activities. In the text a limited number of terms are used for simplicity and economy. For example, the terms ‘licence’, ‘authorization’ and ‘permit’ are considered to be synonymous; authorization may take different forms, such as licensing, certification, granting of a permit, registration, agreement, consent or granting of another similar regulatory instrument, depending on the governmental and regulatory framework of the particular State. In the text only the

words authorization, (which may be in the form of licensing or registration), and notification appear. The term “authorized party” is used in this Safety Guide to indicate the person or organization responsible for an authorized facility or an authorized activity, whether they are a licensee, registrant, operator or operating organization. Also, on grounds of simplicity and economy, the term “safety” is used throughout to mean “radiation protection and nuclear safety” and similarly the reference to “facilities and/or activities”, is used to cover all practices and applications of radiation sources. Finally, “lifetime of facilities and activities” is used to cover both the full “lifecycle of a facility” and the “duration of an activity”. “Lifecycle” is used to cover the stages of site evaluation, design, construction, installation, commissioning, operation, decommissioning and removal from regulatory control, though it is noted that whilst these stages apply for all facilities, they may not do so for all activities.

STRUCTURE

1.14. Section 2 of this document sets out the general requirements for applying a graded approach to nuclear and radiation safety regulation. Section 3 establishes the guidance for the regulatory functions and processes. Appendices 1, 2, 3 and 4 give more detailed guidance on authorization for the supply of consumer products, authorization conditions for stages of the authorization process, topics to be covered by review and assessment, and inspection areas for nuclear facilities, respectively.

2. GRADED APPROACH

2.1. Principle 5 of the Fundamental Safety Principles [1], states that: "The resources devoted to safety by the [licensee] authorized party, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the possible radiation risks[3] and their amenability to control." To apply this principle, a graded approach needs to be taken in carrying out the regulatory functions for the wide range of facilities and activities described in Section 1, owing to the very different levels of possible radiation risks associated with them.

2.2 Requirement 1 of GSR Part 1 (Rev.1) [2] applies this principle to establishing a national policy and strategy for safety and its implementation "which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities". It is also stated that the intention is "to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body".

2.3. Specifically, reference is made to the use of the graded approach in relation to the six main functions that are subject to Requirements in GSR Part 1 (Rev.1) [2]:

- **Regulations and guides** "shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach". (Requirement 34: paragraph 4.62).
- **Notification and Authorization "**The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach." (Requirement 24: paragraph 4.33).
- **"Review and assessment** of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach." (Requirement 26).
- **"Inspections** of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach." (Requirement 29).
- **Enforcement** "The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach." (Requirement 31, paragraph 4.54).

[3] The term 'possible radiation risks' relates to the maximum possible radiological consequences that could occur when radioactive material is released from the facility or in the activity, with no credit being taken for the safety systems or protective measures in place to prevent this [9].

- **Communication and consultation with interested parties "**Public information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach." (Requirement 36, Paragraph 4.69).

Furthermore, GSR Part 7, the Requirements for Preparedness and Response for a Nuclear or Radiological Emergency [11], requires that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency (Requirement 4).

2.4. Thus all the functions discussed in later sections should be subject to a graded approach so that whilst descriptions of the functions are generic, the degree of application varies in accordance with the facility or activity. For example, the degree of review and assessment applied to a nuclear power plant would clearly not be to the same as the one for a medical X-ray unit.

2.5. The main factor that should be taken into consideration in the application of a graded approach is that the application of the regulatory functions has to be consistent with the magnitude of the possible radiation risks arising from the facility or activity. The approach should also take into account any exposures to radiation and discharges or releases of radioactive substances during normal, abnormal and accident conditions, as well as the possibility of events with a very low probability of occurrence [19][4].

2.6. Other relevant factors, such as the maturity or complexity of the facility or activity and the knowledge and expertise of the authorized party, should also be taken into account in a graded approach to regulatory activities. The consideration of maturity relates to the use of established practices and procedures, established designs, data on operational performance of similar facilities or activities, uncertainties in the performance of the facility or activity, and the continuing and future availability of experienced manufacturers and constructors. Complexity relates to the extent and difficulty of the effort required to construct and operate a facility or to implement an activity, the number of related processes for which control is necessary, the extent to which radioactive material has to be handled, the longevity of the radioactive material, and the reliability and complexity of systems and components, and their accessibility for maintenance, inspection, testing and repair. These factors need special consideration during decommissioning or clean-up activities which will involve new procedures and processes not used during other lifecycle stages, e.g. institutional controls, including continuing environmental monitoring programs and radiological status.

2.7. The application of the graded approach should be reassessed as a better understanding is obtained of the radiation risks arising from the facility or activity. For example, the extent and frequency of inspections (GSR Part 1 (Rev.1), para 4.52 [2]) in the periodic inspection planning may be adapted according to the trend of findings from previous inspections. In each of the following sections of

[4] An approach to screening of events based on their probability is included in [19].

Chapter 3, more detailed consideration is given to the application of the graded approach to the specific main functions described.

3. MAIN REGULATORY FUNCTIONS AND PROCESSES

3.1. The main functions of a regulatory body are described in the following sections. The first sub-section describes the Regulations and Guides that set out the safety requirements for operating a facility or conducting an activity and procedures and processes that should be carried out by the regulatory body staff and the organizations that are regulated. These include the process for Notification or Authorization of the use of radioactive material which is expanded on in the next subsection. The following subsections cover the regulatory body responsibilities from initial application to operate a facility or conduct an activity and subsequently during the whole lifecycle. The regulatory body carries out Review and Assessment on all information relevant to safety, much of which will be submitted by the regulated organisation as part of the notification or authorization process, to ensure that all safety requirements are being addressed. The regulatory body also carries out Inspections of the facility or activity to ensure compliance with the safety requirements. Where there is non-compliance or violations, Enforcement is used to return the facility or activity to a safe situation. The regulatory body, in most States also has a role in emergency preparedness and response, though this varies according to national practices. Finally, Communication and Consultation with interested parties is important throughout all the whole lifetime of the facility or activity to inform and obtain the views of the public.

REGULATIONS AND GUIDES

General

3.2. The provision of regulations and guides are subject to Requirements 32-34 of GSR Part 1 (Rev.1) [2].

3.3. The system of regulations and guides should suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated.

3.4. The provision of regulations and guides should be a means for the regulatory body to ensure that regulatory control is stable and consistent, to emphasize the continuous enhancement of safety as its general objective and to build confidence among interested parties [2].

3.5. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms should ensure that such regulations are developed and approved in a timely manner. The regulatory body should advise the government on the need to issue regulations on matters affecting safety.

3.6. The regulatory body should specify the purposes of the various regulatory documents necessary to perform its functions. The documents may be categorized as comprising legislation and regulations (mandatory by law), supporting guides (not mandatory by law) to be used either by the authorized parties or by the regulatory body (internal guidance) and other advisory documents.

3.7. A system of guides will help the regulatory body to maintain consistent practices in implementing its requirements. However, the regulatory body should refrain from prescribing specific solutions. The advisory status of a guide carries the implication that alternative approaches would be acceptable provided that the authorized party can demonstrate that the required level of safety will be achieved.

3.8. Internationally recognized standards and recommendations as well as technical standards developed by organizations working in various technological fields may be referenced by the regulatory body in regulations and guides, set out in the authorization conditions or proposed by the authorized party in the authorization process.

3.9. The regulatory body should establish a system to ensure the implementation of regulations and guides based on a graded approach, such that the application of regulatory requirements is commensurate with the radiation risks associated with the types of facilities and activities and the exposure situations.

Objectives of Regulations and Guides

3.10. An important objective of the regulations and guides is to ensure the stability and consistency of regulatory control and to prevent subjectivity in decision making by the individual staff members of the regulatory body. In this way, the regulatory body should be able to justify its decisions if they are challenged. The regulations and guides should also enable the regulatory body to inform authorized parties and applicants of the objectives, principles and associated criteria for safety on which its requirements, judgments and decisions, in connection with its reviews and assessments, inspections and enforcement actions, are based.

3.11. As part of its integrated management system, the regulatory body should establish a process for the development of regulations and guides. This process should ensure that regulations and guides:

- provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization;
- establish the criteria to be used for assessing compliance;
- are kept up-to-date;
- are consistent and comprehensive;
- provide adequate coverage commensurate with the radiation risks associated with the facilities and activities;
- involve consultations with interested parties.

Objectives of Regulations

3.12. Regulations which have the force of law are issued either by the government or by the regulatory body on behalf of the government. The principal purpose of establishing a system of regulations is to

codify safety requirements of general applicability, which require mandatory compliance on all authorized parties. The system of regulations adopted should provide an appropriate balance between regulatory provisions that are numerous and detailed enough to achieve and maintain safety, and flexible enough to permit their application to developing technologies and in new circumstances. The degree to which the regulations are performance based or prescriptive, and the level of detailed guidance produced, depends on the national approaches, however, regulations and guides should not reduce the authorized party's prime responsibility for safety.

3.13. It should be recognized that a system of regulations is no substitute for good technical and good administrative approaches. Unduly detailed formal regulatory requirements can inhibit engineering innovation and good management initiatives, and may even be counterproductive if they have the effect of relieving or tending to relieve the authorized party of the responsibility for safety. Only a serious concern for safety on the part of all those concerned, not limited to the obligation to meet regulatory requirements, will engender a strong safety culture and bring about lasting resolutions of safety issues.

Objectives of Guides

Guidance on Regulations

3.14. Irrespective of the degree to which the Government or regulatory body has developed prescriptive regulations, the regulatory body should give consideration to supplementing its regulations, with supporting guides of non-mandatory nature on how to comply with regulations, where appropriate.

3.15. Guides are advisory in nature; they should be prepared to allow the authorized party more flexibility in applying new technologies and developing new procedures which, in some cases, may enhance safety. They also allow the regulatory body to promote learning by modifying its guides to include innovative good practices and to revoke impractical or unnecessary provisions.

3.16. The overall purpose of guidance is to advise the authorized parties on how to comply with laws and regulations and to provide guidance on how to implement general and specific regulatory requirements, thus enhancing safety and improving effectiveness and efficiency. Guides also provide detailed and specific information on acceptable technical and administrative approaches to satisfying the regulatory requirements established in the regulations. Guides should, of course, always be consistent with the law and regulations.

3.17. In issuing guides, recent operational experience and developments should be taken into account, including technological advances that have been shown by experience or shown by research results to be capable of providing effective and reliable means of satisfying regulatory requirements.

3.18. The regulatory body should, where appropriate, also support the production of guidance documents by professional bodies wishing to help their members in the discharge of their

responsibilities regarding safety.

Internal Guidance

3.19. The regulatory body should provide internal guidance, to be used by its own staff, on the procedures to be followed for the completion of its tasks (e.g. notification, authorization, review and assessment, inspection, enforcement) as well as on the safety objectives to be met. Detailed guidance on specific topics should also be provided, as necessary. Consideration should be given to the extent to which the regulatory body's internal guides may be made available to authorized parties and the public. Publication is an important aspect of communication with interested parties and through openness it demonstrates how the regulatory body is discharging its responsibilities in an appropriate manner.

Relationships between regulations, guides and authorization conditions

3.20. In determining whether a particular topic should be made mandatory and thus be addressed in a regulation rather than a guide, consideration should be given to the regulatory requirements and the extent to which the topic in question can be considered as essential for implementing these requirements.

3.21. Safety requirements that are common to a particular type of facility or activity should be established in the regulations. Other requirements, such as those applicable for only a short duration or relating to particular characteristics, of facilities or activities, should be specified in any conditions attached to the authorization (authorization conditions, see para 3.110) and thus become mandatory. However, the extent to which detailed provisions are made in authorization conditions will depend upon the legal system and the authorization philosophy of the State concerned.

3.22. The authorization conditions should, where appropriate, include or refer to: technical limits and conditions; a system for reporting events, modifications and incidents to the regulatory body; and other requirements, depending on the magnitude of the radiation risk, the nature of the facility or activity, and the stage in the lifecycle of the facility or activity. More information regarding authorization conditions are given in the sub-section dealing with authorization (see para 3.69).

Scope and Content of Regulations and Guides

3.23. The government and regulatory body are required to establish a regulatory system for safety that includes (GSR Part 3, para 2.30 [3]):

(a) Notification and authorization; regulations should provide clarity and transparency in the notification and authorization process;

(b) Review and assessment of facilities and activities; regulations should require a demonstration of the safety of the facility or activity which should enable the regulatory body to make a decision or series of decisions on the acceptability of the facility or activity in terms of safety;

(c) Inspection of facilities and activities; in order to ensure that facilities and activities are inspected to a common standard, based on a graded approach, and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail;

(d) Enforcement of regulatory requirements; the regulatory body should adopt clear administrative procedures and guidelines governing the use and implementation of enforcement actions;

(e) The regulatory functions relevant to emergency and existing exposure situations;

(f) Provision of information to, and consultation with, parties affected by its decisions and the public and other interested parties.

3.24. The Government and regulatory body should ensure that the following technical, administrative and procedural topics and requirements are covered in the regulations, if appropriate, depending on the State's legal system and practices:

(a) The exact name and location of the regulatory body;

(b) The purpose of the regulations, their scope and their date of entry into force;

(c) The powers of the regulatory body, such as powers of authorization, inspection and enforcement;

(d) The relationship of a given set of regulations to other governmental regulations in force;

(e) The criteria to be met in an application for exemption from certain procedural aspects of the regulatory requirements;

(f) Requirements for occupational radiation exposure, public radiation exposure, dose limits, medical exposure, safe decommissioning of facilities, management of radioactive waste, transport of radioactive material and emergency exposure situations;

(g) The financial assurance for dealing with orphan sources, radiological accidents and waste management (including decommissioning and waste disposal);

(h) Acceptance criteria and performance criteria for any manufactured or constructed source, device, equipment or facility that in use has implications for safety;

(i) Criteria and methods for assessing the adequacy of the implementation of remediation following the spread of contamination by radioactive materials;

(j) Safety criteria and planning for predisposal radioactive waste management and discharge monitoring, as well as aspects of institutional controls at different phases of the authorized facility lifecycle, and license termination.

Exposure Situations

3.25. It is required that the regulatory body establish or adopt regulations and guides for safety

covering the different exposure situations[5] namely, planned, emergency and existing exposure situations, (GSR Part 3, Requirement 3 [3]).

Notification and authorization

3.26. It is required that any person or organization intending to operate a facility or conduct an activity should submit to the regulatory body, as appropriate, a notification or an application for authorization, unless exemption applies, (GSR Part 3, Requirement 7 [3]). Within regulations, the regulatory body should provide criteria or lists of activities clarifying those needing notification or authorization.

3.27. The regulations should specify the requirements for authorization of facilities and activities and for ensuring the protection of people and the environment. They should establish at least those requirements considered by the regulatory body to be necessary for achieving and maintaining safety, and should cover all the major aspects to be dealt with at all stages of the authorization process.

3.28. It is required that the applicant submits or to makes available to the regulatory body, in accordance with agreed timelines, all necessary safety related information, as specified in advance or as requested in the authorization process, (GSR Part 1 (Rev.1), para 4.34 [2]). The regulatory body should issue detailed guidance for applicants on how to notify or how to apply for authorization.

This may include as appropriate:

(a) Guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization, including printed (or electronic) forms to be completed by authorized parties in a question and answer format, so that all relevant information is gathered. Guidance on the format and content of the safety analysis report for nuclear power plants is provided in [32];

(b) The regulations and standards to be applied should also be clearly stated;

(c) Advance information, on the requirements for each major stage of authorization, assisting the authorized party to make sound plans and decisions with respect to safety in the siting, design, construction, commissioning, operation and decommissioning or closure of a facility or performance and termination of an activity.

Main contents of an authorization

3.29. The main content of an authorization, as well as the authorization conditions, should be specified within regulations and guides. Details regarding the content of authorization are given in the sub-section dealing with Notification and Authorization.

Documentation to be submitted by the authorized party

[5] For existing exposure situations, the use of the concept of end-state based on a risk-informed approach, considering site specific conditions, is more appropriate, particularly when considering costs, socio-economic factors, and stakeholder input as key factors in developing end-state safety criteria and implementation aspects.

3.30. Regulations and guides covering the authorization process should identify the essential documents to be prepared and submitted by the authorized party in the authorization process. Additional documents may be requested as needed depending on the type of the facility or the activity in accordance with a graded approach and on the specific stage of the authorization process.

3.31. Regulations and guides should indicate other documents that should be submitted to the regulatory body to confirm that the requirements established in the regulations and authorization conditions have been satisfied. Details regarding the documentation to be submitted by the authorized party are given in the sub-section dealing with Notification and Authorization.

Reporting of events, incidents and accidents

3.32. Regulations or authorization conditions should specify the requirements for reporting to the regulatory body events, incidents or accidents considered significant to safety. The regulations or authorization conditions should specify the events that require reporting, the method of reporting and the reporting time limit. They should also specify that an investigation should be carried out by the authorized party and a report prepared and submitted to the regulatory body within a specified period of time, covering details of the event, incident or accident, details of doses associated, the findings of the investigation performed and proposals for corrective actions. All the above should be applied commensurate with the severity of the event.

Reporting of changes, modifications and non-conformances

3.33. Regulations and guides should contain requirements for reporting of, based upon their safety significance: changes to the design, prior to their implementation; and design deficiencies and non-conformances identified during commissioning or operation.

Records to be kept by the authorized party

3.34. Regulations and guides issued by the regulatory body should include the requirements for the authorized party to keep adequate records relating to the safety of facilities and activities. These records, even if not formally requested by the regulatory body for review and approval, should be made available upon request. Regulations or authorization conditions should establish the types of records that should be kept and the periods for which they should be retained. In specifying the retention period, account should be taken of the possible future need to refer to these records and of the difficulties of regenerating the information. More information and indicative types of records that should be kept by the authorized party are included in the subsection on Notification and Authorization.

Records to be kept by the regulatory body

3.35. It is required that the regulatory body make provision for establishing and retrieving adequate records relating to the safety of facilities and activities (GSR Part 1 (Rev.1), Requirement 35 [2]). Internal guides of the regulatory body should clarify the provisions made by the regulatory body for

the establishment and maintenance of the following main registers and inventories, which may be held by the regulatory body or by the authorized party:

—Registers of sealed radioactive sources and radiation generators;

—Records of occupational doses;

—Records relating to the safety of facilities and activities;

—Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;

—Records of events, including non-routine releases of radioactive material to the environment, damage or loss of a source or malfunction of a device;

—Inventories of radioactive waste and of spent fuel.

If the regulatory body is not the sole entity responsible for the maintenance of these registers and inventories, it should ensure that the authorized party has arrangements for their proper retention and retrieval. The responsibility of the regulatory body to maintain safety related records at the national level should not diminish the responsibility of authorized parties to keep their own records, as explained in the following sections of this guide.

Review and assessment

3.36. It is required that the regulatory body reviews and assesses relevant information to determine whether facilities and activities comply with regulatory requirements, (GSR Part 1 (Rev.1), Requirement 25 [2], GSR Part 3 Requirement 13 [3]). It is also required that the review and assessment is commensurate with the radiation risks associated with the facility or activity in accordance with a graded approach, (GSR Part 1 (Rev.1), Requirement 26 [2]). In order to fulfil these requirements, the regulatory body should:

(a) issue regulations for safety assessments to be performed by the authorized party to the facility or activity, which should be submitted prior to the granting of the authorization at each lifecycle stage. These requirements should be in accordance with the relevant provisions of GSR Part 3, para 3.31-3.36 [3];

(b) establish internal guidance on the safety objectives to be met as well as detailed guidance on specific topics for review and assessment, as necessary. The internal guidance should also establish the procedures to be followed in the review and assessment process of an application for authorization, to provide assurance that all topics significant to safety will be covered and that authorized parties for similar facilities or activities will be treated equally.

3.37. The regulatory body should determine which requirements, regulations, guides and industrial standards are applicable to each type of facility or activity, and should determine the requirements to be placed on the authorized party for each type of facility or activity. Where there are no such

requirements, regulations, guides or industrial standards in force, 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 for deciding on the acceptability of an authorized party's submission. The regulatory body should issue guidance on reporting on its review and assessment activities and how it reaches its regulatory decisions. It is considered good practice that the review and assessment procedural and technical guidance documents should be made available to regulatory bodies worldwide.

Regulatory inspections

3.38. The regulatory body should issue guides for its inspectors for performing regulatory inspections, in order to ensure a consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise; each inspector should be given adequate training in following this guidance.

3.39. Appropriate subjects for guidance for inspectors should include:

(a) Policies of the regulatory body regarding inspections;
(b) The legal basis for regulatory inspection and the scope of the inspector's authority;
(c) The use of regulatory requirements, regulations, guides and standards;
(d) Development of an inspection programme;
(e) Implementation of the inspection programme, including:
    - facilities (or areas of the facility) or activities to be subject to inspection;
    - method of inspection to be used;
    - methods for selection of inspection samples;
    - use of relevant technical information;
    - use of inspection questionnaires;
    - follow-up on inspection findings.
(f) Reporting requirements and practices for inspectors;
(g) Standards of conduct of inspectors;
(h) Enforcement policy, procedures and practices.

3.40. The regulatory body should stress in the guidance the importance of objectivity and fairness on the part of inspectors, together with the need to respect the rules for the facility or activity as established by the authorized party.

Enforcement process

3.41. Regulations and guides governing the use and implementation of enforcement actions should be issued by the Government and regulatory body, as appropriate, stating the policy for the use of

regulatory and enforcement measures and the associated authority delegated to inspectors and other regulatory body staff. Depending on national practices, the need to allow the authorized party to state a point of view on regulatory decisions, to respond to enforcement actions and to appeal against enforcement decisions should be recognized and taken into account in regulations and guides. In some Member States, the regulations and guides require that a hearing of the authorized party is initiated before issuing significant enforcement actions. Guides should cover in detail the decision making approach of the regulatory body in determining the level of actions to be taken and the way in which the actions should be taken, including dealing with failure of the authorized party to comply with requirements for regulatory enforcement.

3.42. Guides should indicate which other governmental organizations, if any, should be informed in the event of enforcement actions.

3.43. The regulatory body should issue internal guides for its staff, in order to ensure a systematic and consistent approach to the enforcement process.

Exemption and clearance from regulatory requirements

3.44. GSR Part 3 Requirement 8 [3] states: "The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control."

3.45. In this respect, the regulatory body should determine within the regulations (in keeping with the general approach in this Safety Guide, the word "activities" is substituted for "practices"):

(a) which activities (including use of radiation sources) are to be exempted from some or all of the legislative requirements, including the requirements for notification or authorization. The regulatory body should use as a basis for this determination the criteria for exemption specified in Schedule I of [3], or specify any exemption levels based on these criteria. The regulations should clearly state that exemption cannot be granted for activities which have not been justified;

(b) which sources, including materials and objects, within notified or authorized activities may be cleared from further regulatory control. The regulatory body should use as the basis for this determination the criteria for clearance specified in Schedule I of [3], or specify any clearance levels based on such criteria. By means of these arrangements, the regulatory body should ensure that sources that have been cleared do not again become subject to the requirements for notification, or authorization unless it so specifies.

Release criteria

3.46. In the regulations and guides generic release criteria should be included for the evaluation of potential radiological consequences associated with a site after its release. In order to derive release

criteria (in, for example, Bq/g or Bq/cm^2), all exposure pathways should be considered and dose assessment involving direct radiation, inhalation and ingestion pathways should be used.

3.47. Alternatively, the authorized party can derive site specific release criteria, on the basis of an optimization process, which the regulatory body should review, asses and approve, if considered adequate.

3.48. The release criteria to be used in the regulations and guides should be based on an optimization process. This process should allow for iteration between individual steps of the cleanup process.

Process for Developing, Review and Revision of Regulations and Guides

3.49. GSR Part 1 (Rev.1), para 4.61 [2] states: "The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides." In the following, guidance regarding the general procedure and steps to be followed in developing, reviewing and revising of regulations and guides is given.

Sources of information and general guidance

3.50. The nature of the national legal framework, more than any other single factor, will determine the form and content of the regulations and guides. The regulatory body should base its regulations and guides on national legislation and should utilize existing national regulations or technical standards in areas relating to or adaptable to facilities and activities as its initial sources of information. The degree to which the regulations are prescriptive will depend on national approaches. In some States, for example, detailed guidance would be preferred to prescriptive regulations.

3.51. Whilst regulations may be established, in whole or part, by government, the regulatory body should be involved in the development process. In the following paragraphs, it is the role of the regulatory body that is covered in the development process.

3.52. In developing regulations and guides, consideration should be given to adopting, as a reference, the IAEA's safety standards. The IAEA's safety standards are issued in the form of specific requirements and recommendations so as to facilitate their incorporation into regulations. Although IAEA safety standards may be adopted individually or collectively, adaptation, rewording and amending may be necessary, depending on the national legal system. IAEA safety standards that are expressed in a general way may be implemented in a State by introducing appropriate requirements into regulations or by adapting the standards as national guides. In addition, States embarking on a nuclear programme should also consider regulations developed by the State supplying the facility.

3.53. Consideration should be given to obtaining advice and support in developing regulations and guides from organizations such as the IAEA and from the regulatory bodies of other States. When the design of a facility or the performance of an activity originates in another State, it may be particularly useful to seek advice and support from the regulatory body of that State.

3.54. When regulations, guides and other relevant information produced by regulatory bodies in other States is considered in the development of regulations, particular attention should be paid to the legal framework of that State. Owing to differences between States in legal and governmental infrastructures, and in the structure of industry and available resources, it is unlikely that the regulatory body will be able to adopt without revision regulations issued in another State. In adapting regulations and guides issued in other States, the regulatory body should ensure that it understands the regulations in terms of their technical background and significance, and the legal and regulatory framework in the State that issued them.

3.55. The regulatory body, as part of the drafting process, should consider performing comparison exercises of the national standards with international ones.

3.56. Consideration should also be given to other sources of information relevant to safety, this could include: relevant industrial standards (in their entirety or in part); technical standards developed in other States; experience in the nuclear and radiation industry; and the results of research in nuclear and radiation safety.

3.57. The regulatory body may find it useful to set up advisory committees to advise on the need for regulations and on their technical content. A well founded committee can provide a valuable service to the regulatory body by helping to ensure that policies and regulations are clear, practicable and complete.

3.58. The regulatory body should follow a general and consistent process for establishing, reviewing and revising regulations and guides. It should be well documented, comprehensive, covering all regulated activities and facilities, with clear allocation of responsibilities.

3.59. The process should be based on clear procedures and should be flexible enough to take account of changing technological, legal and practical. Due to variations in the legal systems and practices of States, it is impossible to provide detailed procedural guidance for establishing regulations and guides to be used by all States. However, certain basic steps for establishing regulations and guides could be specified.

Process for developing regulations and guides

3.60. The process used by the regulatory body to establish regulations and guides should include the following steps:

(a) *Determination of the need for the regulations and guides.* The need for the regulations and guides may arise from the regulatory body's activities within its sets of responsibilities and

functions and from the inventory of facilities and activities in the State. Alternatively, the need may be identified as a result of a request or enquiry by an authorized party. Additionally, regulations may be needed as a result of national debates or to meet international obligations;

(b) *Setting the priority for the development of regulations and guides.* The regulatory body should consider the advantages and disadvantages of the proposed regulations and guides, including such matters as: the risk associated with the facility or activity; the need and associated costs for improvements in safety; the number of authorized parties to be affected; the effects on the efficiency of the authorization process; and the feedback of information and experience from review and assessments, inspections, investigations and enforcement activities;

(c) *Determination of the scope of the regulations and guides.* The first step towards the development of regulations should be to identify clearly the facilities and activities to which regulatory requirements are to be applied as well as the stage of the authorization process to be covered and the technical topic to be addressed.

(d) *Determination of the resources necessary.* Development of regulations and guides requires sufficient suitably qualified, competent and experienced people to be available and adequate financial resources [4]. The need for the regulation or guide and the timescale required for the preparation and establishment will be a factor in determining the resources required.

(e) *Collection of information.* The information necessary to prepare the proposed regulations and guides should be collected;

(f) *Drafting of the regulations and guides.* The staff of the regulatory body, consultants, professional societies or advisory committees may draft the initial versions of the regulations and guides. Regulations and guides should be written in a style that is clear and easy to understand. They should be relevant, precise and unambiguous so as to be readily applicable and enforceable;

(g) *Review of the regulations and guides.* Although practices vary widely, legal staff and special advisory committees, as appropriate, would usually review the initial versions of the proposed regulations and guides. In some States, authorized parties, professional societies or other organizations participate in these reviews. A draft version may also be published provisionally with an invitation for comment from the interested parties. Comments received as a result of the review should be analyzed, evaluated and resolved as appropriate. A review of the final draft for quality control should be carried out before formal approval. At this stage consideration should also be given to the implications of the regulations for existing facilities and activities;

(h) *Establishing and issuing the regulations and guides.* Regulations should be established and promulgated in a manner that makes them legally binding according to the national legal system, thereby ensuring that their provisions can be enforced by the regulatory body. The

procedure for issuing safety guides should follow steps similar to those for regulations, but a guide can be formally issued with a lower level of approval, since its contents are only advisory in nature.

3.61. Consideration should be given to grouping the guides into several broad categories as follows, but not limited to:

(a) Detailed or specific recommendations, concerning facilities, activities, equipment, operating procedures and protocols, and the qualification and training of personnel, that pertain to a specific radiation activities and that can be adopted by authorized parties as a means of meeting regulations;
(b) Practical protection and safety manuals covering various activities and procedures that serve as aids for the training of workers and for management in setting up local rules;
(c) Procedural guides such as those pertaining to instrument calibration, individual monitoring, environmental surveys and radioactive waste management, for use by authorized parties and/or technical service providers;
(d) Guidance relating to the safety of persons undergoing medical exposure;
(e) Safety assessment plans that identify areas that need to be evaluated or reviewed for the authorization;
(f) Guidance on the safe transport of radioactive material;
(g) Procedures for the conduct of investigations;
(h) Plans and procedures for emergency preparedness and response.

Process for review and revision of regulations and guides.

3.62. The regulatory body should ensure that regulations and guides are kept up to date and should establish procedures, within its integrated management system, for their periodic review.

3.63. Experience in implementing the regulations should be examined and any problems or difficulties that may arise should be duly considered. The status of applicable requirements should also be examined in the light of new safety related developments. The possible effects of frequent changes in regulations and guides on the stability of the regulatory system should be taken into account. However, events may occasionally occur that necessitate more frequent revisions. The reasons for revising regulations may include: changes in legislation; changes in the organization, responsibilities, policies or procedures of the regulatory body; experience gained by the regulatory body in the authorization process; feedback of information and experience from events, incidents and accidents, as well as from relevant national and international good practices; technological advances; and the need to improve or eliminate any impractical, misleading, unenforceable or otherwise inadequate regulations.

3.64. The procedures applicable in the development of regulations can also be followed when making any necessary revisions. Authorized parties and other interested parties potentially affected by the revised regulations should be given adequate time to complete any preparations that may be necessary to enable them to comply with newly established requirements.

3.65. The process and procedures established for the revision of regulations and guides should not diminish the authority of the regulatory body to take immediate action if required for reasons of safety.

Impact of revision of regulations

3.66. It is required that the regulatory body should recognize the risks associated with making modifications to well-established procedures and processes. Prospective changes in regulatory requirements should be subject to careful scrutiny, in accordance with the procedures in the integrated management system, to evaluate the possible enhancements in safety that it is intended to achieve. The regulatory body should also inform and consult interested parties in relation to the basis for such proposed changes in regulatory requirements, (GSR Part 1 (Rev.1), para 4.27 [2]).

3.67. In revising regulations, special care should be taken to ensure that no contradictions or inconsistencies arise between the retained and the revised parts of a regulation.

3.68. The extent to which the proposed changes should be applicable to facilities and activities that have already been authorized and the degree of back-fitting to be required should also be considered.

NOTIFICATION AND AUTHORIZATION

General and Basic Principles

3.69. GSR Part 1 (Rev.1), Requirement 23 [2] requires that "Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process".

3.70. The authorization process is the principal mechanism connecting the legal framework of the regulatory system (laws and regulations) with the responsibilities of the principal parties concerned with the regulatory system (the regulatory body, applicant and the authorized party).

3.71. The terms notification and authorization (by registration or licence) indicate broadly an appropriate type of control based upon the levels of risk or complexity associated with facilities and activities.

3.72. The regulatory body should determine which facilities or activities may be exempted from the requirements for notification or authorization using as the basis for this determination the criteria for exemption specified in Schedule I of [3] or any exemption levels specified by the regulatory body based on these criteria.

3.73. Notification is defined in [3] as a document submitted to the regulatory body by any person or organization intending to operate a facility or conduct an activity which involves the use of radiation sources. Notification alone is sufficient provided that the exposures expected to be associated with the facility or activity are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible.

3.74. Where notification alone is insufficient because the exposures expected to be associated with the facility or activity have the potential to exceed the limit, as specified by the regulatory body, an application for authorization should be submitted to the regulatory body. An application for authorization may also serve as notification. Where a notification has been submitted, but the regulatory body determines that the potential exposure limits exceed the limit, an authorization should be required.

3.75. Authorization should be in the form of registration or granting of a licence. Other terms are used for authorization including certification, granting of a permit, agreement, consent, approval or granting of another similar regulatory instrument, depending on the governmental and regulatory framework of the particular State. For more complex facilities or activities and where the potential radiation risks are significant, the authorization process is usually referred to as a licensing process which results in a licence, in the form of a legal document, issued by the regulatory body granting authorization to perform specified activities relating to operation of a facility or conduct of an activity and is a product of the authorization process.

3.76. Registration is defined in [3] as a form of authorization for facilities or activities of low or moderate radiation risks whereby the legal person responsible should prepare and submit a safety assessment of the facilities or activities and equipment to the regulatory body. The activity or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to a facility or an activity subject to registration should be less severe than those for licensing.

3.77. With regard to material being transported in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material [7], the requirements established by [3] for exemption, notification and authorization are fulfilled by means of compliance with the Regulations.

3.78. Authorizations should be granted or denied in accordance within the national governmental, legal and regulatory framework and should cover all stages of the lifetime of a facility or activity, for example, for a nuclear facility, site evaluation, design, manufacturing, construction, installation, commissioning, operation, decommissioning and subsequent release of the site from regulatory control.

3.79. The legal framework of the State should set out the responsibilities for issuing an authorization and, in particular, determine who is empowered to issue the authorizations. Depending on the system used in the particular State, different authorizations may be issued by different authorities.

3.80. An applicant is a legal person or organization who applies to a regulatory body for authorization. The holder of a current and valid authorization is termed an authorized party. The authorized party is the legal person or organization having overall responsibility for a facility or activity. It is required that the applicant should refrain from carrying out any actions covered by the applications until the authorization has been granted, (GSR Part 3, para 3.9 [3]).

3.81. The authorized party is required to have prime responsibility for safety and retain this responsibility even if the validity of an authorization lapses, or the authorization is revoked by the regulatory body, (GSR Part 1(Rev.1), Requirement 5 [2]). However, the responsibilities conferred by the authorization may be transferred to a different authorized party, e.g. upon change of ownership, which should be approved by the regulatory body.

3.82. The regulatory body should specify the conditions under which consumer products that contain radioactive material may be made available to the public who have no regulatory obligation with respect to the product. In this context, the consumer product can be used and disposed of without any special safety measures being required. The supply of consumer products to the public should be authorized by the regulatory body.

Objectives of notification and authorization

3.83. The objective of notification is to provide initial information to the regulatory body that a person or organization is intending to operate a facility or conduct an activity. The regulatory body should utilize the information received in the notification process to update the register of sources, facilities and activities and to decide on the level of regulatory control to be applied.

3.84. The objective of granting authorizations is for the regulatory body to establish effective regulatory control throughout the lifetime of a facility or activity in relation to safety. The authorization process should require assurance that the applicant can fulfill its safety obligations; demonstrate sufficient competence in its staff, where appropriate; and demonstrate adequate safety. These aspects should be subject to suitable review and assessment by the regulatory body before the authorization is issued. In the granting of an authorization for a facility or an activity, the regulatory body should consider whether to impose limits, conditions and controls on the authorized party's subsequent activities.

General principles of an authorization

3.85. Authorization principles should be established in the regulatory and legal framework. Examples of authorization principles are the following:

(a) A facility and/or activity should be authorized only when the regulatory body has confirmed that the facility or activity is going to be used or conducted in a manner that does not pose an unacceptable radiological risk to people or the environment. This should include confirmation that the applicant has the organizational capability, organizational structures, adequacy of resources, competence of managers and staff, and appropriateness of management arrangements to fulfill its safety obligations as an authorized party;

(b) The regulatory framework for dealing with authorization requests should be clear, especially the process for applying for authorization;

(c) The regulatory regime for the authorization process should be explicitly established by regulation and by the regulatory body;

(d) The authorization of a facility or activity should be based on predefined documents that are submitted to the regulatory body by the person or organization responsible for the facility or activity. These documents should be reviewed by the regulatory body and, where required, should be updated regularly by the authorized party, as indicated in authorization conditions or regulations;

(e) Expenses associated with the authorization process and the person or organization that will be charged these expenses should be clearly specified;

(f) A clear and explicit set of requirements, criteria and standards forming the authorization basis should be defined;

(g) A graded approach should be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization process. Such an approach should be reflected in regulations and guides, and the extent of reviews, assessments or inspections should be commensurate with the magnitude of the possible radiation risks posed by the facility or the activity;

(h) Clear conditions should be established for public participation in the authorization process;

(i) The authorization process should be transparent to the public, and any authorization should be published or made available to the public by other means, with taking into account information security and proprietary information;

(j) The scope of the authorization (the site, a facility, parts of a facility and activities, or a series of authorizations), its validity period and any incorporated conditions should be clearly defined by the regulatory body;

(k) The regulatory body should include conditions in the authorization, as appropriate;

(l) An authorization may be transferred, depending on national regulations; however, this should be done only with the agreement of the regulatory body, which may attach provisions and conditions to the transfer;

(m) The applicant and the regulatory body should take into account international good practices, as appropriate, throughout the authorization process;

(n) The analysis approach to safety should be clearly defined, including the use of deterministic and probabilistic methodologies and analytical tools as appropriate;

(o) Safety reviews should be carried out by the authorized party either on a periodic basis or as required by the regulatory body, and the results should be submitted to the regulatory body for review and assessment. Appropriate regulatory decisions may then follow, including a decision to suspend operation, if doing so is deemed necessary;

(p) The prime responsibility for safety is assigned to and assumed by the person or organization responsible for any facilities and activities that give rise to radiation risks. Compliance with regulations and requirements imposed by the regulatory body does not relieve the person or organization responsible for any facility and their activities of the prime responsibility for safety. The person or organization responsible for any facilities and their activities should demonstrate to the satisfaction of the regulatory body that this prime responsibility has been and will continue to be fulfilled;

(q) The means of challenging or appealing against an authorization or part of an authorization should be made clear by the regulatory body or within the regulatory framework.

3.86. The legislative and regulatory framework should require unfettered access for designated regulatory staff at any time, to any authorized facility or activity and any documents related to safety and considered necessary for granting authorizations.

3.87.Nuclear security and safety should be viewed as being complementary, and the regulatory body with responsibility for safety should ensure that any interface between safety and nuclear security measures are addressed by the authorized party or the applicant for an authorization and are appropriately considered in conjunction with the regulatory body with responsibility for nuclear security.

Authorization

3.88. It is required that authorization should take the form of either registration or licensing, (GSR Part 3, par. 3.8 [3]). The regulatory body should determine which facilities and activities require only registration or to be subject to a licensing process.

3.89. In the regulations and guides, the regulatory body should explicitly state the obligations, roles and responsibilities of the applicant or authorized party. In this respect, the regulatory body should

include in regulations, that the applicant or authorized party should accomplish the following, or part of, depending on the facility or activity:

(a) Prepare and submit a comprehensive application to the regulatory body that demonstrates that priority is given to safety; that is, that the level of safety is as high as reasonably achievable and that safety will be maintained for the entire lifetime of the facility or activity, until this is released from regulatory control by the regulatory body;

(b) Have the capability within its own organization (either on-site or within the organization as a whole) to understand the design basis and safety analyses for the facility or activity, and the limits and conditions under which it should be operated or performed;

(c) Exercise control over the work of contractors, understand the safety significance of this work ("intelligent customer" capability) and take responsibility for its implementation;

(d) Submit a procedure or description of the process for dealing with modifications, which may be subject to approval by the regulatory body;

(e) Have a design capability and a formal and effective external relationship with the original design organization;

(f) Assess safety in a systematic manner and on a regular basis;

(g) Develop a safety assessment and submit it to the regulatory body as part of the application, if there is a possibility for an exposure to be greater than a level specified by the regulatory body;

(h) Have an appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity;

(i) Demonstrate in its application that it has and will continue to maintain:

  i. adequate financial resources for construction, operation and maintenance of facilities and/or activities as well as for the timely decommissioning of facilities or termination of activities and the management of radioactive waste and/or spent radiation sources, including disposal;

  ii. adequate human resources to safely construct, maintain, operate and decommission the facility or activity and deal with any radioactive material and to ensure that regulatory requirements and safety standards are met and will continue to be met.

3.90. An additional requirement to be included in the regulations is that the authorized party should put into place procedures within its management system for each stage of the lifetime of a facility or activity, including, where appropriate, procedures for the provision of independent advice. Procedures should be put into place:

(a) For controlling the facility or activity within the limits specified in the regulations and the authorization;

(b) For managing incidents and accidents and responding to a nuclear or radiological emergency.

Procedures should be periodically assessed, reviewed and revised, as appropriate, to take into account operating experience, modifications, and national and international best practices.

3.91. Throughout the authorization process, the regulatory body should ensure that proposed modifications are categorized by the authorized party according to their safety significance. This categorization should follow an established procedure, which should be subject to agreement or approval by the regulatory body. Modifications that are categorized as significant to safety should be submitted to the regulatory body for review and approval or agreement. The regulatory body should inspect compliance with categorization procedures on a regular basis. Further information on modification control at Nuclear Power Plants is provided in [30].

3.92. In the regulations it should be clearly stated that even if authorization expiry dates are established, on expiry they do not relieve the person or organization in charge of the facility or activity of the prime responsibility for safety until the regulatory body so decides.

Information needed in making notification and /or applying for authorization

3.93. Requirement 7 of GSR Part 3[3] requires that: "Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body, as appropriate a notification or an application for authorization". The application should be submitted in a form prescribed by the regulatory body with the information that is commensurate with the level of radiation risk in operating the facility or conducting the activity. Requirement 23 of GSR Part 1 (Rev.1) [2] requires that "Authorization by the regulatory body … shall be a prerequisite for all facilities and activities that are not either explicitly exempted or approved by means of a notification".

Notification

3.94. The minimum information required to be submitted in support of notification is the following:

(a) Clear identification of the applicant submitting the notification;

(b) The location(s) where the source(s) will be stored and where they will be used;

(c) Specification of the system to be used for source management;

(d) Clear specification of the source(s) and associated equipment to be used in the facilities or activities.

Authorization

3.95. Requirement 24 of GSR Part 1 (Rev.1) [2] requires that: "The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity."

3.96. The applicant should provide all relevant information describing the approach to safety in order to demonstrate that the facility or the activity will not present unacceptable radiological risks to people and the environment. This should include proposed objectives, principles, criteria, standards and analyses in relation to safety for all stages of the authorization process. The aim should be to provide the relevant information such that the regulatory body can conduct its review and assessment process without needing to seek further information or clarification.

3.97. The documents submitted to the regulatory body in the framework of the licensing process should be updated, as appropriate, during the lifetime of facility or activity, to ensure they cover relevant aspects. The documents submitted to the regulatory body (which may be divided or combined into different documents, as appropriate) should be incorporated as part of the authorization, if required by national regulations, regulatory regimes and practices.

3.98. For complex facilities or activities, before an applicant submits an application, the regulatory body should consider implementing a preparatory phase, during which basic safety requirements and the authorization process to be followed are made clear to the applicant. This may include specification of, for example, the language, units, methodology and format of the proposed application. During this phase, the staff of the regulatory body should be trained so they have sufficient knowledge of the designs of facilities or of the phases of the activities that may be proposed. Nevertheless, detailed and explicit design requirements of the facility or characteristics of the activity should be developed during the early phases of the authorization process.

3.99. Early assessment of the competence and capability of the applicant should be conducted to ensure that the applicant will be able to manage the later phases of the project of the facility or to carry out the activity. The applicant should be encouraged to conduct a staffing study at the very beginning of the project of the facility or of the activity to evaluate the staff and competencies it will need during the different project phases or activity phases and should give consideration to how and from where it will recruit such staff.

3.100. The level of information to be submitted to support an application for authorization should take into account the kind of facility and activity. The scope of the information required should depend on the lifecycle stage for which the authorization is being considered. The information should include, as applicable:

– Legal information:

    (a) The formal name and address of the applicant and any additional contact information such as the individual(s) representing the applicant; Details of any relevant existing authorizations (licences);

(b) Information on whether the facility or activity is fully or primarily owned or controlled by a person from another State or by a foreign corporation, and, if so, details of the ownership structure.

– Applicant's Organization:

Information regarding organizational matters which should include:

(a) Management structure and resources;

(b) The organizational structure;

(c) Evidence that the applicant has and will continue to maintain adequate financial resources to cover necessary costs associated with safety such as regulatory fees, liability insurance, and funding decommissioning or waste management, as applicable, depending on national legislation and regulation;

(d) Evidence that the applicant has adequate human resources to ensure that regulatory requirements and safety standards are met and will continue to be met throughout the lifetime of the facility or activity.

– Physical characteristics of the site, facility and activity:

(a) The nature of the facility or activity that is subject of the application;

(b) A description of the relevant premises including the layout of the facility, buildings and equipment;

(c) Where relevant, a description of the site in terms of geography, demography, topography, meteorology, hydrology, geology and seismology;

(d) A description of the safety relevant equipment, e.g. a facility's structures, systems and components.

– Staff qualification and training:

(a) Identification of the necessary qualifications and training of staff that will have safety related responsibilities;

(b) For authorization of certain facilities or activities, the identification of persons by name may be required to be included in the application, e.g. the name of radiation protection officers or qualified experts;

(c) Details of qualifications and training in radiation protection of workers engaged in activities that involve or could involve occupational exposure;

(d) Evidence of trustworthiness of all staff who will be engaged in responsible or sensitive positions.

– Management system:

(a) For relevant safety systems of facilities or activities with significant risk, copies of the operating and maintenance procedures that will be followed;

(b) Description of the system for identification, traceability and preservation of documents and records control;

(c) System for the development of procedures;

(d) Procedures for reporting on and learning from accidents and other incidents;

(e) Procedures for learning from national and international good practices;

(f) Procedure or description of the process for dealing with modifications of facility or activity , which may be subject to approval by the regulatory body, depending on national legislation, regulations and practices if these requirements dealing with modifications are not established directly in the regulations;

(g) Description of the quality assurance system established to ensure that all items to operate the facility or conduct the activity are designed, manufactured, constructed, assembled, tested, qualified, operated, maintained and replaced in compliance with the relevant safety requirements;

(h) Quality assurance arrangements, including internal and external audits.

– Safety activities:

(a) Applicable safety regulations, guides and industrial standards;

(b) Safety assessments for exposures during normal operation, including potential exposures that may be greater than a level as specified by the regulatory body;

(c) An appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity if required by national legislation;

(d) The occupational radiation protection programme, including arrangements for monitoring of workers and the workplace, and the provision and maintenance of personal protective equipment and equipment for radiation detection;

(e) Safety assessments and other design related documents that address the optimization of safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public;

(f) For activities involving medical exposure, information relating to the radiological protection of patients, including arrangements for the calibration of sources used

for medical exposure, clinical dosimetry and the description of the management system;

(g) For new, unusual or complex activities, or for the supply of consumer products, a demonstration that the principle of justification for engaging in the regulated activity is fulfilled;

(h) The specifications on how to implement and maintain safety for all the stages of the lifetime of the facility or activity;

(i) The safety concepts and criteria used in the design of the facility or for carrying out the activity, including the classification of equipment, systems and components, the application of the defence in depth principle, the use of multiple barriers to prevent radioactive releases and the approach to issues relating to the human–machine interface;

(j) A description of the safety relevant equipment to operate the facility or to conduct the activity, e.g. a facility's structures, systems and description of components, including their design criteria, the processes involved in their design, and the modes of operation and testing;

(k) Arrangements for the management of radioactive waste generated during the lifetime of the facility or activity, including the decommissioning, the management of disused sources (disused sources should either be managed in the State concerned or be returned to the supplier or manufacturer), and information on the financial arrangements for such purposes;

(l) The results of an analysis of the normal operation of the facilities and activities, and for a waste disposal facility, of the long term period after closure should be provided to demonstrate the acceptability of the design, including a demonstration that radiation protection criteria, waste management requirements and effluent limits are met by the design;

(m) The results of a safety analysis should be provided to demonstrate how the design and related operational procedures of the facility or activity will contribute to the prevention of accidents and to the mitigation of the consequences of accidents if they do occur. The analysis should describe and evaluate the predicted response of the facility or activity to events, both internal and external, which could lead to abnormal and accident conditions. The analysis should be extended to relevant combinations of such disturbances, malfunctions, failures, errors and events. Consideration should be given to aspects such as the initial conditions assumed,

the physical or mathematical models used and their correlation with experiments, and the method of presenting the results;

(n) A safety analyses that should show the extent to which the authorized party can control or accommodate situations at the facility or in conducting the activity relating to various events and abnormal and accident conditions. The limits and conditions for safe operation should be defined. If any part of the analysis has been independently reviewed by another organization, the results of this review should also be presented Additional recommendations and guidance on safety analysis for Nuclear Power Plant are provided in [28];

(o) Information on other plans and programmes that are established by the authorized party in support of its safety activities. This includes areas such as:

i. the radiation protection programme (including how to apply the 'as low as reasonably achievable' (ALARA) principle);
ii. the environmental monitoring programme;
iii. emergency preparedness and response;
iv. fire protection;
v. radioactive waste management;
vi. research and development in relation to the safe design, operation, decommissioning or closure of the facility or the activity;
vii. feedback of operating experience;
viii. the decommissioning (or closure) strategy.

(p) Arrangements to ensure safety and nuclear security of sources in order to prevent loss of control due to theft, diversion or severe environmental conditions.

– Emergency arrangements:

(a) Emergency arrangements, including an emergency plan, and financial arrangements for a radiological emergency where appropriate, that address the general and functional requirements as specified in GSR Part 7 [11].

Form of Notification/Authorization for a facility or activity

Notification for a facility or activity

3.101. An application to inform the regulatory body of the intention to operate a facility or conduct an activity for which normal exposures are expected to be very small and the likelihood and magnitudes of potential exposures are negligible, but which are not suitable for exemption for some reason (e.g. to prevent uncontrolled waste disposal) should be made in the form of a notification. The regulatory body should set out what information is required which may be described in a notification form. The notification form should be available so that an applicant is able to give information in the respect of

the provisions for justification of the activity and demonstrate that notification is sufficient to allow operation of the facility or conduct of the activity. Depending on national requirements, the regulatory body might prefer to have separate notification forms for radioactive materials and other radiation sources. The regulatory body should acknowledge the notification, within a specified period, and, if appropriate, set out what regulatory actions it will put in place.

Authorization for a facility or activity

3.102. An authorization is a written permission for an authorized party to operate a facility or to conduct an activity or a set of activities dealing with the siting, design, construction, commissioning, operation, decommissioning or closure of a facility. It also establishes, directly or by reference, conditions governing the safe performance of these activities.

3.103. Authorizations may be granted:

(a) For a specific time period (e.g. 10 years, 40 years) or for a specific stage in the lifetime of the facility (e.g. construction, operation) or activity. In such a case, a mechanism should be put in place to ensure that the authorized party responsible for the facility and its activities remains responsible for safety and nuclear security at the facility, even if the authorization has expired, unless the site has been removed from regulatory control;

(b) For an indefinite period of time (a permanent authorization), under certain conditions and until the authorization is officially terminated by the regulatory body;

(c) For a specific activity or a specific condition of the facility (e.g. temporary storage of spent fuel).

3.104. The format of an authorization will depend upon the kind of authorization, its content and the conditions deemed necessary by the regulatory body for a given stage of the authorization process for complex facilities or activities in accordance with national legal procedures. For example, the authorization may incorporate by reference the underlying documents and provide only the material necessary to define the basic terms not previously defined elsewhere. Thus, the format of an authorization will vary not only among States, but also within a State, from stage to stage, and from authorization to authorization for a given stage. However, the authorization should contain information such as:

– *Statutory authority*. The authorization should have a unique identification and explicitly refer to the laws and regulations on which it is based;

– *Issuing authority*. The authorization should identify the official designations of those who are empowered by law or regulation to issue the authorization, whose signature and stamp will appear on the authorization, and to whom the authorized party will be accountable under the terms of the authorization;

- *Fulfillment of requirements*. The authorization should include a summary statement that all legal and technical requirements in respect of safety have been fulfilled and that the facilities can be operated and the activities can be conducted without unacceptable radiological risk to people or the environment;
- *Documentary basis*. The authorization should identify the documents provided by the authorized party in support of the application and those prepared by staff of the regulatory body in the review and assessment process, which together forms the basis for issuing the authorization;
- *Relationship to other authorization*. The authorization should indicate whether it is contingent upon a prior authorization or is a prerequisite for a future authorization;
- *The authorized party*. The authorization should contain a precise identification of the individual or organization both legally responsible for the authorized activity and in day to day control of the facility or the activity;
- *Period of authorization*. The authorization should state an effective date of authorization. It may also include a termination date, which may be based on a fixed term. Alternatively a period of validity may be stated over which the assumptions underlying the licensing decision will remain valid and at the end of which the basis for licensing will be re-examined;
- *Authorized activity*. The authorization should clearly describe in sufficient detail the facility, its location and the activities or inventory of sources, including a clear depiction and description of the site boundaries, and other drawings, as appropriate, covered by the authorization;
- *The authorized party's responsibility for compliance*. The authorization should contain:
    - an appropriate declaration that the authorized party has the responsibility for compliance with the legal requirements, regulations and conditions referenced or contained in the authorization or in other references, if applicable;
    - a statement that establishes that the authorization may be transferred to a different authorized party, with the approval of the regulatory body.

Form of Notification/Authorization for individuals

3.105. In some States, the legislation determines that an authorization in terms of qualification is needed for a person to perform specific functions. In that case the authorization should be the means of verifying the competences of the personnel to carry out those specific activities.

Form of Notification/Authorization for objects

3.106. Authorization for objects should be considered where it is more effective for regulating a facility or to conduct an activity. An example is the authorization (certificate of approval) of package design, special form radioactive material or low dispersible radioactive material as requested by the IAEA “Regulations for the safe transport of radioactive material” SSR-6 [7].

3.107. The regulatory body should require the manufacturer of consumer products to apply to the regulatory body and receive authorization to supply products to the public to ensure that consumer products meet all the requirements for design and performance that were taken into account in the generic safety assessment, Appendix 1.

3.108. It is required that for consumer products notification should only be used with respect to manufacture, assembly, maintenance, import, distribution and, in some cases, disposal (GSR Part 3, para 3.7 [3]).

3.109. It is required that providers of consumer products should ensure that such products are not made available to the public unless the justification of their use by members of the public has been approved by the regulatory body, and either their use has been exempted on the basis of the criteria specified in GSR Part 3, Schedule 1 [3] or any exemption level specified by the regulatory body based on these criteria, or their provision to the public has been authorized, (GSR Part 3 para 3.138 [3]).

Authorization Conditions

3.110. Authorization should state explicitly, or should impose by reference or attachment, all conditions as determined by the regulatory body, which are obligations with which the authorized party is required to comply. Laws and practices relating to authorization vary between States. In some States, conditions are specified in the law and in regulations of the regulatory body, and are merely referenced in the authorization, while in other States some or all conditions are stated explicitly in the authorization.

3.111. Authorization conditions should cover, as appropriate, safety aspects affecting the facility or activity throughout its lifecycle encompassing site evaluation, design, construction, installation, commissioning, operation and decommissioning of the facility or activity and its subsequent release from regulatory control so as to enable effective regulatory control at all stages. These requirements should cover, among other things, important aspects such as design, radiation protection, maintenance programmes, emergency plans and procedures, modifications, the management system, operational limits and conditions, procedures and authorization of personnel. Furthermore, authorization conditions may refer to, but should not duplicate, regulations, to avoid discrepancies or inconsistencies when the regulations are amended.

3.112. While authorization conditions may vary in format, there are certain basic qualities and definitions that should characterize the set of conditions, to make them understandable and effective.

Each authorization condition should be consistent with all other authorization conditions in that the fulfillment of one should not conflict with the fulfillment of another or with any other legal requirement. In the event that it is necessary to specify several authorization conditions addressing various technical and administrative aspects, it may be useful to group the conditions into categories, such as:

- *Authorization conditions that set technical limits and thresholds such as*:
  - any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorization).
- *Authorization conditions that specify procedures and modes of operation:*
  - the obligations of the authorized party in respect of its facility, equipment, radiation source(s) and personnel;
  - conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities; encouragement for waste minimization should be addressed;
  - the emergency preparedness arrangements.
- *Authorization conditions pertaining to administrative matters such as:*
  - the requirements for notifying the regulatory body of any modifications to safety related aspects;
  - any additional separate authorizations that the authorized party should obtain from the regulatory body;
  - the reports that the authorized party should make to the regulatory body;
  - the means and procedures for changing any information stated in the authorization;
  - procedures for, information about and identification of the legal framework for challenging the authorization or part of the authorization.
- *Authorization conditions relating to inspection and enforcement:*
  - the records that the authorized party should retain and the time periods for which they must be retained.
- *Authorization conditions pertaining to the response to abnormal conditions*:
  - the requirements for event reporting.

General authorization conditions

3.113. General authorization conditions should include the following provisions:

(a) The authorized party should provide the authorized representatives of the regulatory body with full access to personnel, facilities and records that are under the authorized party's control, when such access is deemed necessary by the regulatory body to verify compliance and to assess safety;

(b) The authorized party should keep the regulatory body fully and continuously informed of any significant or potentially significant events or changes in the considerations, information, assumptions and expectations upon which the issue of the authorization was based;

(c) The authorized party should take such corrective actions or measures as the regulatory body may require in the interests of safety;

(d) The authorized party should not extend its activities beyond those specifically authorized in the authorization without the prior approval of the regulatory body;

(e) The authorized party should develop, preserve, update and maintain a complete set of records relating to the safety of the facility or the activity including those referenced in the applications and those required by law, regulations and the authorization, and should dispose of them only as authorized by the regulatory body;

(f) The authorized party should carry out its activities in accordance with an approved management system programme covering all stages of the authorization process, so as to provide a basic framework for ensuring that all activities are carried out with due regard for safety;

(g) The authorized party should report on modifications to operate the facility or conduct the activity in accordance with the requirements established by the regulatory body;

(h) The authorized party should report on all accidents, incidents and events relating to safety as required by the regulatory body;

Stages in the Authorization process

3.114. Though national practices vary, the regulatory body should carry out authorization in several stages for complex facilities or activities, usually an application being required for each stage, Appendix 2. For nuclear facilities or industrial irradiators and facilities for industrial radiography, nuclear medicine and radiotherapy, the regulatory body may require a multistage process of authorization (e.g. it may require the submission of an application to construct before construction can begin). The regulatory body may also prohibit the procurement of nuclear material or radiation sources (including their import) until a particular stage of construction has been completed and the safe and secure storage of nuclear material or radiation sources can be ensured. The authorization process should be subdivided into various steps (which may be determined by the lifecycle stages or be at

specific points in a particular lifecycle stage) and the regulatory body should require additional information before the authorized party is given authorization to move from one step to the next.

3.115. The authorization process should be understood by the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable). The authorization process should be established in a systemic way to facilitate efficient progression of regulatory activities. The steps of the authorization process should be discrete and should follow a logical order.

3.116. In developing an authorization process, consideration should be given to adoption or adaptation of 'pre-licensing' processes, for example, steps that provide for early approval of sites and advance certification of standardized plant designs for authorization for construction and operation of a complex facility or activity. Such a licensing process may help to minimize duplication of effort through the different steps and may allow for some steps to be conducted in parallel. It also provides for a clear division of responsibilities, at the various steps, between regulators, vendors and authorized parties; gives the public opportunities for early participation; and ensures that the most important safety issues are dealt with properly in the pre-licensing phase.

3.117. The authorization process, and in particular an authorization (licence) renewal process, should be carried out in a very transparent manner, providing opportunities for communication with the public and their involvement. In some Member States the authorization renewal process is carried out in a transparent manner. The regulatory body should consider holding meetings with interested parties providing information on the authorization renewal processes.

Authorization process for particular type of facility

3.118. Whenever submissions for a particular type of facility (or parts thereof) may be repeated many times, it may be appropriate for an authorized party 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.

3.119. Provided that the review and assessment by the regulatory body has been completed satisfactorily and the regulatory body has authorized the generic facility, the reference facility or the design, during a pre-licensing assessment, the authorized party 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 authorized party 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. In particular, authorization of a design that has been subjected to a pre-licensing assessment will need to consider the actual site characteristics and ensure that those assumed in the design adequately bracket them. In moving to authorization of a design that has been authorized in a pre-licensing process, the regulatory body should also require a submission by the applicant of how it will take over, manage and operate the facility.

Different stages of the authorization process for a complex facility or activity

3.120. The authorization process for a complex facility or activity should be considered to consist of a series of lifecycle stages each subject to the need for regulatory input to allow progress from one stage to the next. These stages may depend on national legislation but are normally labelled as follows:

- siting and site evaluation (which may include the environmental impact assessment);
- design;
- construction;
- commissioning;
- operation;
- decommissioning;
- release from regulatory control.

Each stage of the licensing process may be divided into several sub-stages or may be merged or combined as appropriate to facilitate the regulatory process. Combining the authorizations (e.g. for construction and operation) may also give more predictability to the process for the authorized party. At each hold point set down by the regulatory body or in the licensing process, different authorizations from the regulatory body may be required. Conditions may be attached to authorizations granted at each step and may require that the authorized party obtain further, more specific, authorizations or approvals before carrying out particular activities.

3.121. As a practical matter, review and assessment of each step of the licensing process 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 or the activity, review and assessment of some steps may be combined. The degree to which the respective steps should be considered will depend on the nature of the facility or the activity and the risks associated with it.

3.122. Once an application has been accepted and the initial authorization has been issued, subsequent licensing process activities and arrangements should be undertaken between the authorized party and the regulatory body. These will include requests for carrying out further activities, including, in some States, the construction of additional facilities on the site.

3.123. On a particular site, there may be different facilities and activities at different stages of their lifetimes. Where there are different authorized parties on the same site, or on neighboring sites, the regulatory body should ensure co-operation between the authorized parties. Whilst authorizations having different licensing bases may be used, depending on the type of regulatory control established in the State, a process for keeping all of them consistent should be put in place. In cases where several authorized party share common safety related features, arrangements should be made to ensure that overall safety is not compromised.

Site evaluation

3.124. Site evaluation for many facilities or activities is initially determined by processes not greatly influenced by highly prescriptive technical criteria. However, general requirements concerning remoteness, environmental concerns, local population density and transport arrangements will apply, usually at a governmental level. For waste disposal sites, geological and hydrogeological considerations should be major factors in site evaluation. For such sites the regulatory body should consider being involved in the formulation of site selection criteria and in the process of determining the general suitability of a site. Further guidance on site evaluation is given in [18–25].

3.125. For a facility or an activity that is to be operated or conducted at a permanent site a decision should be reached on the acceptability of a specific site from the safety point of view, after information on the site itself and preliminary information on the facility or activity and its interaction with the site have been reviewed and assessed by the regulatory body.

Design, construction, manufacture and installation

3.126. Construction, manufacture or installation of the facility should not be authorized until the initial design has been reviewed and assessed, including verification of the compatibility of the design with the site, as appropriate. Further information on the design requirements for nuclear power plants is provided in [31].

Commissioning

3.127. There is some overlap between the construction and commissioning stages in that individual structures, systems and components may be commissioned before completion of the entire facility or activity systems. There are several steps in the commissioning process for which the regulatory body may require the authorized party to obtain prior approval and at which regulatory decisions may be made. However, the introduction of fissile and/or radioactive material into the facility or activity marks a significant step in the commissioning procedure and is often considered the main point at

which regulatory decisions are made at this stage. Introduction of fissile and radioactive material should not be authorized until the proposed commissioning programme has been reviewed and assessed, preliminary operational limits and conditions have been established, the final design has been assessed and conformity of the construction with the design of related systems has been verified. Further recommendations on commissioning are provided in Refs [35, 36].

Operation

3.128. Commencement of routine operation should only be authorized once commissioning tests have been completed and their results assessed, and operational limits and conditions have been reviewed and assessed by the regulatory body.

3.129. Over the full operational lifetime of the facility or activity, the regulatory body should require the authorized party to provide evidence at appropriate intervals, in the form of a comprehensive safety review, such as a periodic safety review [8], that the facility or the activity is still fit to continue in operation. In many States, this reassessment period is around ten years for a major nuclear installation. In the comprehensive safety review, account should be taken of the potential nature and magnitude of the associated hazards, operating experience, significant changes to safety standards, technical developments, and new safety related information from relevant sources. Depending on the national laws and regulations and the outcome of the comprehensive safety review, the regulatory body may renew the authorization of the authorized party at this stage.

3.130. Before bringing a facility back into operation following a major outage, the authorized party should be required to demonstrate to the satisfaction of the regulatory body that the facility will be able to continue to operate in compliance with the safety requirements, until the next outage.

3.131. During the lifetime of the facility or activity modifications will be made to both equipment and management and operational procedures. Where these affect safety they must be subjected to proper consideration by the authorized party and may require approval by the regulatory body. Significant modifications should result in changes to the safety assessment and safety documentation so that it properly reflects the actual situation [30].

3.132. Plans for radioactive waste management and decommissioning (including technical solutions, waste streams, the policy framework for disposal and funding) should be reviewed and updated periodically during operation [33, 37, 38].

Decommissioning

3.133. Decommissioning or closure should only be authorized once the detailed plans and procedures to be used, the conditions to be observed during decommissioning or closure, and the proposed final state of the facility, including the radiological status, have been inspected, reviewed and assessed by the regulatory body.

3.134. The regulatory body is required to ensure that relevant documents and records are prepared by the authorized party, kept for an agreed time and maintained to a specified quality before, during and after decommissioning, (GSR Part 6 para 7.7 [16]). In addition, the regulatory body should ensure that an effective record system for the released sites is in place and is maintained for future users of the sites. The responsibilities for maintaining site release records should be clearly assigned, with account taken of the fact that these records could be maintained by a specific organization. Further Requirements for decommissioning are established in [16]; further recommendations are provided in [33, 34, 37 and 38].

Release from regulatory Control

3.135. Before release from regulatory control, the authorized party should be required to demonstrate to the regulatory body that the site meets the release criteria. The regulatory body should review the authorized party's demonstration, confirm compliance with the criteria and only then release the site from regulatory control.

3.136. If the site does not meet the release criteria, restrictions should be imposed in relation to future use of the site ('restricted use' option). If after further cleanup and survey demonstrate that the site meets the release criteria, restrictions are not needed, the selected option should be 'unrestricted use'.

3.137. For restricted use, the type, extent and duration of the restrictions and controls for release of the site can range from monitoring and surveillance to restriction of access to the site. The restrictions should be proposed by the authorized party on the basis of a graded approach and after consideration of factors such as the type and level of residual contamination after the completion of cleanup, the relevant dose constraints and release criteria, and the human and financial resources needed to implement the restrictions and controls. The restrictions proposed by the authorized party should be submitted to the regulatory body for their agreement and should be of a form that is enforceable. It should be clear which organization will ensure that the restrictions are maintained. In addition, the way in which the restrictions would be removed when they are no longer necessary should be specified in the cleanup plan.

Review and assessment of documents produced by the authorized party in the authorization process

3.138. Essential documents to be prepared by the authorized party in the authorization process should be identified in the regulations and guides issued by the regulatory body. Additional documents may be requested as needed, depending on the type of facility or activity concerned as well as on the specific stage of the authorization process.

3.139. Documents of different types are required to be prepared by the authorized party in discharging its responsibilities with respect to the safety of the facility or the activity. Some of these documents are required to be submitted formally to the regulatory body for review and assessment in the course of the authorization process. Other documents are reports that should be submitted to the regulatory body

periodically, or event, incident or accident reports to keep the regulatory body fully informed of the conditions prevailing at the facility or for the activity. A third type of document is for internal use by the authorized party but should be made available upon request to the regulatory body to ensure its complete understanding of the design and operation of the facility or the activity, so that it can confirm that the requirements established in the regulations and authorization conditions have been fulfilled.

3.140. To facilitate the review and assessment process of the facility or activity, the regulatory body should consider developing lists of approved equipment containing radiation sources, based on the submission of a certificate confirming compliance with the international industry standards (of the IEC and the ISO). An expert with the appropriate skills or an independent accreditation laboratory of the State concerned, or of another State or an international organization, should issue the certificate after reviewing a generic safety assessment. The generic safety assessment should be documented, together with a summary of the conditions of use of the device and any appropriate limitations on its use.

3.141. The regulatory body should not issue an authorization solely because a model of equipment was 'type approved' or carried a certificate of compliance, in accordance with IEC standards or nationally recognized equivalent standards in the State of use. The safety of each facility or activity will depend on many factors in addition to the design and manufacture of the structures, systems and components which are required for safety, such as the qualification and training of the staff, and managerial and operational procedures and processes.

3.142. A fundamental feature of the process of review and assessment of an application for authorization by the regulatory body is its consideration of the documentation submitted by the applicant. For significant radiation risks or unusual or complex facilities or activities, the regulatory body should also verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used. 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 the managerial, engineering and operational aspects of the application for authorization and to foster links with specialists of the operating organization.

Modification or revocation of authorizations

3.143. The granting of an authorization should not restrict or preclude subsequent amendment, suspension or revocation of that authorization by the regulatory body within the period of its validity. Once it has been issued, however, the terms of the authorization, including any conditions attached to it should be binding on the authorized party unless and until amended, suspended or revoked by the regulatory body. A request for an amendment may be initiated by the authorized party, or an amendment may be imposed by the regulatory body in the interest of safety. A modification of the authorization may be desirable or necessary as a result of proposed changes relating to the facility or

activity, experience from the facility itself or elsewhere, or technological advances, or as a consequence of research and development relating to nuclear or radiation safety.

3.144. Any subsequent amendment, renewal, suspension or revocation of the authorization should be undertaken in accordance with a clearly defined and established procedure. The procedure should include requirements for the timely submission of applications for renewal or amendment of authorizations.

3.145. The regulatory body may require the renewal of an authorization after a set time interval, depending on national legislation. In such instances, a review would usually be made of the findings of inspections and of other information on performance, and its results would be documented as part of the revalidation process. Authorization details should be kept up to date.

3.146. The regulatory body should require notification by the authorized party of any significant changes to safety of the facility or activity and to apply, where necessary, for an amendment to, or a renewal of, the authorization. Any modification to safety of a facility or an activity should be subject to an assessment by the authorized party, with account taken of the possible magnitude and nature of the associated risk.

3.147. At any stage of the lifetime of the facility or activity, proposals to change or modify the site, the facility, the activity, the organizational structure of the authorized party, and associated managerial and operational procedures, processes including plans for future activities (e.g. decommissioning) may be made. These proposals should (depending on factors such as the nature of the changes and the magnitude of the risks involved) be subject to prior review, assessment and approval by the regulatory body and revision of the authorization as appropriate.

3.148. An authorization for an activity involving the use of radiation sources may be cancelled because the radiation sources are no longer required or because the regulatory body has taken an enforcement action. The regulatory body should ensure that the radiation sources are transferred to an authorized party that possesses a valid authorization [3] or are disposed of to an authorized waste management facility. The regulatory body should provide guidance on radiological criteria for the removal of regulatory control from materials, facilities and sites. Further information is provided in [33].

REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES

3.149. Requirement 25 of GSR Part 1 (Rev.1) [2] requires that “The regulatory body shall review and assess relevant information —whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of

the facility or activity, as specified in regulations promulgated by the regulatory body or in the authorization."

General

3.150. The review and assessment process is a critical appraisal, performed by the regulatory body, of information submitted by the authorized party or which comes from inspection, information on events, relevant operational experience at national and international level or other specified reports (e.g. records, comprehensive safety reviews, dose records) to demonstrate the safety of the facility or activity. 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 or activity in terms of safety. The process consists of examining the authorized party`s submissions, and other information as described above, on all aspects relating to the safety of the facility or activity. It should include consideration of normal, abnormal and accident conditions, 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 verify the claims made in the submissions. For facilities or activities with significant risk, the authorized parties 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 authorized party.

3.151. A primary basis for review and assessment activities is the information submitted by the authorized party. A thorough review and assessment of the authorized party's technical submission should 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 should 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 authorized party, to satisfy itself that:

(a) the available information demonstrates the safety of the facility or proposed activity;

(b) the information contained in the authorized party submissions is up to date, accurate and sufficient to enable confirmation of compliance with regulatory requirements;

(c) the technical solutions, and in particular any novel ones, have been verified or qualified by experience or testing or both, and are capable of achieving the required level of safety. Additionally, the justification for engaging in the activity should be evaluated, if required (in some States justification is considered by other processes and not within the responsibility of the regulatory body).

3.152. In undertaking its own review and assessment of a safety submission presented by the

authorized party, the regulatory body should not rely solely on any safety assessment performed for it by consultants or on that conducted by the authorized party. Accordingly, the regulatory body should have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants.

Objective of Review and Assessment

3.153. The basic objective of regulatory review and assessment is to determine whether the authorized party's submissions demonstrate that, throughout the lifetime of the facility or activities, it complies with all safety requirements stipulated or approved by the regulatory body.

3.154. The specific objectives of the review and assessment will depend on the stage of the lifetime of the facility or activity. Examples of these specific objectives include but are not limited to the following:

(a) To determine whether the authorized party uses an appropriate safety management system that meets the regulatory body's requirements;

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

(c) To determine whether the authorized party`s personnel meet the regulatory requirements, in terms of both number, competence and reliability;

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

(e) To evaluate safety reviews performed by the authorized party;

(f) To determine whether the authorized party´s plans and commitments in respect of decommissioning meet the requirements of the regulatory body;

(g) To determine whether the authorized party´s plans and commitments in respect of the closure and post-closure stages for a disposal facility meets the requirements of the regulatory body;

(h) To evaluate the final radiological survey documentation [29];

(i) To determine, if relevant, whether the performance indicators proposed by the authorized party are appropriate;

(j) To determine whether the programme proposed by the authorized party for confirmation of performance is acceptable (this is particularly important for waste disposal facilities);

(k) To determine whether any additional requirements (or authorization conditions) have been fulfilled by the authorized party.

3.155. 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.

Information to be reviewed and assessed

Reporting by the authorized party

3.156. The requirements for periodic reporting and progress reporting and the general criteria for notifying the regulatory body of events, incidents or accidents should be specified in regulations or authorization conditions.

3.157. Reports should be required from the authorized party at set times or upon the completion of specific activities over the lifetime of the facility or the activity.

3.158. During the stage of site evaluation and construction, reports should be prepared to keep the regulatory body informed of the progress of the project. The reports should cover:

- the progress of site studies;
- the progress of construction;
- results of the pre-operational environmental monitoring programme.

3.159. During commissioning and operation, reports should be prepared to demonstrate to the regulatory body the continuing safety of the facility. The reports should cover:

- the results of commissioning tests;
- operational data, including data on the facility's output and performance;
- modifications;
- results of the radiation protection programme;
- results of the environmental monitoring programme;
- radioactive waste management.

3.160. In order to enable the regulatory body to consider the release of any facility from regulatory control, or to require institutional controls for the post-closure phase, reports should include details of, but not limited to:

- the amounts and destinations of radioactive waste resulting from the decontamination and dismantling programme;

– levels of residual activity in the facility;

– results of environmental monitoring and other performance confirmation programmes.

Where necessary owing to the nature of the facility (for example, for a waste disposal site), reports or safety case should also include such details of:

– the overall waste inventory;

– the sealing arrangements;

– any institutional controls intended for the post-closure phase.

Information collected by the regulatory body

3.161 During its inspection activities, the regulatory body inspectors will collect on-site information, for example when examining records kept by the authorized party. Such information should be subjected to review and assessment by the regulatory body, in addition to any violations and non-compliances. Whilst this source of information may only represent a small part of the review and assessment, it is an essential part as it provides factual insights on how the authorized party complies with regulatory requirements.

Review and Assessment Process

3.162. Review and assessment should be carried out in a formalized approach.

3.163. 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 lifecycle stages should be considered at each stage in the authorization process in order to ensure that the acceptability of the authorized party'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 3.

3.164. 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 or activity, review and assessment of some areas may be combined. Since this Safety Guide covers a wide range of facilities and activities, 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 or activities of each type. However, this section provides a general overview of major areas for review and assessment; a graded approach should be used to determine how the respective areas should be considered depending on the nature of the facility or activity and the risks associated with them.

Site evaluation

3.165. The site of the facility or where the activity is to be conducted should be qualified by review and assessment to determine the potential interaction between the proposed facility or activity 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. Natural phenomena should include earthquake, high winds, flooding, and other phenomena as appropriate for the geographical location of the activity.

3.166. For waste disposal facilities, the safety of any disposal facility depends primarily on the favourable characteristics or properties of natural barriers and the engineered barriers. The arguments to be made will depend on an understanding of the features of the facility and its host environment and of the factors that influence its safety after closure. Such an understanding is unlikely to be complete at this stage and should be reinforced and confirmed in the construction and operational stages to complete the technical basis and gain the public confidence necessary. The process of review and assessment of the site characteristics could take many decades and indeed may last into a period of institutional control following closure of the facility.

Design, construction, manufacture and installation

3.167. Before authorization of construction, review and assessment will be concentrated on the applicant's or authorized party'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 or activity systems 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 [31]. In addition, before authorizing construction or installation, the regulatory body should review and assess the authorized party's arrangements for the control of activities in construction, manufacture and installation. Once construction and installation 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 applicant or authorized party at the design stage. The plan should be subject to review and assessment by the regulatory body.

3.168. 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 applicant or authorized party and reported to the regulatory body, which should carry out the necessary review and assessment.

Commissioning

3.169. 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.

3.170. The inactive stage of commissioning is aimed at ensuring that the facility or systems for an activity have 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, by reconsideration of the safety documentation, that safety has not been compromised. The results of inactive commissioning should also confirm the operational features and should lead to the finalization of detailed instructions for operators, which should be confirmed during the active stage.

3.171. Active commissioning, after 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 or activity systems 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 authorized party and reported to the regulatory body, which should carry out the necessary review and assessment.

3.172. As the active commissioning processes move closer to completion, review and assessment should be concentrated on how the facility is operated or the activity performed, how the necessary safety systems, procedures and processes are maintained, and on the procedures for controlling and monitoring operations 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

3.173. For routine operation the regulatory body should require that the authorized party 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 operation of the facility or conduct of the activity is able to continue.

3.174. While the need for reassessment may arise in a number of ways (see para 3.184), a comprehensive safety review, such as a periodic safety review [8], should be carried out by the authorized party at intervals to review the cumulative effects of ageing of the facility or activity

systems 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 or activity and the potential magnitudes of the risks it presents. The objective of the reviews should be to assess the facility against current national and/or international safety standards and operating practices and to determine whether adequate arrangements are in place to maintain its safety. When a review shows that the facility or activity does not meet current standards and operating practices, the significance of the shortcomings should be assessed and possible ways of meeting the standards or practices should be considered. The comprehensive safety review should enable the regulatory body to judge whether it is acceptable for the facility to continue to be operated until the next comprehensive safety review is carried out.

3.175. The regulatory body should require the authorized party to provide evidence that in routine operation the facility or activity is being operated or the activity is being conducted in accordance with the safety requirements, in particular the operational limits and conditions. This evidence may be provided by means of reporting on operational parameters and occurrences relevant to safety. The regulatory body should review and assess the reports, and should perform inspections to ensure that the facility or activity complies with the safety requirements and is fit to continue in operation.

3.176. During the operation of the facility or conduct of the activity, the outline plan for decommissioning should be updated by the authorized party 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

3.177. Decommissioning of a facility or cessation of an activity, such that regulatory controls may be removed, includes decontamination and the dismantling and/or removal of radioactive materials, radioactive waste, structures, systems and components. Decommissioning comprises: the planning for decommissioning; the conducting of decommissioning activities including the management of waste arising from these activities; and the termination of the authorization for decommissioning. Just before the permanent shutdown of the facility or cessation of the activity, a detailed plan should be prepared by the authorized party and submitted to the regulatory body for authorization or approval. The decommissioning plan should be reviewed and assessed by the regulatory body in order to ensure that decommissioning can be accomplished safely with a progressive and systematic reduction in radiological hazards. In the case of a deferred dismantling strategy, in whole or in part, it should be demonstrated that no undue burdens will be imposed 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

3.178. To enable a disposal facility to proceed beyond the operational stage to closure, surface facilities should be decommissioned and the facility should be appropriately sealed. Detailed proposals for closure and for assessment of the safety of a disposal facility in the long term should be reviewed and assessed by the regulatory body. Further guidance is given in [26, 27]. 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 irretrievability; and the migration of radionuclides and potential pathways.

3.179. 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

3.180. Before an authorized party 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 authorized party. The authorized party should be required to provide evidence of this and, in particular, should be required to 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.

Information exchange between the regulatory body and the authorized party

3.181. The process of review and assessment is conducted by means of exchanges between the regulatory body and the authorized party, which should be formally recorded. The records will concern mainly:

- requests for additional information and questions by the regulatory body;
- responses by the authorized party (including those provided by its contractors);
- records of meetings between regulatory body staff and authorized party personnel.

3.182. This information should be kept in an organized way that permits retrieval according to different criteria such as subject, type, date or originator.

3.183. The regulatory body should request any necessary additional information and should be prepared to suspend or terminate its review and assessment if, in its judgment, 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, by the authorized party, under an effective management system, which should include a proper quality assurance system and an appropriate internal review process.

Reassessments

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

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

Performance of Review and Assessment

Internal Guidance

3.185. 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.

3.186. In carrying out a review and assessment of an applicant's or authorized party´s safety documentation, the regulatory body should employ a systematic process implemented through specific procedures to provide assurance that all topics significant to safety will be covered consistently with submissions for similar facilities or activities. This process should encompass the following steps:

(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 as 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 authorized party´s safety arguments or the need for further submissions.

3.187. A major feature of the authorized party´s safety documentation will be its safety assessment, including the analysis of normal, abnormal and accident conditions. However, the importance of the other aspects of the safety documentation should be recognized: the safety of a facility or activity 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.

Bases for Review and Assessment

3.188. 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 authorized party for guidance in preparing its documentation.

3.189. Safety objectives and regulatory requirements should specify safety goals for levels of performance of the safety structures, systems and components and managerial and operational procedures and processes to be achieved in operating the facility or conducting the activity. The regulatory body should refrain from prescribing specific designs, safety management systems or operational procedures.

3.190. 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.

3.191. 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 external experts including 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 or activities in respect of technologies or safety.

3.192. The safety objectives and regulatory requirements should cover, among other things, as

appropriate:

- Prevention of, rather than mitigation of accidents;
- 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 the use of passive systems over an active or operator based safety systems;
- 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 and response.

3.193. 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 authorized party or applicant on a case-by-case basis against general principles. Consideration of the proposals may lead to the production of additional regulations and guides or in the modification of existing ones.

3.194. In some instances, the authorized party may propose an alternative approach to that suggested in a guide to achieving a safety objective. In such a case, the authorized party should be required to demonstrate that its proposed approach will provide an equivalent level of safety. Further details on regulations, guides and authorization conditions are provided in the sub-section on Regulations and Guides.

Comparison with regulations, guides and industrial standards

3.195. The regulatory body should establish which requirements, based on regulations, guides and industrial standards are applicable to the facility or activity in question and to be placed on the authorized party. Where no such requirements 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 authorized party´s submissions.

Confirmatory calculations

3.196. The regulatory body may decide to perform a limited number of confirmatory calculations to check that the authorized party has justified a particular aspect of safety correctly, for specific purposes. However, in general it is not a resource-effective approach to carry out a significant amount of confirmatory calculations and where additional analyses are deemed necessary, the regulatory body should require the applicant or authorized party to perform them. Confirmatory calculations can provide information that can assist in:

(a) Identifying weaknesses, if any, in the authorized party safety case;

(b) Estimating safety margins or the degree of conservatism in the authorized party safety case;

(c) Performing sensitivity analyses and uncertainty analyses in order to verify the authorized part`s designation of the risk significance of various structures, systems and components;

(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;

(h) Extending, on a quantitative basis, the task of reviewing and assessing the design and operation of facilities and activities.

Verification of the Safety Analysis

3.197. The review and assessment process by the regulatory body consists in examining the submissions from the authorized party on its managerial arrangements, engineered systems and operational procedures and on the safety analysis for the facilities or activities. This safety analysis should cover both normal, abnormal and accidents conditions in order to demonstrate that the safety of the facility or activity 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 authorized party´s responsibility for the safety of the facility or activity. The following sections deal with major aspects of such verification; further details of topics for these aspects are set out in the Appendix 3.

3.198. In carrying out its review and assessment, the regulatory body should determine, if applicable, whether the authorized party has defined criteria which meet the safety objectives and requirements relating to:

(1) Engineering design;

(2) Operational and managerial aspects;

(3) Normal, abnormal and accident conditions.

3.199. The general aim of the regulatory review of a safety analysis report [9], whether based on deterministic or probabilistic analyses, should be 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, abnormal and accident 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

3.200. The safety analysis should demonstrate that the safety functional requirements on the structures, systems and components and operations are sufficient to ensure adequate safety. The review and assessment by the regulatory body should ensure that the authorized party has performed a suitable and sufficient safety analysis to confirm the requirements on the structures, systems and components and has used the results to demonstrate 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) Definition and categorization of the Safety functions;

(b) Identification and classification of structures, systems and components;

(c) Ensuring the quality of engineered features in terms of good engineering practice or as set out in the regulatory requirements;

(d) Demonstration of control of the facility or activity in normal, abnormal and accident conditions, with account taken of automatic systems, the human–machine interface and operating instructions;

(e) Adequacy of the safety management system, covering structures, systems and components and operational aspects such as the training, qualification and experience of the authorized party´s personnel and quality assurance procedures.

Operational safety performance

3.201. The regulatory body should review reports submitted periodically by the authorized party, in

compliance with established requirements, so as to monitor the operational safety performance of the facility or activity. Additionally, reports on safety significant events should be thoroughly reviewed by the regulatory body.

3.202. 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. Operational safety performance should not be restricted to considering the facility or activity itself but should consider a wide range of both radiation and non-radiation based facilities and activities from which lessons may be learnt.

Organization and management

3.203. A well-engineered facility or activity may not achieve the required level of safety if it is not operated or managed well. Review and assessment by the regulatory body should therefore include consideration of the authorized party´s organization, management, procedures and safety culture [10], which may affect the operation of the facility or conduct of the activity. The authorized party should be required to demonstrate by documentary means that there is an effective safety management system in place which gives safety the highest priority.

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

(1) Whether the authorized party 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 authorized party 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 authorized party 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 authorized party 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 authorized party 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.

3.205. The review and assessment by the regulatory body should cover all aspects of the authorized party´s managerial and organizational procedures and systems which have a bearing on 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 Appendix 3 for further details). The regulatory body should also review and assess the authorized party´s procedures for the control and justification of changes to the authorized party´s managerial and organizational procedures and systems which could have an impact on safety.

Radiological consequences in normal conditions

3.206. The assessment of routine operation is directed towards the determination of occupational radiation doses and radioactive discharges [3]. 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 authorized party´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 people and the environment in routine operation, which include:

(1) Inventory of radiation sources;

(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.

3.207. 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.

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

Safety analysis of abnormal and accident conditions

3.209. The consideration of abnormal and accident conditions strongly influences the design limits for the safety systems and for most structures, systems and components needed for the operation of the facility or activity [9, 28]. It will also strongly influence the operational instructions and procedures that operating personnel should follow. In addition, the potential radiological consequences for people and the environment of abnormal and accident 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 the abnormal and accident conditions provided by the authorized party. It should be performed in accordance with the potential magnitude and nature of the risks associated with the particular facility or activity.

3.210. 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.

Record of Review and Assessment

Records of the Regulatory Body's Review and Assessment

3.211. The review and assessment process will invariably involve the production of reports by various experts in the regulatory body and by any external experts 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

3.212. Review and assessment should result in a decision on the acceptability of the safety of the facility or activity 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. Typically, the following topics should be covered:

- Reference to the documentation submitted by the authorized party;
- The basis for the evaluation;
- The evaluation performed;
- Comparison with regulatory requirements, regulations and guides;
- Comparison with another similar (reference) facility or activity 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 authorized party.

INSPECTION OF FACILITIES AND ACTIVITIES

3.213. Requirement 27 of GSR Part 1 (Rev.1) [2] requires that "The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."

3.214. In accordance with the graded approach, for facilities and activities with a significant risk, the regulatory body should also verify the contents of the documents submitted by the applicant by means of inspection of the facility and activity where radiation sources are to be installed or used. These inspections will also allow the regulatory body to supplement the information and data needed for review and assessment.

3.215. The regulatory body should conduct inspections of manufactures authorized to supply consumer products, Appendix 1.

3.216. GSR Part 1 (Rev.1), para 4.49 [2] states that the regulatory inspection cannot diminish the prime responsibility for safety of the authorized party, and cannot substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party.

3.217. GSR Part 1 (Rev.1), para 4.52 [2] requires that the regulatory inspections cover all areas of responsibility of the regulatory body, and the regulatory body has the authority to carry out independent inspections. It is also required that regulatory inspectors have free access to any facility or activity at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections.

3.218. In conducting inspections, the regulatory body should consider a number of aspects, including:

- Radiation risks associated with the facility or activity, including areas of higher potential risk;
- Structures, systems and components important to safety;
- Management systems;
- Operational activities and procedures;
- Records of operational activities, performance and results of monitoring;
- Correction action plans;
- Liaison with contractors and other service providers;
- Competence, performance and resources of staff;
- Safety culture;
- Liaison with the relevant organization for joint inspections, where necessary;
- misadministration of radiopharmaceuticals to patients;
- theft or diversion of radioactive material.

3.219. Requirement 29 of GSR Part 1 (Rev.1) [2] states that the "Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."

3.220. The priority and frequency of inspections should reflect the risk associated with the radiation source and the complexity of the activity, as well as the possible consequences of an accident and the type and frequency of any violations found by inspections.

3.221. In implementing the inspection programme, the regulatory body should also establish a graded approach in responding to unforeseen circumstances – see also sub-section on Enforcement.

Objectives of Inspection

3.222. Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide a high level of confidence that authorized parties are in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that:

(a) All applicable laws, regulations and license conditions and all relevant codes, guides, specifications and practices are complied with;

(b) The authorized party has in place an effective management system and a strong safety culture and self-assessment systems for ensuring the safety of the facility or activity and the radiation protection of people and the environment;

(c) The required quality and performance are achieved and maintained in the safety related items and activities of the authorized party throughout the lifetime of the facility or activity;

(d) Persons employed by the authorized party (including contractors) possess the necessary competence for the effective performance of their functions throughout the whole lifetime of the facility and activity;

(e) Deficiencies and abnormal conditions are identified and promptly evaluated and remedied by the authorized party and duly reported to the regulatory body as required;

(f) Any other safety issue that is neither specified in the authorization nor addressed in the regulation is identified and appropriately considered;

(g) Any lessons learned are identified and propagated to other authorized parties and suppliers and to the regulatory body as appropriate.

Organization of Regulatory Inspection Function

3.223. Specific responsibilities of the regulatory body with respect to inspection should include:

- conducting planned inspections at all stages of the authorization process;
- carrying out reactive inspections, if appropriate, in response to events, incidents or accidents;
- identifying and recommending necessary changes to the requirements approved by the regulatory body, specified in the authorization or contained in the regulations;
- preparing reports to document its inspection activities and their findings;
- verifying the authorized party's compliance with regulatory requirements and confirming adherence to safety objectives;
- ensuring that the authorized party has adequate, comprehensive and up to date information on the status of the facility or activity and information for demonstrating its safety, and a procedure to maintain this information up to date;
- tracking recurrent problems and non-compliance;
- developing procedures and directives as necessary for the effective conduct and administration of the inspection programme;
- determining and recommending suitable enforcement actions when non-conformance with requirements is encountered.

3.224. The major activities of the inspection process are related to the stages of the authorization process. The regulatory body should organize and modify its inspection activities to conform to the stage of the lifetime of the facility or activity. Specifically, as a facility passes from one stage of its lifecycle to another, the regulatory body will normally find it necessary:

- to adjust the levels of attention given to particular inspection areas and to redeploy its human resources accordingly;
- to alter the extent to which various inspection techniques and methods are employed;
- to modify the rigour and frequency of the inspections.

Inspection Programme

3.225. This safety guide focuses on technical aspects of the development of inspection program while the organization and management of inspection program is addressed in [4].

3.226. It is required that the regulatory body develops and implements a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization It is also required that the inspection programme, specifies the types of regulatory inspection (including scheduled inspections and unannounced inspections), stipulates the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach, (GSR Part 1 (Rev.1), para 4.50 [2]).

3.227. Regulatory inspection programmes should be comprehensive and consistent with the overall regulatory strategy. The inspection programmes should be thorough enough to ensure that the regulatory objectives and requirements are met thereby providing the regulatory body with a high level of confidence that authorized parties are effectively maintaining the safety of their facility and activities. The inspection programme should also be developed so that the regulatory body can determine if the authorized party has an effective self-assessment process capable of prompt identification and correction of actual and potential problems and conducts activities in accordance with previously established high quality procedures.

3.228. For all areas of responsibility, the regulatory body's inspection programme should include as key elements:

- a system of prioritizing inspections based on a graded approach;
- on-site visits of inspectors;
- the investigation and follow-up of events and deviations from normal operation;
- the submission of information on key operational safety parameters by authorized parties.

On-site inspection[6] is the one element of the regulatory regime closest to actual operations, and a significant proportion of the regulatory body's resources should be allocated to this task.

3.229. The regulatory inspection programme should give due consideration to technology, human as well as organizational (leadership and management system) factors. Accordingly, the inspectors' training and qualification program should also be tailored to develop competencies of regulatory inspectors in these areas.

3.230. In addition to verifying compliance with all applicable regulatory requirements, the regulatory body's inspection programme should be such as to provide a general sense of the 'safety' of operations. Perspectives on safety in general should be aided by the use of indicators of the potential for degraded safety performance. The more common indicators of degraded performance include, but not limited to:

- poor housekeeping;
- poor financial stability;
- insufficient staffing;
- high turnover of staff;
- poor record retrieval systems;
- lack of set investigation levels;
- lack of procedures to be followed in the event that investigation levels are exceeded;
- inadequate training;
- lack of retraining of staff;
- higher than average occupational exposures for the type of facility or activity;
- Repetitive failures of important facility equipment (reliability);
- Frequent unavailability of the facility;
- Increasing frequency of safety allegations or other enforcement actions.

These indicators could be used as a basis to inform authorized parties of the need to improve and as a basis for establishing the frequency of inspections for any particular authorized party. The regulatory body should require authorized parties to pay attention to such indicators of degraded safety performance. This focus on indicators and the underlying performance issues should contribute to the enhancement of a strong safety culture.

3.231. Different methods may be used in establishing or modifying an inspection programme, with associated priorities, to achieve the objectives of regulatory inspections. The regulatory body should consider the following:

– the results of previous inspections;

[6] On-site should be interpreted appropriately: some activities do not take place on fixed sites so inspection may need to be carried out in an appropriate, but variable, location

- the safety analysis performed by the authorized party and the results of regulatory review and assessment;
- performance indicator programmes or any other systematic method for the assessment of the authorized party's performance;
- operational experience and lessons learned from operating a facility or conducting an activity, including similar facilities and activities at national and international level, as well as results of research and development;
- inspection programmes of the regulatory bodies in other States.

3.232. The regulatory body should have the capability to undertake inspection activities when necessary; in particular, sufficient inspection resources should be available for reactive inspections. For verification of the overall performance of the authorized party, inspections of adequate depth should be conducted in a wide range of subject areas and at appropriate intervals. Each planned inspection should have objectives which have previously been specified by the regulatory body to serve to the extent practicable as guidance for inspection personnel.

3.233. The regulatory body should establish a process of periodically evaluating the findings of inspections, identifying generic issues and making arrangements to enable inspectors from various locations or projects to meet to exchange views and discuss the findings and issues.

3.234. The authorized party should be required to keep the regulatory body informed of its schedules for carrying out activities and tests of regulatory interest and should submit or make available to the regulatory body in a timely manner the procedures for these activities. To facilitate this process, the regulatory body should specify well in advance to the authorized party the activities and tests of which it wishes to be informed.

3.235. As part of the inspection program, the regulatory body should compile and assess regularly, data on the performance of authorized parties, outcome of regulatory inspection programme (inspection findings, corrective actions, and inspection reports) and trends to identify potential areas for improvement in the performance of authorized parties and regulatory processes. The reports of such assessments and analyses should be shared and communicated within the regulatory body.

Types of Regulatory Inspection

3.236. GSR Part 1 (Rev.1), Requirement 28 [2] states that "Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."

3.237. Regulatory inspection should include a range of planned and reactive inspections over the lifetime of a facility or activity and include inspections of other relevant parts of the authorized party's organization and contractors to ensure compliance with regulatory requirements.

3.238. Inspections should be conducted by individuals or teams and may be announced or unannounced, as part of a general programme or with specific aims.

Planned inspections

3.239. Planned inspections, either announced or unannounced, are carried out in fulfilment of, and in conformity with, a structured and largely prearranged or 'baseline' inspection programme developed by the regulatory body. They may be linked to authorized party schedules for the performance or completion of certain activities at all stages of the authorization process. Planned inspections differ from reactive inspections in that they are scheduled in advance by the regulatory body and are not initiated because of unusual or unexpected circumstances. Planned inspections provide an opportunity for the examination of the authorized party's activities in order to confirm the authorized party's performance and to identify potential problems at an early stage.

3.240. In planned inspections, emphasis should be given to the observation and assessment of continuing safety activities in order to assess the effectiveness of the authorized party's performance.

3.241. The regulatory body should consider conducting special inspections of specific issues which may be of interest to the regulatory body, such as refurbishment, new findings from research and development work and experience from other facilities or activities. Special inspections are usually in the category of planned inspections, since they are scheduled in advance; however, in certain circumstances they may be reactive inspections. This type of inspection may range from a single inspector reviewing a specific inspection area to a team of inspectors reviewing different inspection areas.

Reactive inspections

3.242. In addition to routine inspection activities, the regulatory body should carry out inspections at short notice if an abnormal occurrence warrants immediate investigation. Such regulatory inspection does not diminish the responsibility of the authorized party to investigate any such occurrence immediately.

3.243. Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be occasioned by an isolated incident or a series of lesser events occurring at the particular facility or activity under consideration. Similarly, a reactive inspection may be made in response to a generic problem encountered at another facility or activity or identified by the review and assessment staff of the regulatory body. Unlike planned inspections, which are scheduled, reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules. The regulatory body should assume that there will be a need for reactive inspections and should plan to meet its needs for staff and external experts accordingly. All available resources may be needed in

responding to a serious event, whereas in the simplest of cases only one inspector may be needed. A pre-established graded approach in responding to special circumstances will assist in determining the appropriate level of resources for use in inspections.

3.244. The regulatory body should use the authorized party's reports of safety related activities or events for assistance in preparing for both planned and reactive inspections. Matters to be included in reports from the authorized party should be clearly defined so that difficulties in interpretation can be avoided. A suggested list is given in para 3.218.

3.245. The inspection programme of the regulatory body should include provisions for investigation of incidents and accidents by leaving some inspection resources available for reactive inspections. As such, for more serious accidents or potentially serious accidents, or when operational parameters (e.g. doses) exceed regulatory limits or are significantly elevated, an independent investigation should be conducted by the regulatory body and in some cases by other governmental bodies, in addition to the investigation to be conducted by the authorized party. There are usually two main objectives in an investigation of a serious accident by the authorities, which are not completely separable but which need to be distinguished:

(1) Determination of the reasons why the accident happened so as to take measures to prevent its recurrence;
(2) Consideration of the legal aspects concerning liability for the accident.

3.246. Determining why the accident happened is of central interest with regard to safety. Investigations should be carried out by, or in consultation with, a person with appropriate knowledge and experience. With regard to the regulatory investigation of the accident, the following should be included:

(a) The determination of the root causes, the sequence of events and the contributory factors;

(b) The assessment of the consequences;

(c) The identification of preventive and corrective actions;

(d) The documentation of lessons to be learned;

(e) The recommendations of measures to be taken for the prevention of similar accidents in the future, including changes in the regulatory programme, as well as any adjustments in the safety programmes of authorized parties;

(f) The dissemination of all findings, lessons to be learned and recommendations to relevant authorized parties, manufacturers and suppliers, both nationally and internationally.

Announced and unannounced inspections

3.247. An announced inspection is an inspection of which the authorized party has been informed in advance by the regulatory body. The regulatory should consider the timing of the announcement of the

inspection, which may vary according to the circumstances of the inspection to be performed. Inspections may be announced, for example, when the regulatory body wishes to observe a specific test or activity, to review a specific self-assessment by the authorized party while it is in progress or interview a specific member of the authorized party's staff.

3.248. The main advantage of announced inspections is that the regulatory inspector is able to discuss plans and needs with the authorized party's personnel in advance in order to secure assurances that documentation will be available for inspection, personnel will be available for interview and activities can be inspected as scheduled. Hence, the announcement of inspections may enhance their effectiveness.

3.249. Unannounced inspections may not always be feasible, but they have benefits. The advantage of unannounced inspections is that the actual state of the facility and the way in which it is being operated can be observed. Inspections may be carried out at any time of the day or night so as to provide a more complete picture of the situation at the facility or activity. However, the regulatory body should be sensitive to activities on-going at the site.

Team Inspections

3.250. Team inspections, which may be multidisciplinary, provide an in-depth, independent and balanced assessment of the authorized party's performance. This type of inspection may vary in both scope and complexity. Team inspections are of particular value once safety problems have been identified, since other inspections may cover only small samples of the authorized party's activities in any particular area. Inspections of this type should identify underlying causes of problems in order to determine whether a safety concern represents isolated cases or may signify a broader, more serious problem.

3.251. Different approaches should be used in planning team inspections. Some team inspections may be broad in focus and cover a wide subject area ('horizontal slice') in the programme area of interest. For example, during a team of inspectors may assess the performance of operations at a facility or the conduct of an activity, or a team of maintenance and engineering inspectors may assess activities during an outage of the facility or activity. Other team inspections may be narrow in focus and cover a smaller subject area ('vertical slice'). For example, a number of specialist inspectors may review in depth a single safety system in order to confirm that the system is in full compliance with the regulatory requirements or a team may inspect the same safety aspect at similar facilities or activities in the State.

Planning of Regulatory Inspection

3.252. The organization and management of inspection planning and the allocation of inspection resources is described in [4], whereas this safety guide focuses on technical aspects of the inspection plan.

3.253. The particular aspects that should be considered in determining the intervals between inspections in the various areas and the level of effort to be applied in the inspection include:

- the safety significance of the issues;
- the inspection methods and approaches used (for example, the use of resident inspectors may influence the intervals and the scope and depth of inspections);
- the performance record of the authorized party and the facility, for example, the number of violations, deficiencies, incidents and problems and the number of reactive inspections;
- the results of regulatory review and assessment;
- the type of facility or activity;
- the personnel and other resources that must be available to the regulatory body;
- the results of previous inspections.

3.254. To facilitate management of the allocation of resources for inspections, the regulatory body should develop specific inspection plans in which the aforementioned factors are taken into account. The inspection plans should be recorded in such a way that they can easily be modified to take into account continuing activities, and they should be reviewed periodically and modified as necessary.

3.255. The inspection plan for a specific facility or activity should be flexible enough to permit inspectors to respond to particular needs and situations. On major facilities, many States allow for 25% of the inspection time to be available for reactive inspection.

3.256. The planning of the programme of inspections will also be influenced by the locations of the regulatory body's offices and of the facility or activity to be inspected.

3.257. Arrangements should be made to ensure that all relevant staff of the regulatory body can fully contribute to the planning of inspections and in particular, if the offices of the regulatory body are distributed over a wide area, that inspectors are involved in the planning process. This will ensure the best use of the skills and knowledge of its staff.

3.258. The regulatory body should have an overall plan for the programme of inspections that it is to undertake at a facility or during an activity. The plans for inspection specific facilities or activities should be determined using a graded approach.

Selection of Inspection Areas

3.259. Inspections by the regulatory body should be concentrated on areas of safety significance. These are those items and activities affecting safety or processes important to safety which are identified as such in the safety documentation submitted by the authorized party or in the findings of the regulatory body's review and assessment, or which are stipulated in the conditions attached to the authorization (or regulations as appropriate).

3.260. The regulatory body's attention to major inspection areas does not begin and end in a single stage but continues with varying degrees of emphasis throughout the lifetime of the facility or activity. This Safety Guide covers a wide range of types of facilities and activities, and it is not possible to provide for each type details of specific areas that would be subject to inspection at each lifecycle stage. The degree to which the areas should be considered will depend on the nature of the facility or activity and the risks associated with it. Major inspection areas for nuclear facilities are listed in Appendix 4.

3.261. Inspection should not be limited to the facility or activity itself and should cover any relevant central services which may be supplied at an authorized party's headquarters or other offices such as safety assessment development, outage planning or training.

3.262. Whenever the authorized party makes use of the services or products of a contractor, the regulatory body should include the contractor's activities in its inspection programme in all lifecycle stages of the authorization process. This may comprise inspection of the design and manufacturing of components, including, where appropriate, activities performed in other States. Inspection of the authorized party's contractors should only be performed in connection with the authorized party so that the authorized party is not relieved from the prime responsibility for safety.

Performance of Regulatory Inspection

Internal Guidance

3.263. To ensure that all authorized parties are inspected to a common standard the regulatory body should provide its inspectors with written guidelines and procedures in sufficient detail. Appropriate subjects for guidance and instructions for inspectors are covered in paragraph 3.39.

3.264. The authority vested in inspectors should oblige them to conduct themselves in a manner that inspires confidence in and respect for their competence and integrity. They should, for example, make adequate preparation by gathering and reviewing all relevant information and data before proceeding on assignment and should be knowledgeable about the area which they are required to inspect. The importance of objectivity and fairness on the part of inspectors should also be stressed by the regulatory body in its guidance, together with the need to respect the rules as established by the authorized party provided these do not prevent the inspector from fulfilling their duty.

Preparation for an Inspection

3.265. Before an inspection is carried out, the inspection personnel should be thoroughly prepared for the task. The type of preparation will depend on the type (planned, reactive, announce or unannounced, and team) and method (see para 3.267) of inspection. Preparation may include a review of the following:

– regulatory requirements relating to the authorized facility or activity, and conditions on the authorization issued to the authorized party;

- experience feedback relating to the inspection area;
- findings of previous inspections and enforcement actions relating to the inspection area, and any unresolved issues from previous inspections;
- past correspondence between the regulatory body and the authorized party relating to the inspection area;
- the safety documentation and operational limits and conditions;
- documentation on operation and design for the facility or activity;
- the authorized party's management system.

3.266. Preparations should be made by the individual or team (including any external experts) who will be conducting the inspection. It is generally useful to establish a specific plan for the inspection by compiling a questionnaire and a list of the documents to be reviewed with the authorized party.

Methods of Inspection

3.267. The inspection procedures of the regulatory body should incorporate and use a variety of methods:

- monitoring and direct observation (such as of working practices and equipment);
- discussions and interviews with personnel of the authorized party and the contractor, if needed;
- examinations of procedures, records and documentation;
- confirmatory tests and measurements.

In individual inspections, one or more of these methods should be employed in a balanced way, depending on the specific issues being considered.

Monitoring and direct observation

3.268. The inspection methods should include provision for direct monitoring of items, such as: human factors significant to safety (performance of personnel, managerial attitudes), tests and other safety related activities carried out by the authorized party.

3.269. The regulatory body may prescribe certain categories of structures, systems and components, tests and activities which should be directly observed by its inspectors in whole or in part. In some cases, the regulatory body may require regulatory monitoring of a specific structure, system, component, test or activity as a condition for the authorized party to be permitted to proceed to subsequent stages of work or operation. Monitoring is particularly useful during the commissioning stage, or as a means of verifying corrective action at any stage over the lifetime of the facility or

activity as required by the regulatory body after an abnormal occurrence or a finding of serious non-compliance.

3.270. The regulatory inspection programme should provide time for general surveillance of the facility or activity site by regulatory inspectors. Such surveillance is aimed at gaining an overall impression of the authorized party's capabilities and performance and is not restricted to specifically designated components and systems or designated scheduled activities and tests.

Examples of areas for observation include:

- workplaces;
- transfer of job between persons;
- radiation protection arrangements including boundaries of controlled areas;
- features important for the safety of facility and activity;
- fire barriers;
- housekeeping;
- the presence of management;
- internal and external interfaces and communications;
- arrangements for emergency preparedness and response.

Discussion and interviews with authorized party personnel

3.271. Regulatory inspectors should, as appropriate, communicate directly with the authorized party's personnel responsible for supervising and performing the activities and tests being inspected. This is especially important in follow-up investigations in which the inspector is engaged in reconstructing events and assessing the authorized party's response.

3.272. The authorized party's personnel should be kept appropriately informed of inspection activities. These considerations can be partly satisfied by means of discussions and interviews. Interviews[7] with workers, the facility or activity manager and, as appropriate, with other senior managers should be standard features of most inspection visits. In interacting with the authorized party's staff, the inspector should exercise mature judgment concerning the prerogatives and responsibilities of the facility's management.

Examination of procedures, records and documentation

3.273. The authorized party should be required to record all activities, results and considerations important to safety at all lifecycle stages of the facility or activity.

[7] Note that the word "interview" does not necessarily imply a formal, pre-arranged, process, but should also include less formal discussions

3.274. Examination of the authorized party's documentation contributes to the regulatory body's verification of the authorized party's compliance without unduly disrupting work schedules or interfering with the authorized party's primary responsibility for safety during all lifecycle stages. Documentation examined by regulatory inspectors may include:

- procedures and schedules for maintenance and testing;
- quality assurance records;
- test results and data;
- operational and maintenance records;
- records of deficiencies and incidents;
- modification records including modifications to management and operating procedures;
- training records;
- dose records.

3.275. The regulatory body should examine samples of the authorized party's documentation sufficient to satisfy itself that the authorized party is fulfilling the requirements for authorization and is operating in accordance with the practices proposed by the authorized party and approved by the regulatory body and that, where deviations or deficiencies have been detected, they have been adequately addressed.

3.276. The examination of documentation by regulatory inspectors may in some cases take place, in part, off the site, for example at the regulatory body's or authorized party's headquarters, and can contribute towards their preparation for inspection of the facility or activity.

Tests and measurements

3.277. The extent to which the regulatory body does its own confirmatory testing and measurement work independently of the authorized party varies greatly between States, depending upon such factors as the qualifications of personnel available to the regulatory body, its regulatory philosophy, and the experience and demonstrated performance of authorized parties. However, the regulatory body should not engage in the conduct of confirmatory tests or measurements which would necessitate it assuming direct operational control of the facility or activity or any of its systems.

3.278. In some States, the inspection staff of the regulatory body conduct confirmatory tests and measurements as part of the inspection programme. Tests of components and systems of the facility should only be undertaken after consultation with the facility's management. In most instances, these confirmatory tests and measurements replicate and serve as an independent verification of tests and measurements performed by the authorized party. The conduct of these confirmatory tests and

measurements by the regulatory body shall not relieve the authorized party of its prime responsibility for safety. The regulatory confirmatory test should not place the facility in an unsafe condition.

3.279. Since the regulatory body itself conducts only limited testing, a detailed review should be carried out of a sample of the authorized party's procedures for tests and its interpretation of their results. If external experts are used to monitor the confirmatory tests and measurements, their reports also should be reviewed. Where further confirmatory tests or measurements are needed, the regulatory body should request that they are performed by the authorized party.

3.280. Whatever its inspection programme may be, the regulatory body should have the authority and resources [4] to be able to carry out confirmatory tests and measurements as necessary, at fixed points or in places of special interest, as applicable, using own equipment.

Conduct of Inspection

3.281. The inspections should be conducted according to the approved inspection programme, plan, guidelines, procedures and checklists. The techniques utilized for the inspections should commensurate with the inspection requirements and the activity or area being inspected. Certain activities may require the inspectors to avoid immediate discussions with the personnel performing the activity whereas some of the inspections may not have opportunities for taking direct observations.

3.282. Inspectors should note down their observations while conducting the inspections. Upon completion of the inspection, the inspectors should conduct an exit briefing with senior management and share the details about the inspection activities, observations, good practices, deficiencies and deviations with the inspected organizations and also obtain feedback about the conduct of inspection.

Records of Regulatory Inspection

3.283. It is required that the regulatory body shall record the results of inspections and shall take appropriate action (including enforcement actions as necessary). It is also required that the regulatory body uses the results of inspections as feedback information for the regulatory process and be provided to the authorized party, (GSR Part 1 (Rev.1), para 4.51 [2]).

Inspection Reports and Findings

3.284. A report of each regulatory inspection should be prepared by the inspector (or inspectors) who performed the inspection. The report should be reviewed and approved according to established internal procedures. The scope, layout, content, timing and distribution of inspection reports may vary according to the:

- general administrative and legal structure in the State and the requirements established by the regulatory body;
- type of facility or activity and its stage of authorization;
- location of the inspection;

- type of the inspection, whether planned, reactive, announce or unannounced, or team;
- purpose of inspections (e.g. team inspections, special inspections, site visits by non-resident site inspectors, weekly inspection activities carried out by resident inspectors).

3.285. The purposes of inspection reports are to:

- record the results of all inspection activities relating to safety or of regulatory significance;
- document and record an assessment of the authorized party's activities in relation to safety;
- record discussions held with authorized party's staff, management and other concerned persons;
- provide a basis for informing the authorized party of the findings of the inspection and of any non-compliance with regulatory requirements, and to provide a record of any enforcement actions taken;
- record any findings or conclusions reached by inspectors;
- record any recommendations by inspectors for future actions by the authorized party or the regulatory body and to record progress on recommendations from previous inspections;
- inform other members of the regulatory body;
- contribute to maintaining an organizational memory.

Content of inspection reports

3.286. Inspection reports should typically contain:

- details of the authorized party inspected, the purpose and date of the inspection and the inspectors' names;
- the methods used in the inspection (interviews, observations, review of documents);
- reference to applicable requirements;
- criteria used in the assessment;
- details of areas, activities, documents, processes, items, and qualification and training of the personnel which have been inspected, assessed or reviewed;
- a record of actual or potential problems relating to safety;
- a record of the results of any checks for compliance with the terms and conditions of the authorization and applicable State regulations;
- a record of any deficiency or violation found in regulatory inspections, including a record of which requirements or regulations have been contravened;

- a record of discussions held with the authorized party's staff, managers and other persons, including a record of discussions with authorized party's managers about points of concern;
- a record of the inspectors' opinion about the response of the authorized party's management to any matter of concern to which their attention was drawn after a regulatory inspection;
- a record of any regulatory action taken by inspectors and any consequent action taken by the authorized party in the period covered by the report;
- a record of the findings or conclusions of the inspectors, including corrective actions that should be taken;
- a record of recommendations made by inspectors for future action, such as a need to advise other inspectors or authorized parties about particular problems, proposals for further inspections or proposals for enforcement actions.

Distribution and use of inspection reports

3.287. Inspection reports should be distributed, or made available electronically, according to established procedures in order to provide for the following:

- a basis for future regulatory action;
- a contribution to maintenance of the regulatory history by providing a record of inspections, discussions and associated findings and conclusions;
- a basis for identifying major or generic issues which necessitate special inspections, changes to inspection plans or generic regulatory action;
- information to regulatory staff responsible for review and assessment;
- information to regulatory staff responsible for reporting incidents;
- information to regulatory staff responsible for regulations and guides;
- a basis for periodic reviews of inspection findings, including trends and root causes;
- information to regulatory staff responsible for the development of requirements for authorization or new regulations;
- a means of sharing information with other inspectors;
- a means of passing information to interested parties or governmental bodies;
- self-assessment activities.

3.288. Inspection findings should typically be discussed at regular meetings attended by groups of inspectors. It is also a good practice in many States to include those regulatory body staff involved in review and assessment activities or authorization activities in such meetings.

3.289. Inspection findings should be forwarded to the authorized party for information and records, as well as for necessary corrective actions. Whenever corrective action is needed, a formal communication including findings detailed in inspection reports should be sent to the authorized party. In some States, the full inspection report is forwarded to the authorized party. In communications with the authorized party, caution should be exercised in identifying individuals by their name or their post because of the possible implications (including those of a legal nature) for the individuals concerned.

3.290. Documents that are made available to the inspector by the authorized party during an inspection should be referenced in the inspection report. Inspection reports and copies of documents received in connection with the inspection should be stored in a manner that permits ready retrieval and that follows the applicable classification procedures.

3.291. From time to time the regulatory body may find it useful to produce a composite report covering a type of facility, activity or a specific aspect of inspection, drawing together findings from a number of relevant inspection reports.

Publication of inspection findings

3.292. In order to inform the public of the safety of facilities and activities and of the effectiveness of the regulatory body, findings of inspections and regulatory decisions should be made publicly available. The extent to which such information is made publicly available will depend on the legal provisions in the State concerned.

3.293. Although it may be the practice in some Member States to publish individual inspection reports or inspection follow-up letters sent to the authorized party, they may contain confidential information, such as nuclear security information, information which the regulatory body may wish to use in connection with future regulatory actions, proprietary information, personal or medical information relating to individuals and proprietary information. Such information should be withheld.

3.294. All information exchanged between the regulatory body, other governmental bodies, the authorized party, its contractors, advisory committees and the regulatory body's consultants and, as appropriate, members of the public should be formally recorded upon receipt and stored in a manner that permits ready retrieval.

Follow-up on Inspection Findings

3.295. A programme to monitor and follow up inspection findings should also be in place. The programme should include provisions for regular/periodic review and surveillance of the follow up actions to verify that the applicant or authorized party is taking necessary actions in response to inspection findings. Upon satisfactory completion of the actions, the inspection findings should be closed in writing and necessary documents and records maintained.

ENFORCEMENT OF REGULATORY REQUIREMENTS

3.296. Requirement 2 of GSR Part 1 (Rev.1) [2] requires in part that the government promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety, including provisions for the enforcement of regulations, in accordance with a graded approach.

3.297. Requirement 30 of GSR Part 1 (Rev.1) [2] requires that the regulatory body establishes and implements an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.

3.298. Requirement 31 of GSR Part 1 (Rev.1) [2] requires that enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance.

3.299. The authorization process itself is a form of enforcement as refusing an application for an authorization means that operation of the facility or conduct of the activity is prohibited and legal sanctions can be used if the prohibition is not complied with. However, in most States the term “enforcement process” is restricted in use to actions in connection with non-compliances and violations of legally binding requirements occurring during operation of a facility or conduct of an activity.

3.300. Regulatory enforcement activities should cover all areas of regulatory responsibility. Enforcement actions should be applied as necessary by the regulatory body using a graded approach appropriate to the legal system and the authorization practices of the State.

Objective of Enforcement

3.301. The principal objectives of enforcement should be to provide a high level of assurance that the authorized party at all stages of the authorization process and all stages during the lifetime of a facility or activity complies with all safety requirements and meets the safety objectives and authorization conditions, and promptly identifies and corrects non-compliances with safety requirements.

3.302. Regulatory enforcement actions are actions taken by the regulatory body to address non-compliance by the authorized party with specified conditions and requirements. These actions should be taken to ensure that the authorized party modifies or corrects any aspect of its procedures and practices, or of a facility or activity’s structures, systems and components, or managerial or operational procedures and processes, that are necessary to ensure safety. Enforcement actions should also include the imposition or recommendation of civil penalties and other sanctions, as appropriate, depending on national legislation.

Methods of Enforcement

Verbal and written notification

3.303. As the main purpose of enforcement is to ensure safety by deterring noncompliance and encouraging prompt identification and correction, enforcement actions should be chosen to achieve this end. However, the method chosen should also be appropriate to the severity of the violation or non-conformance. The next paragraphs describe some of the main enforcement methods followed by a discussion of the factors affecting the choice of method.

3.304. A range of enforcement actions should be available to the regulatory body but in many cases it may be possible to resolve the non-compliance by means of discussion with the authorized party.

3.305. If necessary, the verbal notification should be formalized in a written notification, based on the legal system of the Member State.

Written warnings or directives

3.306. Deviations from, or violations of, requirements [of the authorization], or unsatisfactory situations which have more than minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances, the regulatory body should issue a written warning or directive to the authorized party which should identify the nature and regulatory basis of each violation, the period of time permitted for taking remedial action, and may provide guidance on the nature of the corrective action. This is the most common form of enforcement action and will, in most cases, suffice to remedy the safety issue.

Imposition of additional regulatory requirements and conditions

3.307. If there is evidence of a deterioration in the level of safety, or in the event of serious violations which in the judgment of the regulatory body pose an imminent radiological hazard to people or environment, the regulatory body should require the authorized party to curtail [specific] activities and to take any further action necessary to restore an adequate level of safety.

Modification, suspension or revocation of the authorization

3.308. In the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctioning of equipment, damage to structures, systems and components or incorrect operation of a facility or conduct of an activity, the regulatory body should direct the authorized party to curtail operation or activities and may suspend or revoke the authorization. The authorized party should be directed to eliminate any unsafe conditions. In considering the withdrawal of an authorization, the regulatory body should ensure that operations or activities important to maintain safety continue to be performed by the authorized party.

Penalties

3.309. The regulatory body should have the authority to impose or to recommend penalties, for example, fines on the authorized party, whether a corporate body or an individual, or to institute prosecution through the legal process, depending on the legal system and the authorization practices of the State. The use of penalties is usually reserved for serious violations, for repeated violations of a less serious nature, or for wilful non-compliance. Experience in some States suggests that imposing penalties on the authorized party rather than on individual workers is preferable and is more likely to lead to improved safety performance.

Factors in Determining Enforcement Actions

3.310. The factors to be taken into account by the regulatory body in deciding which type of enforcement action is appropriate in each case should include:

(a) The safety significance of the deficiency and the complexity of the corrective action needed;
(b) The seriousness of the violation;
(c) Whether the violation is a repeat violation of a less serious nature;
(d) Whether there has been a wilful violation of the limits and conditions specified in the authorization or in regulations;
(e) Whether or not the authorized party identified and/or reported the non-compliance;,
(f) The past performance of the authorized party and the performance trend;
(g) The need for consistency and openness in the treatment of authorized parties; and
(h) Whether the violation impacted the ability of the regulatory body to perform its regulatory oversight function.

Implementing Enforcement

The inspector's authority in relation to enforcement

3.311. The extent of the authority of the regulatory inspectors to take on the spot enforcement actions should be determined by the regulatory body considering the national legislation and regulations. The authority given to an inspector may depend on the structure of the regulatory body and on the inspector's duties and experience.

3.312. In many States, inspectors are empowered to implement enforcement actions for non-compliances or violations to enable a more rapid response and improvement in safety. Where on the spot enforcement authority is not granted to individual inspectors, the transmission of information to the regulatory body should be suited to the urgency of the situation so that necessary actions are taken in a timely manner; information should be transmitted immediately if the inspectors judge that the health and safety of workers or the public are at risk, or the environment is endangered.

3.313. Significant enforcement actions, particularly those involving fines, the curtailment of activities or the suspension of authorization, are not taken on the spot by regulatory inspectors except in unusual

situations. Normally, decisions concerning these types of enforcement actions should be approved by the regulatory body through its established procedures.

Use of the enforcement process

3.314. The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures.

3.315. If there is no immediate risk to safety, the regulatory body should allow the authorized party a reasonable period of time in which to complete a corrective action. The time period should reflect the seriousness of the issue and the complexity of the corrective action required. However, in an integrated approach to safety, the contribution of each deficiency requiring a corrective action to the total risk for the facility or activity should be considered.

3.316. Procedures should stipulate which other governmental bodies, if any, should be informed in the event of enforcement actions being made.

3.317. To inform the public and interested parties about the enforcement process, a formal enforcement policy statement from the regulatory body should be developed and made available to the public.

3.318. Regulatory procedures should state the circumstances under which it is appropriate to carry out further inspections to check whether the authorized party has responded to regulatory and enforcement measures. The purpose of these inspections should be to:

(a) Confirm that the authorized party has complied with the enforcement measures within the periods of time specified;

(b) Check that corrective actions in response to enforcement measures intended to protect the people, patients and the environment against an imminent radiological hazard have been taken by the authorized party, even though the authorized party may intend to appeal against the decision of the regulatory body.

Records of Enforcement

3.319. It is required that, at each significant step in the enforcement process, the regulatory body identifies and documents the nature of any non-compliances and the period of time allowed for correcting them, and should communicate this information in writing to the authorized party, (GSR Part 1 (Rev.1), para 4.56 [2]).

3.320. All enforcement actions should be recorded in accordance with an established procedure and with legal and regulatory practices. Whenever an enforcement action has to be taken urgently to ensure the radiation protection of people and the environment, the action should be confirmed in writing as soon as possible.

3.321. Internal records of decisions relating to enforcement actions and any supporting documentation should be kept in such a way that it is easily accessible and retrievable when required.

3.322. Moreover, requirement 35 of GSR Part 1 (Rev.1) [2] requires that the regulatory body use such records in support of its regulatory functions and to support the enforcement of regulatory requirements.

EMERGENCY PREPARDENESS AND RESPONSE

3.323. The responsibilities of the Government in the area of emergency preparedness and response are set out in Requirement 8 of GSR Part 1 (Rev.1) [2], Requirement 43 of GSR Part 3 [3] and Requirement 2 of GSR Part 7 [11]. Within these requirements, the Government is required to clearly specify and assign the roles and responsibilities in emergency preparedness and response, which will include the regulatory body.

3.324. Paragraph 4.13 of GSR Part 7 [11], states that: "The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions." These arrangements should address coordination and integration of on-site emergency arrangements with other relevant plans (such as those of other response organizations or the nuclear security plans of the authorized party).

3.325. The Government may assign the regulatory body other roles and responsibilities in emergency preparedness and response but their precise nature will depend on the specific legal and organizational structures in the State. In the following text, therefore, it is only possible to identify the necessary functions and processes that the regulatory body should perform, in relation to these roles and responsibilities, in a generic manner.

3.326. The functions and processes for which the regulatory body will have a role can be considered under the following four general headings:

- Ensuring on-site emergency arrangements;
- Ensuring coordination with off-site response organizations;
- Establishing and maintaining internal arrangements;
- Discharging its assigned responsibilities in emergency response.

Much of this is carried out through the functions and processes described in earlier sections.

3.327. Whilst much of the efforts by the regulatory body and authorized parties in preparedness and response for nuclear and radiological emergencies will be devoted to incidents and accidents at facilities and activities within the State, some nuclear and radiological emergencies in other States may have an impact on these facilities and activities. Such impacts should be considered in the hazard

assessment carried out for these facilities and activities and should be addressed, as appropriate, in the response planning.

Ensuring on-site arrangements

3.328. The Regulatory body should have the responsibility for ensuring that the authorized party has adequate on-site arrangements to prepare for and respond to a nuclear or radiological emergency.

Regulations and Guides

3.329. It is required that the regulatory body establish or adopt regulations and guides which include principles, requirements and associated criteria for emergency preparedness and response (GSR Part 7, paragraph 4.12 [11]).

3.330. The regulations and guides in emergency preparedness and response should cover provisions for: performing a hazard assessment; notification and activation; obtaining off-site support and coordination with off-site authorities; taking necessary emergency response actions on-site and, as relevant, off-site; protecting emergency workers (including for health surveillance, medical follow up, monitoring and controlling their exposure during the response); analysis of an emergency and emergency response; terminating the emergency; establishing and maintaining adequate infrastructure to support the performance of emergency response actions (e.g. plans, procedures, training and exercise programmes, staffing, equipment, tools, facilities, quality management programme and records keeping).

Review and assessment

3.331. The regulatory body should review and assess the on-site emergency arrangements developed by the authorized party to verify compliance with its requirements. This review and assessment should ensure that on-site emergency arrangements provide, to the extent practicable, assurance of an effective response to a full range of postulated nuclear or radiological emergencies, including those of very low probability [19].

3.332. The review and assessment should consider that the on-site emergency arrangements:

- Are based on a hazard assessment that identifies all postulated nuclear or radiological emergencies that might occur in relation to the facility or activity, including those of very low probability [19];
- Include emergency arrangements for managing the on-site emergency response and for coordination with off-site response;
- Include, as applicable, the operability and habitability of emergency response facilities (e.g. emergency centre, technical support centre, operational support centre) under the range of postulated emergency conditions (as identified in the hazard assessment);

- Include emergency procedures covering all postulated nuclear or radiological emergencies, including where necessary severe accident management guidelines [12], which satisfactorily cover the necessary operator actions and functions in emergency response (including procedures for notification and activation of off-site emergency response);
- Identify tools, instruments, supplies, equipment and communication systems needed for response to a nuclear or radiological emergency and demonstrate their adequacy for the usage expected;
- Include a specific training programme (which includes drills) and instructions for all the authorized parties staff on how to respond to a nuclear or radiological emergency and on the discharge of their expected duties;
- Include sufficient suitably qualified staff to be available at all times to implement the emergency plans and procedures;
- Include arrangements for obtaining support from off-site response organizations and for coordination with relevant off-site response;
- Describe the coordination with other plans such as plans for nuclear security and plans for fire-fighting;
- Include an exercise programme to ensure that all the emergency arrangements are tested satisfactorily within specific period.

Inspection

3.333. As part of its inspection plan, the regulatory body should inspect the on-site emergency arrangements, including observing emergency exercises, to ensure that they are effective and are in compliance with the regulatory body requirements. It is required that the regulatory body evaluate some of the emergency exercises, (GSR Part 7, paragraph 6.30 [11]). To do so, the regulatory body should take part in preparation, conducting and evaluating some of the exercises and should develop necessary evaluation guides and checklists. When appropriate, this evaluation should assess the adequacy of coordination and integration of the on-site emergency arrangements with those off-site.

3.334 The regulatory body should ensure that the authorized party demonstrates the effectiveness of the on-site emergency arrangements as a pre-cursor to issuing the authorization to bring nuclear and radioactive material on the site and to be completed before the start of commissioning or operation of a facility or commencement of the activity.

Enforcement

3.335. The normal approach to enforcement should be applied in regard to on-site emergency arrangements as set out above.

Ensuring coordination with off-site response organizations

3.336. As noted above, the various Safety Standards put the specific responsibility for emergency preparedness and response on the government e.g. Requirement 8 of GSR Part 1 (Rev.1) [2] states that "The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency." Requirement 2 of GSR Part 7 [11] states that: "The government shall make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly specified and assigned."

3.337. The regulatory body is part of the coordinating mechanism that is required to be established by the Government in accordance with GSR Part 7, paragraph 4.10 [11]. The coordinating mechanism ensures that emergency arrangements are coordinated, consistent and are in place for all postulated nuclear or radiological emergencies, including those beyond borders. In its capacity, the regulatory body should ensure that the authorized party provides the information necessary for establishing and maintaining adequate and coordinated off-site emergency arrangements at all levels, as appropriate.

3.338. It is usual, in most Member States, that the regulatory body will be either a source of advice during the preparation of the national emergency response plan or a lead organization for its preparation. In many Member States, the regulatory body may be assigned the responsibility to provide advice, in an emergency, to the government and other response organizations. In some Member States, the regulatory body may provide expert services (e.g. services for radiation monitoring and risk assessment for actual and expected future radiation risks) in accordance with the responsibilities assigned to it. Whatever the assigned responsibility in emergency response, the regulatory body should develop and maintain necessary arrangements (e.g. plans, procedures, tools, equipment, training, exercises) to effectively discharge this responsibility.

3.339. The regulatory body should take part in the regular exercises including national exercises and should evaluate its own performance against pre-established objectives associated with its duties in emergency response. The results of the self-evaluation should be used to identify where and what further improvements are needed on its emergency arrangements.

3.340. An important aspect of the regulatory body evaluation of the national exercises should be to assess the interface between the authorized party, off-site response organizations and itself.

Establishing and maintaining internal arrangements

3.341. The regulatory body should set up internal processes and procedures to ensure that it will fulfil the duties set out above in previous paragraphs, both at the preparedness stage and during an emergency response.

3.342. The regulatory body, within its sphere of responsibility, should coordinate its emergency arrangements with those of the authorized parties, and also at the national and local level and with its related international agreements and obligations.

3.343. Reference [4] describes the management provisions, organisation and training needs necessary for organising a cadre of regulatory body staff with appropriate training to carry out these responsibilities. The regulatory body should, as applicable, have mechanisms in place to:

- send staff to appropriate positions during a nuclear and radiological emergency;
- collect data on the progress of the event either directly or remotely, which may require having access to the authorized bodies systems;
- analyse and draw conclusions on the likely progression of the emergency;
- advise the appropriate response organizations, which includes the authorized party, of its findings;
- communicate securely and reliably between its staff and other organizations.

3.344. The regulatory body should develop and implement internal training and exercise programmes to ensure that the arrangements are tested and staff are well-versed in the roles they will be expected to take on should a nuclear or radiological emergency occur.

Discharging its assigned responsibilities in emergency response

3.345. The roles and responsibilities of the regulatory body during a nuclear or radiological emergency can be considered under the headings of on-site and off-site below:

On-site

3.346. The prime responsibility for safety remains with the authorized party during nuclear or radiological emergencies confined to the site of the facility or where the activity is taking place. The role of the regulatory body should observe the actions the authorized party takes.

3.347. The regulatory body should collect information and analyse the situation and compare its prognosis with that of the authorized party; furthermore, without interfering with the responsibilities for safety of the authorized party it should consider the actions that the authorized party takes. To do so, the regulatory body may assign its staff to a position on-site or to other places. These staff should record the way the decisions are taken and implemented regarding on-site emergency response actions.

Off-site

3.348. The regulatory body's responsibilities should have been set out in the government's provisions for dealing with nuclear or radiological emergencies. In most Member States, in the event of an emergency, the regulatory body's role will be to advise the government and competent authorities: in some situations in some States, the regulatory body may provide expert services e.g. services for radiation monitoring.

3.349. Where applicable, the regulatory body should make information on incidents and accidents available to authorized parties, governmental bodies, international organizations, and the public, as appropriate, in accordance with the pre-planned arrangements.

COMMUNICATION AND CONSULATATION WITH INTERESTED PARTIES[8]

3.350. Principle 2 of the Fundamental Safety Principles [1], states that the regulatory body must: set up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes; and to consult parties in the vicinity, the public and other interested parties, as appropriate, in an open and inclusive process.

3.351. Requirement 36 of GSR Part 1 (Rev.1) [2] applies this principle to the communication and consultation with interested parties, requiring the regulatory body to promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks and other environmental information associated with facilities and activities, and about the processes and decisions of the regulatory body.

3.352. The regulatory body should develop and implement a communication and consultation strategy and a culture of transparency and openness, and to involve interested parties in order to establish and maintain trust in its independence, competence, integrity and impartiality. Throughout this Safety Guide, it has been noted that the dissemination of information to the public and other interested parties is considered a good practice: this is included in requirement 34 of GSR Part 1 (Rev.1) [2] for example. Recommendations and guidance covering the communication and consultation with interested parties are covered in [13].

[8] The inclusion of this section is dependent on a decision by the safety committees and CSS on the future of DS460, i.e. DS460 to remain a standalone document or parts of it to be incorporated into DS473, see minutes of 34th CSS meeting, item 2.6-1.

APPENDIX 1 SUPPLY OF CONSUMER PRODUCTS

Authorization for the Supply of Consumer Products

A1.1. The regulatory body should require the manufacturer of consumer products to apply to the regulatory body and receive authorization to supply products to the public to ensure that consumer products meet all the requirements for design and performance that were taken into account in the generic safety assessment. The manufacturer should provide the regulatory body with sufficient documentation and certification to enable it to review and assess the proposed product. The documentation should include the following:

(a) A description of the product, its intended uses and benefits, the radionuclide(s) incorporated and the function served by the radionuclide(s). Documentary evidence that the radioactive substance fulfils its function should also be provided;

(b) The activity of the radionuclide(s) to be used in the product.

A1.2. The following additional information should be provided as may be appropriate or as required by the regulatory body:

(a) Justification of the choice of a radionuclide, particularly in relation to other radionuclide(s) that could be of lower toxicity (e.g. emits less penetrating radiation and/or has a shorter half-life). The reason for choosing the radioactive substance in preference to a non-radioactive alternative should also be justified;

(b) The chemical and physical forms of the radionuclide(s) contained in the product;

(c) Details of the construction and design of the product, particularly as related to the containment and shielding of the radionuclide in normal and abnormal conditions of use and disposal, and the degree of access to the radioactive substance;

(d) The quality testing and verification procedures to be applied to radioactive sources, components and finished products to ensure that the maximum specified quantities of radioactive substances or the maximum specified radiation levels are not exceeded, and the devices are constructed according to the design specifications;

(e) A description of the prototype tests for demonstrating the integrity of the product in normal use and for possible misuse and accidental damage, and the results of these tests;

(f) External radiation levels arising from the product and the method of measurement;

(g) Dose assessments, including individual doses and, if appropriate, collective doses arising from normal use, possible misuse and accidental damage and disposal and, if applicable, servicing and repair;

(h) The anticipated useful lifetime of the product and the total number of items of the product expected to be distributed annually;

(i) Information about any advice to be provided to customers on the correct use, installation, maintenance, servicing, repair and disposal of the product;

(j) An analysis to demonstrate that the product is inherently safe;

(k) Information on how the product is intended to be labelled.

Inspection for the Supply of Consumer Products

A1.3 Periodic inspections of the premises of manufacturers authorized to supply consumer products should be carried out so as to confirm that the products are being manufactured and distributed in accordance with the specifications and conditions established in the regulations and the authorization. The regulatory body should also conduct investigations, or review the results of investigations, of any accidents or instances of misuse. If the regulatory body receives new information that casts doubt on part or all of the original safety assessment, then appropriate enforcement measures should be taken.

APPENDIX 2 AUTHORIZATION CONDITIONS RELEVANT TO CERTAIN STAGES OF THE AUTHORIZATION PROCESS FOR COMPLEX FACILITIES OR ACTIVITIES

A2.1 In addition to general authorization conditions which are applicable to all authorizations, there are some conditions that are relevant only to authorizations issued at certain stages of the authorization process. The following listing is not all-inclusive, nor is it the only possible arrangement of such conditions, but it may be helpful in determining which conditions are relevant.

A2.2. *Site preparation*. The regulatory body should specify the controls that the authorized party is required to exercise over the use of the site and the degree to which the authorized party may prepare the site without conducting activities which, under the laws and regulations of the State, require a construction authorization.

A2.3. *Construction*. When authorizing construction, there are several conditions which should be fulfilled to ensure that this stage can proceed in a manner that ensures safe operation of the facility. These conditions should include the following:

- The facility should be designed and constructed in accordance with the relevant site parameters approved by the regulatory body;
- The facility should be constructed in accordance with the design that has been approved by the regulatory body. The authorized party should not deviate from the approved design in any way that might affect safety without the prior approval of the regulatory body;
- The authorized party should initiate a radiological study of the region, including an appropriate baseline survey, prior to the start of operation;
- The authorized party should prepare reports during the stage of site evaluation and construction to keep the regulatory body informed of the progress of the project, covering the progress of site studies, the progress of construction and results of the pre-operational environmental monitoring programme;
- The authorized party should keep records of site evaluation and construction of a facility (where necessary), such as the results of site evaluation studies (geological, meteorological and hydrological data, as well as results of the pre-operational environmental monitoring programme), construction design records, manufacturing records (including shop quality control results) and erection records (including quality control results and as built design records). They may be useful later in the investigation of events or generic problems and in decommissioning.

Furthermore, at the time of authorizing construction, conditions may be imposed on the authorized party requiring that it obtain from the regulatory body additional approvals relating to the design of certain parts of the facility.

A2.4. *Commissioning*. In authorizing the commissioning of a facility, the regulatory body should specify a number of conditions, including the following:

- Commissioning should be carried out in accordance with a programme approved by the regulatory body;
- Completed structures, systems and components important to safety should only be put into service once they have been inspected, tested and approved as being in accordance with the terms of the authorization;
- Commissioning records, including records of equipment and system test, test procedures and test results should be kept to demonstrate to the regulatory body the continuing safety of the facility covering:
    - the results of the commissioning tests and their evaluations;
    - operational data, including data on the facility's output and performance;
    - modification performed;
    - results of the radiation protection programme;
    - results of the environmental monitoring programme;
    - radioactive waste management.
- The authorized party should provide approved storage facilities for nuclear or radioactive materials. The regulatory body responsible for nuclear security may require that appropriate nuclear security measures be in effect before nuclear or radioactive material is brought into the facility;
- Fissile or radioactive material should only be brought onto the site with regulatory authorization;
- Beginning with the introduction of fissile and radioactive material into the facility, the authorized party should operate the facility only under the control and supervision of authorized personnel using written procedures, in accordance with the operational limits and conditions approved by the regulatory body. Any changes made to these limits and conditions should be approved by the regulatory body prior to their implementation;
- The authorized party should have an approved emergency plan, coordinated with the other authorities involved in emergency preparedness and response.

A2.5. *Operation*. In authorizing routine operation, the conditions imposed for commissioning should be appropriately amended in the light of commissioning results. The regulatory body should add conditions such as the following to the authorization, as necessary:

- The authorized party should not operate the facility or conduct the activity outside the limits authorized by the regulatory body;

- The authorized party should have a procedure for modifications to be approved by the regulatory body in order to ensure that no part of the approved facility that is important to safety will be modified without the prior approval of the regulatory body;
- The authorized party should ensure that the facility is subjected to in-service inspection and testing, to be carried out as specified for structures, systems and components important to safety, to a time schedule approved by the regulatory body;
- The authorized party should keep operational records from the main documentation to be used in the regulatory oversight for possible examination by the regulatory body that should include:
    - operational data and performance records of the facility or activity;
    - operating log books;
    - inventory of fissile and radioactive materials;
    - periodic calibration of equipment;
    - periodic testing of equipment and system;
    - internal reviews or inspections;
    - preventive maintenance and repairs;
    - personnel training;
    - personnel radiation monitoring;
    - radiation monitoring and contamination records for the facility or activity;
    - radioactive waste management;
    - effluent discharges and environmental monitoring programme;
    - abnormal and accident conditions.
- The authorized party should ensure that the maintenance of safety related equipment and systems is carried out in accordance with a schedule approved by the regulatory body;
- Only changes given prior approval by the regulatory body should be made to the approved arrangements, schedules, procedures and rules;
- The authorized party should ensure that the facility is operated or the activity is carried out only under the control and supervision of authorized personnel in adequate numbers that are acceptable to the regulatory body.

Other possible authorization conditions relating to such matters as the liability of the authorized party in the event of accidents are not covered in this Safety Guide.

A2.6. *Decommissioning*. In authorizing the activity of decommissioning of a facility, the regulatory

body should take particular care in specifying requirements to ensure compliance, since the sanction of shutting down the facility or revoking the authorization is unlikely to be effective at this stage. The regulatory body should examine a final radiological survey conducted by the authorized party. The radiological survey should be conducted after the completion of decommissioning activities to ensure that regulatory requirements are met prior to terminating the authorization and releasing the site.

A2.7. *Closure*. Following the closure of a waste disposal facility, continuing control, including environmental monitoring, may be necessary. Depending on national legislation, requirements may be specified in a post-closure authorization held by the authorized party or responsibilities may be taken by a relevant national authority prior to agreeing to closure of the facility.

APPENDIX 3 TOPICS TO BE COVERED BY REVIEW AND ASSESSMENT

A3.1. This appendix provides a generic list of topics that should be considered in the review and assessment process throughout the lifetime of a facility or activity, 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 or activity and on the particular stage of the 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

A3.2. The following information on the facility or activity and on the processes conducted should be provided by the authorized party at various stages and used as a basis for review and assessment:

(a) A detailed description of the facility or activity, supported by drawings of the layout, the systems and the equipment;

(b) Information on the functional capability of the facility and the nature of the activity, 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 structures, systems and components 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

A3.3. Throughout the lifetime of any facility or activity, the authorized party 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.

A3.4. 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

A3.5. Throughout the lifetime of the facility or activity, the regulatory body should review and assess the information on the facility or activity provided by the authorized party, and in particular information covering:

(a) A compilation of the safety analysis and its assumptions;

(b) structures, systems and components important to safety;

(c) Limits and permitted operational states;

(d) Anticipated operational occurrences;

(e) PIEs for the safety analyses:

—External hazards (e.g. external floods, earthquakes, aircraft crashes, transportation accidents, explosions, external fires, meteorological hazards, etc.);

—Internal failures (e.g. mechanical or electrical);

—Internal hazards (e.g. internal fires, internal floods, missiles).

(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, abnormal and accident conditions;

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

A3.6. The impacts of the facility or activity 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 abnormal and accident conditions, which are the subject of safety analysis, should be considered.

THE AUTHORIZED PARTY AND THE MANAGEMENT SYSTEM

A3.7. At all stages of the facility's lifetime, the authorized party should be required to demonstrate that:

(a) It will be in control of the facility or activity;

(b) It has an adequate safety management system to be able to manage and control the facility or activity;

(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.

A3.8. The information that the authorized party should provide to the regulatory body for review and assessment should include:

(1) Details of the structure of the authorized party, 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.

A3.9. The authorized party should be required to 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 people and the environment will be met. This will include having operational procedures in place.

A3.10. The authorized party should be required to 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 or conduct of the activity 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, where appropriate;

(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

A3.11. The authorized party should be required to 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

A3.12. The authorized party should be required to 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;

(l) In selection of equipment, the minimum detection limit (MDL) should be commensurate with the compliance level such that the MDL should be around 10% of the level to be measured for demonstration of compliance.

MANAGEMENT OF AGEING

A3.13. The authorized party should be required to provide a programme for the management of ageing of equipment that covers:

(1) Documented methods and criteria for identifying structures, systems and components covered by the ageing management programme;

(2) A list of structures, systems and components 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 structures, systems and components;

(4) Details of the extent of understanding of the dominant mechanisms of ageing for structures, systems and components;

(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 structures, systems and components;

(7) Awareness of the physical condition of structures, systems and components, including actual safety margins.

AUTHORIZED PARTY'S SAFETY PERFORMANCE

A3.14. The authorized party should be required to 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 the effects of equipment failure on the qualification of equipment not covered by the equipment qualification programme:

—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 failures, 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

A3.15. The authorized party should be required to provide information on its arrangements for:

(a) Feedback of experience relevant to safety from similar facilities and activities and from other nuclear and non-nuclear facilities and activities;

(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.

APPENDIX 4. INSPECTION AREAS FOR NUCLEAR FACILITIES

A4.1. This appendix sets out areas of nuclear facilities that may be of particular interest for inspection at different stages of the authorization process. Depending on the facility or activity and on the particular stage of the lifetime, some topics will be more important than others, and the degree of their applicability may vary.

SITE EVALUATION STAGE

A4.2. Before the construction of a nuclear facility is begun, the regulatory body should monitor as appropriate, by means of its inspection programme, site preparation activities undertaken by the applicant or authorized party, including verification of site characteristics and authorized excavation and earthwork.

A4.3. The specific objectives of regulatory inspection in these areas include verification that the authorized party is undertaking siting activities in full conformity with existing regulatory requirements and assurance that the work on site preparation does not proceed beyond that permitted by any authorization in force. During site preparation, the regulatory body should also confirm that the site characteristics remain consistent with the description presented by the authorized party in its licence application and in the subsequent supporting documentation submitted to the regulatory body. This is vital for disposal sites, for which the action of a major barrier to the movement of radionuclides is dependent on the characteristics of the site. In addition, inspectors should be alert to any new conditions or information revealed as a result of activities for site preparation, which should then be considered by the regulatory body in making subsequent decisions on authorization.

DESIGN AND CONSTRUCTION STAGE

A4.4. The chief objectives of the regulatory inspection programme in the design and construction of the facility should be to verify that:

- Safety related materials and structures, systems and components meet the requirements established by the regulatory body and conform to good practices;
- Construction activities associated with manufacturing and installing structures, systems and components and items are conducted in accordance with regulatory requirements and inconformity with general safety objectives;
- The as-built configuration of structures, systems and components is in conformity with the assumptions made in the regulatory review and assessment, any deviation is analysed and justified and the documentation is updated accordingly;

– The authorized party's system and procedures for quality assurance and inspection are adequate to ensure the conformance of equipment to the technical specifications.

A4.5. The regulatory body should inspect design and construction activities in a number of areas in order to attain these objectives. In particular, the following areas should receive close attention in the construction stage, primarily because of the difficulty of detecting and correcting deficiencies in these areas once fissile and radioactive material has been brought to the site and the facility enters the active commissioning stage:

(a) mixing and placement of concrete and its reinforcement, especially in:
  – foundations,
  – safety related structures, particularly containment structures;
(b) construction of cooling intakes and discharge systems;
(c) installation of safety related components, particularly:
  – containment and shielding boundaries;
  – internals of vessels which will contain fissile and radioactive material;
  – equipment to be used in radiation areas.
(d) installation of safety related control, protection and power systems;
(e) areas of the facility that are inaccessible after construction is completed, particularly systems and components embedded in the foundations or the building structure;
(f) housekeeping in respect of safety related structures, systems and components;
(g) the safety management systems of the designer, manufacturer and constructor.

COMMISSIONING STAGE

A4.6. Activities associated with commissioning will normally begin before construction is completed. Accordingly, the regulatory body should be prepared to inspect areas of commissioning activity in parallel with activities of the construction stage. In some States the regulatory body approves the commissioning programme and its agreement should be obtained before advancing beyond certain hold points.

A4.7. Inspection by the regulatory body during the commissioning stage should focus on four broad areas of the authorized party's activity:

1) testing before the introduction of fissile and radioactive material;
2) initial introduction of fissile and radioactive material;
3) testing of operations involving fissile and radioactive material;
4) other commissioning activities.

Testing before the introduction of fissile and radioactive material

A4.8. The inspection area of testing before the introduction of fissile and radioactive material encompasses those activities and tests performed before the introduction of such material by the authorized party in order to demonstrate that structures, systems and components function properly and conform to design requirements. It also covers the inspection and acceptance criteria for the receipt at the facility of fissile and radioactive material. The regulatory inspection programme should include:

- examination of documented procedures to verify that they accord with the conclusions of the regulatory review and assessment;
- review of the implementation of these procedures;
- direct observation of the performance of certain key pre-operational tests;
- examination of the results of selected tests;
- confirmation of the integrity of any engineered barriers.

A4.9. The number of tests and the key tests that are to be examined and directly witnessed by the regulatory body will vary depending on such factors as the importance of the test for safety and whether the facility to be commissioned is the first of its kind or one of several similar facilities. The regulatory body should, however, place particular emphasis on inspection by the examination of documentation and by the direct observation of some of the tests performed on:

- structures, systems and components that prevent unsafe conditions or that mitigate the consequences of anticipated operational occurrences and accident conditions;
- structures, systems and components whose failure to operate properly will require action from one or more safety related components or systems.

A4.10. This may involve the regulatory body in inspecting tests of:

- safety systems (such as instrumentation and control systems, shutdown systems and standby systems);
- the integrity of the containment and shielding boundaries (such as hydraulic tests of pressurized structures) as appropriate;
- the susceptibility of structures, systems and components to vibration or to other design loads;
- secondary containment integrity (such as overpressure and leak rate tests) as appropriate;
- emergency power systems as appropriate;
- communication capabilities;
- ventilation systems;
- integrated cold and hot functional tests.

Initial introduction of fissile and radioactive material

A4.11. In the regulatory inspection programme, close attention should be paid to authorized party activities relating to the preparation for and actual introduction of fissile and radioactive material. Regulatory inspection personnel should be present at the facility site to observe some of these activities directly.

A4.12. Although some of these tests may be performed at times other than the time when fissile and radioactive material is first introduced, the regulatory body should inspect the following:

- tests of the main control room;
- access control and implementation of the radiation protection programme;
- emergency preparedness and response and demonstration of the emergency plan;
- systems for monitoring radioactive releases and meteorological monitoring systems;
- the distribution of fissile and radioactive material (such as the fuel loading pattern in a reactor) and process calculations and/or criticality calculations, as appropriate;
- systems involved in the handling or movement of radioactive or fissile material.

Testing of operations involving fissile and radioactive material

A4.13. The inspection area of testing of operations involving fissile and radioactive material encompasses activities of the authorized party performed in conditions up to nominal operating conditions. At this point, structures, systems and components are tested in an operational environment to ensure that they have been constructed and installed properly and are capable of functioning in compliance with the design requirements. Consideration should be given to the performance of radiation surveys of facility shielding (such as concrete walls) during starting up of the facility. This will help to identify any voids or faulty joints in the shielding or any radiation penetrating through joints. In the event of such an occurrence, alterations should be made prior to further operation. During this period the authorized party carries out tests at increasing operational levels; this testing includes the recording and analysis of data relating to temperatures, pressures, radiation levels, flows and variations in process parameters as well as other relevant parameters.

A4.14. Regulatory inspection personnel should examine and assess the safety aspects of a sample of the authorized party’s procedures for conducting operational tests. In addition, as the tests are completed, a sample of the test documentation and the results of the inspection should be examined by regulatory personnel to verify that the tests have been completed in accordance with the test instructions and that the results are acceptable. Regulatory inspection should also include the monitoring and direct observation of several tests.

A4.15. Tests during this stage, which should be subject to regulatory review and inspection, will depend on the type of facility being commissioned. They include tests to demonstrate as far as possible that:

- the facility is being operated in accordance with the descriptions given in the safety analysis report;
- systems respond to malfunctions in accordance with the claims made in the safety analysis report.

Other commissioning activities

A4.16. In addition to the examination of documentation and the surveillance of tests, there are a number of other areas necessitating inspection by the regulatory body in the commissioning stage. The ability of the authorized party's management to progress from supervising construction to supervising operation and its arrangements for doing so should also be inspected. This inspection should cover the management's provisions for putting the emergency plan into effect and for the training and qualification of operating personnel. Hold points during the operational testing stage and into the full operational stage should be closely monitored. These areas largely overlap, necessitating continuing attention in inspections during the operation stage.

OPERATION STAGE

A4.17. Once the facility has attained the authorized operation stage the regulatory body shall implement an inspection programme to verify systematically the authorized party's compliance with regulatory requirements and achievement of general safety objectives, and to detect potential safety problems. This verification should consist of: a balanced approach to monitoring and direct observation of activities; interviews with personnel, including managers; review of qualifications of the authorized party's personnel; and sampling of documentation. For waste management facilities and particularly for waste disposal facilities, the structure of the programme and the tests to be carried out will primarily relate to conformance to the relevant design criteria and waste acceptance criteria for the facility and will constitute an element in providing confidence for the long term safety case. For all facilities, these inspections should cover the aspects detailed in paras A4.18–A4.41.

Operations

A4.18. The area of operations should include the control and execution of activities directly relating to operating a facility to the operational limits and conditions established by regulatory requirements or by procedures or specifications. Inspection personnel should perform safety verification of: operating procedures; the operating configuration of safety related systems; control room activities; and the

abilities of the operations staff to perform their duties. Simulator training and the responses of operating staff to abnormal events and emergency conditions, as well as the adequacy of the management's actions, should also be assessed. In performing this safety verification, the reviews described in paras A4.19–A4.22 should be carried out.

A4.19. *Operating procedures.* A sampling review of operating procedures should be performed, including all the procedures for normal operations, anticipated operational occurrences and accident conditions. Inspections should be focused on the operating personnel's adherence to procedures, including operational limits and conditions. The usability and adequacy of the procedures should also be evaluated. This may necessitate sustained observations in the control room. The inspection programme in this area may necessitate sustained observation to cover 24 hour operation as necessary, in particular shift turnovers. The inspectors should check the availability of safety systems and the presence of alarm systems, and the way in which they are handled by the operations staff.

A4.20. *Authorized party's training programme*. The adequacy of the authorized party's staff training programme should be assessed routinely to ensure that the training reflects actual conditions in the facility.

A4.21. *Safety systems.* A sampling review of safety systems should be performed to evaluate: any identified degraded equipment; discrepancies between installed components and/or system hardware and the facility drawings; controls for performing maintenance on equipment; and the quality of performance of the operations staff in log keeping and record keeping and in routine monitoring of equipment. Note should be taken of the effectiveness of the operations staff in getting the degraded equipment repaired by the maintenance staff or its prompt evaluation to ensure operability. Inspection of the facility should also include observations of non-safety-related areas to ensure that they have no adverse effects on the safety related areas of the facility. The adequacy of the fire protection and prevention programme, including the management's attention to this area, should be noted in these inspections.

A4.22. *Management.* The management's involvement in the facility and its effectiveness in paying appropriate attention to operational issues, including abnormal events, should be evaluated. In inspections it should be considered: whether the organizational structure is suitable; whether there are adequate numbers of staff; how well management and staff communicate; and how the management emphasizes the importance of safety and fosters a strong safety culture.

Outages

A4.23. Inspections should cover outage activities. In addition to providing opportunities to observe modifications being made to the facility, outages provide opportunities to observe activities in areas

that are not always accessible during normal operation. Certain activities such as inspections in highly radioactive areas or the maintenance and repair of highly contaminated systems present a challenge to the authorized party's organization. Outages can provide valuable insights into the management's ability to perform tasks outside the normal operational mode. Furthermore, movements of fissile and radioactive material need to be well controlled and special checks may be necessary before returning the facility to normal operation to ensure that it is still within its safety justification. Before returning the facility to normal operation, it is usual for the regulatory body to perform a special inspection.

Radiation protection and radioactive waste management

A4.24. The area of radiation protection should cover all related activities at the facility, including radiation protection of staff and contractor personnel and of the public [14] The area of radioactive waste management should cover treatment, conditioning, storage and transport of waste, the release of effluents and the environmental monitoring programme [15].

A4.25. *Organizational structure for radiation protection.* The structure of the organization responsible for the implementation of the radiation protection programme, the procedures necessary for implementation of the programme, the effectiveness of the management and its commitment with respect to radiation protection, including application of the optimization principle, should all be assessed in the inspection. Indicators of the effectiveness of the management are the levels of exposure of personnel, levels of contamination in working areas, levels of releases of effluents, and the understanding on the part of management and workers of their responsibilities in the implementation of the radiation protection programme. Any self-assessments performed by the authorized party under this programme should be reviewed.

A4.26. *Records of occupational radiation doses.* Inspection personnel should selectively review records of individual occupational doses, including internal and external doses. Activities should be observed to ensure that procedural and management controls are effective. This includes controls for radiation areas and contamination areas as well as inspection of activities for internal and external dosimetry. Exposures of personnel that result in the authorized party's reference levels for effective doses or intakes being exceeded should be noted. Records of radiation protection training and retraining should be assessed.

A4.27. *Effluents.* The inspection programme should include verification that any releases of effluents are within the authorized discharge limits. This should include the review of systems for the treatment of radioactive waste and for the monitoring of effluents. Training and qualifications for technicians and workers employed in the areas concerned should also be reviewed.

A4.28. *Environmental monitoring*. The environmental monitoring programme should be reviewed to ensure that all environmental monitoring is performed in accordance with established procedures. Independent measurements may be performed to verify the accuracy of the authorized party's monitoring equipment and the results of measurements.

A4.29. *Waste management.* The implementation of arrangements for on-site waste treatment, conditioning and storage should be reviewed and records should be inspected. In particular, the waste characterization process, the compliance with any requirements for waste storage or disposal, and the records for these processes should be subject to inspection.

A4.30. Whenever unpackaged waste is stored or waste packages are stored or have been placed in a waste repository pending a decision on closure of the facility, degradation of the waste with time may occur. The storage conditions for the waste and the waste packages should be inspected at appropriate intervals to provide confidence that the waste remains suitable for treatment or that the waste packages will be suitable for retrieval, transport and further steps in radioactive waste management, as necessary.

A4.31. Transport arrangements for radioactive material on the site should be examined. Receipt and dispatch arrangements should be inspected and attention should be paid to the integrity of packages, residual levels of contamination and associated records.

Maintenance and testing

A4.32. Inspection in the area of maintenance and testing should comprise assessments of the implementation of the maintenance and testing programme. These should cover:

- all types of maintenance performed on structures, systems and components and maintenance of the physical condition of the facility;
- testing, including the conduct of all surveillance testing activities, all in-service inspection and testing, calibration of instruments, equipment operability tests and other special tests.

A4.33. Direct observation by the regulatory body should include a sampling of the authorized party's inspection and testing activities, including such tests as: calibration of nuclear instrumentation systems; verification of containment integrity; testing of local leak rates for the containment; testing of piping support and restraint systems; tests for safety pumps, valve capacity and stroke timing; and surveillance tests for breakers and transformers. Inspectors should note the capability of the individuals performing the tests and, for complex surveillances, should assess the interface between the surveillance personnel and the operations staff involved in the performance of the test. The adequacy and usability of the procedures should be assessed and the control and calibration of the test

equipment should be observed. The inspection personnel should observe the manager's involvement in these programmes to ensure that the programmes are effective and that safety equipment is properly maintained, with few recurring problems. Maintenance backlogs, the intervals at which repetitive equipment repairs are carried out and the amount of maintenance work actually being performed should be routinely noted, as these maybe early indicators of declining performance in the maintenance programme. In this connection, a large backlog of repairs, a high number of equipment failures and a low level of maintenance activity may be indicative of a maintenance programme that is difficult to manage and requires a disproportionate amount of documentation. Self-assessment activities in these programmes should be observed and their findings should be routinely reviewed.

A4.34. A sample of maintenance activities including inspection and testing should be routinely observed to assess the adequacy of programmes and procedures and the capability of the maintenance technicians to perform their assigned tasks. The planning and scheduling of maintenance should be assessed to ensure that maintenance activities are performed by competent staff and are properly coordinated, and that repairs to equipment are handled in accordance with appropriate priorities. All types of maintenance activities should be observed. Before initiating maintenance work, special attention should be paid to the isolation and tagging of safety systems which are out of service. Inspectors should observe the compliance with procedures for these isolation and tagging controls in order to evaluate their adequacy and should evaluate the procedures for ensuring that systems are returned correctly to their operational state. The in-service inspection programme and the in service testing programme should be reviewed to ensure that their purpose, which is to ensure the early detection of degradation of equipment and components, is being served. Programmes, procedures and data should be reviewed and evaluated, particularly for those maintenance tasks that can be performed only during outages. Data which may indicate that a high number of component systems need repair may necessitate an in-depth review of the programmes. Repairs to piping systems, pumps, valves, electrical systems and instrumentation and control systems should all be selectively sampled for review. Welding on systems of safety significance should be observed, including examination by non-destructive means.

Engineering

A4.35. Engineering usually provides necessary support to the operations or maintenance staff anywhere in the facility at any time. Engineering usually assists operations staff with the evaluation of non-conforming or degraded conditions and assists maintenance staff in the performance of activities in the course of which problems may arise. Inspection personnel should review a sample of the evaluations for non-conforming or degraded conditions for both adequacy and quality, and should observe the interface between the maintenance and engineering support groups.

A4.36. The inspector should walk down part of a system to assess how well systems are being maintained and should note any non-conformance. Any problems identified by the inspector but not known to the facility's management would call into question the adequacy of the support programme for system engineering.

Modifications

A4.37. Modifications may be simple or complex and may involve changes to engineering, operating procedures and the organizational structure. For major modifications to the structures, systems and components of a facility, most of the planning, design and manufacture will be performed prior to outages. The regulatory body should inspect the authorized party's record to determine whether its modification process has been effective in controlling modifications in a manner which is appropriate for their safety significance. Where required, the regulatory body should also inspect submissions by the authorized party to the regulatory body concerning a modification. The details of the process should be checked in the inspections by sampling specific modifications and reviewing their execution and their implications for documentation, such as the need for changes to safety related documentation, for updating of maintenance schedules and engineering drawings and for changes to operational procedures and training modules. These checks may involve other parts of the regulatory body in addition to the inspection unit. The regulatory body should also determine whether the qualifications of the authorized party's staff that perform the modifications are suitable for the function they are performing.

Emergency preparedness

A4.38. Inspection of the area of emergency preparedness and response should include a review of emergency response plans and procedures in order to verify that the arrangements for dealing with an emergency are adequate. Procedures for the detection and classification of an emergency and for decision making in an emergency should be assessed. Procedures for notification, communication, shift staffing, shift augmentation, dose calculation and dose assessment should also be evaluated. Emergency exercises should be witnessed to ensure that the emergency planning is adequate and that its implementation is effective.

Management Systems

A4.40. Inspection of the area of effectiveness of management systems should include inspection of those indicators which demonstrate that the management system is focused on safe operation and on the identification and remediation of problems and weaknesses within the programme. This includes the management's involvement in day to day operations and its routine presence in the facility. What is most important is whether the management demonstrates a willingness to hear of problems and then

to ensure that problems are promptly evaluated and solved. The management's ability to create an environment in which problems are openly identified and discussed and self-assessment programmes are effectively supported helps to foster a strong safety culture.

A4.41. The authorized party's quality assurance programme should be reviewed to ensure that it is comprehensive and adequately implemented. The review should cover, in addition to the activities discussed earlier, such activities as: procurement, receipt, storage and handling of equipment; document control; and operational experience. In particular, the adequacy and effectiveness of the authorized party's performance of corrective actions should be assessed.

DECOMMISSIONING STAGE

A4.42. During the decommissioning stage of a nuclear facility, inspection activities should be concentrated on:

- the adequacy of the authorized party's procedure for the control of each stage of decommissioning;
- the removal of radioactive material;
- the strategy for management of radioactive material;
- the drainage of any fluid;
- decontamination and dismantling activities;
- the waste management strategy for the treatment, conditioning, storage and disposal of all radioactive waste;
- the physical condition of the facility, especially surveillance of the integrity and/or the availability of relevant structures, systems and components, including protective barriers, and the appropriateness of the procedures at each stage of decommissioning;
- characterization of the residual activity;
- safeguards and access control; environmental monitoring, radiological monitoring and surveillance, including plans for radiation protection for workers and the public;
- the adequacy and maintenance of instrumentation and control systems for long term safety;
- decommissioning records.

A4.43. After a long period of safe enclosure, some of these regulatory inspection activities may be reduced in thoroughness and frequency.

Closure of waste disposal facilities

A4.44. Before the regulatory body considers the release of any waste disposal facility from further regulatory control, inspection activities should be concentrated on:

- conformance with the overall waste inventory;

- sealing arrangements for the facility including any measures to prevent human intrusion;
- arrangements for any environmental monitoring after closure.

Areas of interest relating to the release of a facility and/or site from regulatory control

A4.45. Before releasing a site from any further control, the regulatory body should carry out an inspection to confirm that any residual activity has been reduced to acceptable levels. This will include review of the cleanup and monitoring procedures, review of the management system, independent monitoring and analysis of compliance with the release criteria for the site or review of the implementation of restrictions at the site. For waste disposal facilities, the release from control will be related to the long term safety of the facility as set out in the post-closure safety case.

REFERENCES

1. INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, SF-1 (2006).
2. INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, GSR Part 1(Rev.1) (2015).
3. INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 3 (2014).
4. INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body, DS472 (in preparation).
5. INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear security recommendations on physical protection of nuclear material and nuclear facilities (INFCIRC/225/Revision 5), IAEA Nuclear Security Series No. 13, (2011).
6. INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14,(2011), and supporting guidance.
7. INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, SSR-6 (2012).
8. INTERNATIONAL ATOMIC ENERGY AGENCY, Periodic Safety Review, SSG-25 (2013).
9. INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, GSR Part 4 (2009).
10. INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, GS-R-3 (2006) (to be replaced by DS456).
11. INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, GSR Part 7 (2015).
12. INTERNATIONAL ATOMIC ENERGY AGENCY, Severe Accident Management Programmes for Nuclear Power Plants, NS-G-2.15 (2009) (to be replaced by DS483).
13. INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, DS460 (in preparation).
14. INTERNATIONALATOMIC ENERGYAGENCY, Occupational Radiation Protection, DS453 (2015).
15. INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Radioactive Waste Management in the Operation of Nuclear Power Plants, Safety Standards Series No. NS-G-2.7, (2002).
16. INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, GSR Part 6 (2014).

17. INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Fundamentals, NSS 20 (2013).
18. INTERNATIONAL ATOMIC ENERGY AGENCY, Site Evaluation for Nuclear Installations, NS-R-3 Rev 1 (2015).
19. INTERNATIONAL ATOMIC ENERGY AGENCY, External Human Induced Events in Site Evaluation for Nuclear Power Plants, NS-G-3.1 (2002).
20. INTERNATIONAL ATOMIC ENERGY AGENCY, Dispersion of Radioactive Material in Air and Water and Consideration of Population Distribution in Site Evaluation for Nuclear Power Plants External Human Induced Events in Site Evaluation for Nuclear Power Plants, NS-G-3.2 (2002) (to be replaced by DS427).
21. INTERNATIONAL ATOMIC ENERGY AGENCY, Seismic Hazards in Site Evaluation for Nuclear Installations, SSG-9 (2010).
22. INTERNATIONAL ATOMIC ENERGY AGENCY, Meteorological and Hydrological Hazards in Site Evaluation for Nuclear Installations, SSG-18 (2011).
23. INTERNATIONAL ATOMIC ENERGY AGENCY, Volcanic Hazards in Site Evaluation for Nuclear Installations, SSG-21 (2012).
24. INTERNATIONAL ATOMIC ENERGY AGENCY, Geotechnical Aspects of Site Evaluation and Foundations for Nuclear Power Plants Safety Guide, NS-G-3.6 (2005).
25. INTERNATIONAL ATOMIC ENERGY AGENCY, Site Survey and Site Selection for Nuclear Installations, DS433 (2015).
26. INTERNATIONAL ATOMIC ENERGY AGENCY, Near Surface Disposal Facilities for Radioactive Waste, SSG-29 (2014).
27. INTERNATIONAL ATOMIC ENERGY AGENCY, Geological Disposal Facilities for Radioactive Waste, SSG-14 (2011).
28. INTERNATIONAL ATOMIC ENERGY AGENCY, Deterministic Safety Analysis for Nuclear Power Plants, SSG-2 (2009) (to be replaced by DS491).
29. INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Medical, Industrial and Research Facilities, WS-G-2.2 (1999) (to be replaced by DS403).
30. INTERNATIONAL ATOMIC ENERGY AGENCY, Modification to Nuclear Power Plants, NS-G-2.3 (2001) (will be replaced by DS485).
31. INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Design, SSR-2/1 (2012).
32. INTERNATIONAL ATOMIC ENERGY AGENCY, Format and Content of the Safety Analysis Report for Nuclear Power Plants, GS-G-4.1 (2004).
33. INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Nuclear Power Plants and Research Reactors, WS-G-2.1 (1999) (to be replaced by DS452).

34. INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Nuclear Fuel Cycle Facilities, WS-G-2.4 (2001) (to be replaced by DS452).
35. INTERNATIONAL ATOMIC ENERGY AGENCY, Commissioning for Nuclear Power Plants, SSG-28 (2014).
36. INTERNATIONAL ATOMIC ENERGY AGENCY, Commissioning of Research Reactors, NS-G-4.1 (2006).
37. INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, GSR Part 5 (2009).
38. INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, SSR-5 (2011).

CONTRIBUTORS TO DRAFTING AND REVIEW

Jones, G.	International Atomic Energy Agency
Kamenopoulou, V.	Greek Atomic Energy Commission (GAEC), Greece
Lungu, S.	International Atomic Energy Agency
Mansoor, F.	Pakistan Nuclear Regulatory Authority (PNRA), Pakistan
Mansoux, H.	International Atomic Energy Agency
Pacheco Jimenez, R.	International Atomic Energy Agency
Parlange, J.	International Atomic Energy Agency
Suman, H.	International Atomic Energy Agency
Trivelloni, S.	Institute for Environmental Protection and Research (ISPRA), Italy
Vaughan, G.	Consultant, United Kingdom
Westermeier, E.	Bundesamt fur Strahlenschtz (bfs), Germany
Wrona, D.	United States Nuclear Regulatory Commission (USNRC), United States of America