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ORGANIZATION, MANAGEMENT AND STAFFING OF A REGULATORY BODY FOR SAFETY

DRAFT GENERAL SAFETY GUIDE

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Contents

1. INTRODUCTION

BACKGROUND

1.1. Regulation is essential for ensuring the safety of all facilities and activities that give rise to radiation risks. The establishment of a legally based, independent, fully resourced and technically competent regulatory body is a fundamental element set out in Principle 2 of the Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1 [1]. This principle is reinforced and further elaborated in the Safety Requirements publications on Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1) [2] and on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3 [3].

1.2. This Safety Guide provides guidance on the organizational structure, management and staffing of the regulatory body for ensuring the control of facilities and activities[1].Organization and management are of fundamental importance for regulatory bodies to be able to perform their functions effectively. This is particularly important for those regulatory bodies having responsibilities covering a range of facilities and activities that give rise to radiation risks, or when interfaces are present between various regulatory authorities, which require effective coordination and cooperation.

1.3. This Safety Guide has been developed in parallel with the Safety Guide on Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. DS473 [4], which covers the technical aspects of the core functions of the regulatory body and the processes by which they are discharged. It is strongly recommended that this Safety Guide and DS473 [4] be read in conjunction with one another.

1.4. The core functions of the regulatory body are described in GSR Part 1 (Rev. 1) [2] and Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7 [5], and include:

- The development and/or provision of regulations and guides;
- Notification and authorization, including registration and licensing;
- Regulatory review and assessment;
- Regulatory inspection;
- Enforcement;
- Emergency preparedness and response;

[1] Facilities and activities is a general term encompassing nuclear facilities, all uses of 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 risks arising from naturally occurring or artificial sources. See footnote 3 of GSR Part 1 (Rev. 1) [2] for a more complete definition.

– Communication and consultation with interested parties.

1.5. Corresponding supporting functions are necessary to ensure that the core functions can be performed efficiently and effectively. These include the following:

– Administrative support, including human resources, finance, management of documents and records, equipment purchasing and control;
– Legal assistance;
– Research and development processes;
– Arrangements for contracting external expert support, where needed;
– Establishment of advisory committees;
– International cooperation.

1.6. The recommendations provided in this Safety Guide and DS473 [4] are intended mainly to be used by regulatory bodies, but can be also useful for governments that are developing a regulatory framework for radiation and nuclear safety. They will also assist authorized parties, and others dealing with nuclear and other radioactive materials, in understanding the organizational and functional aspects of regulatory control for all facilities and activities that give rise to radiation risks.

1.7. This Safety Guide can be used by States embarking on a new nuclear power programme and by States significantly extending an existing nuclear power programme, already having in place a regulatory system for other facilities or activities. Such States should follow the guidance in this Safety Guide as though they were establishing a new regulatory body. Detailed guidance on establishing the safety infrastructure for a nuclear power programme is provided in Establishing the Safety Infrastructure for a Nuclear Power Programme, IAEA Safety Standards Series No. SSG-16 [6].

1.8. This Safety Guide supersedes the Safety Guide on Organization and Staffing of the Regulatory Body[2] issued in 2002, the parts of the Safety Guide on Regulatory Control of Radiation Sources[3], issued in 2004, relating to the organization and staffing of the regulatory body, and the Safety Guide on Use of External Experts by the Regulatory Body[4], issued in 2013.

OBJECTIVE

1.9. The objective of this Safety Guide is to provide recommendations on meeting the requirements of GSR Part 1 (Rev. 1) [2] in respect of the organizational structure, management and staffing of the

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Staffing of the Regulatory Body for Nuclear Facilities, IAEA Safety Standards Series No. GS-G-1.1, IAEA, Vienna (2002).
[3] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Regulatory Control of Radiation Sources, IAEA Safety Standards Series No. GS-G-1.5, IAEA, Vienna (2004).
[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Use of External Experts by the Regulatory Body, IAEA Safety Standards Series No. GSG-4, IAEA, Vienna (2013).

regulatory body, to support regulatory bodies in carrying out their responsibilities and functions efficiently and effectively and in an independent manner.

1.10. This Safety Guide also provides guidance on how an integrated management system should be established and implemented in order to have in place both the core processes that help the regulatory body to perform its core functions, and the management and support processes that are necessary to run the regulatory body.

1.11. This Safety Guide is intended for use by all regulatory bodies, irrespective of the size and type of the facilities and activities they regulate. In applying this Safety Guide, the regulatory body should use a graded approach commensurate with the risks and consequences associated with the facilities and activities, and with account taken of national circumstances, so as to be able to apply resources in an efficient manner.

SCOPE

1.12. This Safety Guide covers the organizational and management aspects of the regulatory body that are necessary for it to perform its core functions. In particular, this Safety Guide covers not only the technical aspects of the organizational structure, management and staffing of the regulatory body, but also the cultural, organizational and individual aspects (human and organizational factors) supporting strong regulatory effectiveness.

1.13. 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 that gives rise to radiation risks who has been granted written permission (i.e. authorized) by a regulatory body or other governmental body to conduct specified activities; the authorized party may be a licensee, a registrant, an operator or an operating organization.

1.14. ‘Interested parties’, sometimes known as stakeholders or concerned parties, are those individuals or organizations with a concern or interest in the activities and performance of an organization, in particular the regulatory body or the authorized party. Interested parties include: the general public, such as people living in the vicinity of facilities; elected officials and governmental authorities at the national, regional and local levels; national and local non-governmental organizations; regulated industry and its employees, trade unions; suppliers; professional and academic organizations; news media; and other States, especially neighbouring States. The term ‘safety’ is used in this Safety Guide to mean the protection of people and the environment against radiation risks, and the safety of facilities and activities that give rise to radiation risks. ‘Safety’ as used here includes the safety of nuclear installations, radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material; it does not include non-radiation-related aspects of safety. Further definitions are provided in the IAEA Safety Glossary [7].

1.15. The scope of this Safety Guide is limited to the regulation of safety and does not extend to nuclear security. However, recommendations are provided in this Safety Guide on the interface between nuclear security and safety, especially for protection of information. Guidance on addressing nuclear security aspects can be found in publications in the Nuclear Security Series: Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities, (INFCIRC/225/Revision 5), IAEA Nuclear Security Series No. 13 [8] and Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14 [9] and supporting guidance.

STRUCTURE

1.16. Section 2 of this Safety Guide sets out the general characteristics of a regulatory body with responsibility for safety, while Section 3 provides more specific recommendations on management for safety focused on leadership for safety and safety culture aspects. Section 4 describes the organizational aspects required for the implementation of the core regulatory functions and supporting regulatory functions of a regulatory body. Section 5 outlines the characteristics of an integrated management system necessary for an effective and efficient regulatory body, and Section 6 provides recommendations on the necessary staffing, qualifications and competences that should be in place in order for the regulatory body to effectively perform its functions and to discharge its responsibilities. Appendices I, II, III and IV provide more detailed guidance on: the use of external expert support; generic processes of the integrated management system; the basic elements of a regulatory body training programme; and on the structure of information in the integrated management system. The Annex provides examples of generic regulatory process descriptions.

2. GENERAL CHARACTERISTICS OF A REGULATORY BODY

GENERAL

2.1. Preparation of a set of organizational values for the regulatory body to guide the behaviour of staff helps to lay the foundations for an effective and efficient organization and to create a strong safety culture that is in line with the mission of the regulatory body. These values should include the following:

- Independent, impartial, transparent, proportionate, objective and evidence-based decision making;
- Individual and collective commitment to safety, based on a scientific and technical approach;
- Acting in the public interest, demonstrating accountable public service and being accountable for decisions;
- Respect, fairness, and courtesy in all the activities of the regulatory body;
- Openness and transparency in dealing with the public and other interested parties, in order to promote confidence and trust in the judgements and decisions of the regulatory body;
- Fostering mutual understanding and respect between the regulatory body and authorised parties, through a frank, open and formal relationship;
- Frank, open and honest communications, including when dealing with appeals, problems and complaints;within and outside the regulatory body;
- A supportive environment with respect for personal integrity, expertise and professionalism;
- A commitment to learning and continuous improvement;
- A questioning attitude, whereby regulatory decisions are challenged and examined.

2.2. The regulatory body should apply a systemic approach[5] so that it can effectively perform its functions [10].

INDEPENDENCE

2.3. The need for independence of the regulatory body is affirmed in the Convention on Nuclear Safety [11], the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [12], the Code of Conduct on the Safety of Research Reactors [13], the Code of Conduct on the Safety and Security of Radioactive Sources [14] and in SF-1 [1] and GSR Part 1 (Rev. 1) [2] and concerns the separation of the regulatory body from the promoters of nuclear technology. The primary reason for the need for regulatory independence is to ensure that regulatory

[5] A systemic approach is an approach relating to a system as a whole, in which the interactions between technical, human and organizational factors are duly considered.

judgements can be made, and enforcement actions taken, without any unwarranted pressure from interests that may conflict with safety. Furthermore, the credibility of the regulatory body with the general public depends on whether the regulatory body is regarded as being independent from the organizations it regulates, as well as independent from other government agencies or industry groups that promote nuclear technologies.

2.4. It is recognized that a regulatory body functions within the national legal and budgetary framework of the State, and therefore cannot be absolutely independent in all respects of other parts of government. Nevertheless, effective independence of the regulatory body to make decisions in respect of radiation protection of people and the environment, without external pressures or influence, will contribute to its effectiveness and credibility.

2.5. The need for independence of the regulatory body does not imply an adversarial relationship with authorized parties or with any other parties. The following paragraphs provide a more detailed description of a number of aspects of regulatory independence.

Political aspects

2.6. Paragraph 2.8 of GSR Part 1 (Rev. 1) [2] states that:

> To be effectively independent from undue influences on its decision making, the regulatory body …. shall be free from any pressures associated with political circumstances or economic conditions, or pressures from government departments, authorized parties or other organizations."

2.7. The regulatory body should, however, be accountable to government and to the general public with regard to effectively and efficiently fulfilling its mission to protect workers, the public and the environment. Formal mechanisms for ensuring accountability may include: establishing a direct reporting line to the highest levels of government; undertaking regular audits and peer reviews and publishing the results; and communication with interested parties.

Legislative aspects

2.8. Requirement 3 of GSR Part 1 (Rev. 1) [2] states that:

> "The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."

2.9. The legal framework defining the powers of the regulatory body should include mechanisms to protect the independence of regulatory decision making from undue interference in decisions on safety issues. Such mechanisms may include, for example, procedures for the documentation and dissemination of regulatory decisions and their legal and technical justification.

2.10. Having a single regulatory body for all aspects of safety offers advantages in terms of clear allocation of responsibilities, and ensuring a comprehensive, proportionate and consistent regulatory approach. However, in many cases the regulation of facilities and activities is spread across more than one organization. Where several authorities have regulatory responsibilities for safety, the legislation should establish clear lines of authority and responsibility so as to avoid gaps or overlaps. The various regulatory authorities should formally establish a system of liaison and working arrangements and procedures so as to ensure an appropriate degree of coordination and cooperation.

Financial aspects

2.11. Adequate and stable financing for all regulatory activities is fundamental to independence. The financing mechanism should be clearly defined in the legal framework. The budget for the regulatory body may include the fees levied for regulatory activities, but should not depend on fines or other penalties arising from enforcement actions, nor should it be decided by or be subject to the approval of those parts of the government that are responsible for the development, promotion and operation of nuclear technologies.

2.12. Although the overall budget of the regulatory body may be fixed by the government, the regulatory body should have the authority to distribute financial resources to its various regulatory activities for the greatest effectiveness and efficiency.

2.13. Specific provisions to fund the regulatory body should be established in the national legal framework or through the national fiscal process. How this is best accomplished will depend on a number of considerations, including the following:

- Precedents for the funding of other national regulatory organizations;
- The types and scale of regulated facilities and activities, and the associated workload based on the application of a graded approach to the execution of the functions of the regulatory body;
- How the regulatory body is structured, including its use of in-house and outsourced competences.

2.14. An open and transparent system of governance and auditing of the regulatory body's funding should be put in place. Review and approval of the regulatory body's budget should be performed only by governmental agencies that are effectively neutral in respect of the development, promotion or operation of facilities and conduct of activities. Such an approach provides additional assurance of the independence of the regulatory body.

Competence aspects

2.15. The independence of a regulatory body's decision making depends greatly on the competence of its staff. The regulatory body should have sufficient internal technical expertise in the areas relevant to its mandate. The management of the regulatory body should therefore have the responsibility and

authority to maintain sufficient staff with the necessary skills and technical expertise to carry out the regulatory functions. Such necessary skills and expertise should include:

- Competence in the relevant scientific and technological areas;
- Competence with regard to the facilities, organizations and activities of authorized parties;
- Competence in applying the regulatory processes in accordance with their underpinning legal framework, ethical principles and codes of conduct.

The principles and considerations on staffing and competence of staff are addressed in greater detail in Section 6.

2.16. The regulatory body may decide to obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, on a temporary or permanent basis. Such advice or services obtained externally should be impartial and free from conflicts of interest and should not relieve the regulatory body of its assigned responsibilities. External expert support may be provided in several ways, as described in further detail in Appendix I.

2.17. As further described in Section 3, the regulatory body should acquire, manage, maintain, develop and preserve knowledge and information for building and maintaining adequate core competences. The objective should be to make informed decisions and to have competence to assess advice provided by advisory bodies and information submitted by authorized parties and applicants. Building and maintaining core competences is a distinct process and should be performed within the regulatory body's integrated management system; this is further addressed in Section 5.

Communication and consultation with interested parties

2.18. The regulatory body should have the authority and the responsibility to establish provisions for communication with interested parties, including the public, about the possible radiation risks associated with facilities and activities, as well as about the regulatory decision making processes and regulatory decisions made. Informing and consulting interested parties and the public should be done by means of a transparent, open, consistent and on-going communication process. This subject is addressed in detail in Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. DS460 [15].

Audits, peer reviews and international cooperation

2.19. A systematic programme of professional reviews and audits of regulatory performance should be put in place in order to promote independence in decision making by the regulatory body. This should include participation in appropriate international professional cooperation exercises and independent peer reviews, either of a specific regulatory activity or of the regulatory body as a whole.

COMMITMENT TO SAFETY

2.20. The protection of people and the environment from harmful effects of ionizing radiation is the main focus of the regulatory body. The regulatory body's oversight should consider all aspects of a facility or activity, including its organization and staffing. The regulatory body should take a systemic approach to discharging its responsibilities, with account taken of human, technological and organizational factors and their respective interactions.

2.21. All individuals of the regulatory body should exhibit a strong commitment to safety. This commitment should be achieved by developing and fostering a strong safety culture within the regulatory body, as further described in paras 3.2 to 3.8.

ACTING IN THE PUBLIC INTEREST

2.22. The prime responsibility for safety rests with the authorized party. Therefore, the regulatory body should not undertake activities that are the responsibility of authorized parties; rather the regulatory body should focus on regulatory functions, as identified in Section 4.

2.23. While the responsibility of the regulatory body is defined by legislation, the expectations of the public may vary. In order to maintain its authority and credibility the regulatory body should establish and maintain arrangements for effective communication and consultation with the public. Examples of such arrangements may be:

- Forums for discussion of public concerns;
- Forums for discussions of technical and regulatory aspects of safety;
- Means to enable the public to communicate its concerns and questions;
- Information channels specifically for public information.

2.24. Any information provided by the public should be carefully analysed and dealt with in a professional and timely manner. The information provided may also be used by the regulatory body when establishing and reviewing its regulations, guides and procedures and practices, where appropriate and when not in contradiction with the mandate of the regulatory body.

OPENNESS, TRANSPARENCY AND CONSISTENCY

2.25. Regulations and guides should be clear and unambiguous, and should be written in a manner that can be clearly understood by authorized parties. Effective communication with interested parties will help ensure that the regulatory body takes account of different perspectives when establishing or modifying the regulatory framework.

2.26. The regulatory body should ensure that regulations and requirements are applied in a consistent, predictable, transparent, balanced and proportionate manner. The regulatory body should establish

policies to promote proportionality, transparency and consistency, and the broad sharing of information and ideas, to help ensure the highest standards of protection and safety. Transparency and openness towards the general public also enhances confidence and trust in the regulatory body.

COMMITMENT TO CONTINUOUS IMPROVEMENT

2.27. Facilities and activities, technologies, and the expected standards of protection and safety, as well as expectation from the public, change over time. The regulatory body's organization, staff, competences and knowledge, as well as its integrated management system, should be designed to be able to adapt to such changes.

2.28. The regulatory body should encourage its staff to have a questioning attitude regarding its functions and activities, and the activities of authorized parties and should apply a process of continuous improvement in respect of its performance. This process is covered in paras 5.60 to 5.62.

3. MANAGEMENT FOR SAFETY

LEADERSHIP FOR SAFETY

3.1. Senior management, managers and leaders at all levels of the regulatory body should demonstrate by their own behaviour consistent adherence to the values of the regulatory body. This should typically include the following:

- Promoting a systemic approach to safety that embraces interactions between all human, technological and organizational factors;
- Developing shared values for safety, establishing behavioural expectations so as to shape a strong safety culture, and encouraging acceptance of personal responsibility for safety among all individuals;
- Establishing and communicating a clear vision for safety, which is elaborated through a safety policy, strategy, plans and objectives, whereby safety is paramount;
- Ensuring that responsibilities and accountabilities are in line with policies, strategies and objectives, to ensure that safety requirements and safety goals are met and to guide decision making at all levels;
- Effectively communicating the regulatory body's vision, strategy, plans and objectives;
- Encouraging the involvement of all individuals in the regulatory body in the implementation and continuous improvement of the regulatory body's vision, strategy, plans and objectives;
- Developing and maintaining leadership capabilities at all levels in the regulatory body, including capabilities for competence management, change management and crisis management;
- Encouraging open communication and seeking feedback on how effective leadership in the regulatory body is in ensuring and improving safety, and taking action as necessary;
- Supporting and encouraging staff to focus on safety and including them in the regulatory decision making process;
- Demonstrating a commitment to continuous improvement of the integrated management system by actively seeking and assessing information on performance within their area of responsibility, and sharing this information within the regulatory body in an open and transparent manner;
- Fostering and encouraging the involvement of all individuals in the regulatory body in the implementation and continuous improvement of the integrated management system and encouraging a readiness to challenge acts or conditions that are inconsistent with the values of the regulatory body;

- Identifying and removing pressures and conflicts that inhibit the discharge of responsibilities and functions;
- Involvement in the resolution of difficult issues, including differences in professional opinion;
- Creating a working environment that allows staff to feel responsible for their work and develop their competences, for example by assigning them challenging tasks and coaching them adequately in the case of difficulties;
- Ensuring timely and effective communication with interested parties.

SAFETY CULTURE

3.2. Requirement 12 of IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [10] states that:

> "Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture."

3.3. Expected attitudes and behaviours (including those of any external experts and technical support organizations) that promote a strong safety culture should be defined and communicated throughout the regulatory body.

3.4. A strong safety culture does not grow by itself, but it can be fostered and sustained. The behaviour and commitment of leaders to safety influences the attitudes and behaviours of individuals. Therefore, a strong safety culture needs the strong commitment and engagement of senior management, with the support of the integrated management system.

3.5. Everyone in the regulatory body, from senior management down, should contribute to promoting and maintaining a strong safety culture, by adopting specific behaviors as routine ways of working.

3.6. A strong safety culture has the following important attributes:

- Safety is a clearly recognized value;
- Leadership for safety is clear;
- Accountability for safety is clear;
- Safety is integrated into all activities;
- Safety is learning driven.

3.6. These attributes should permeate the entire regulatory body and should be reflected in the integrated management system, so that individuals demonstrate a questioning attitude, feel responsible and are supported in identifying safety concerns.

3.7. Attitudes and behaviors that support a strong safety culture in the regulatory body include the following:

- Individual and collective commitment to safety;
- Acceptance of personal responsibility for safety;
- An open attitude that encourages trust, collaboration and free communication, and that values the reporting of problems;
- The prompt acknowledgement of and feedback regarding identified problems and suggestions for improvement;
- Continuously seeking to develop and improve safety and the safety culture;
- Encouraging a questioning and learning attitude and discouraging complacency at all levels in the regulatory body with regard to safety;
- A common understanding of the key aspects of safety and safety culture within the regulatory body;
- An awareness of the potential consequences of regulatory activities, including risks and hazards associated with them;
- Ensuring that all factors that might impact upon safety are taken into account in the regulatory decision making process and other regulatory activities.

3.8. The regulatory body should establish and maintain a programme to develop, to foster and to evaluate its safety culture. Such a programme should include safety culture self-assessments, workshops and seminars for defining improvement programmes, as well as training and support.

RESPONSIBILITY AND ACCOUNTABILITY OF THE REGULATORY BODY

3.9. The regulatory body has the responsibility for regulating the safety of facilities and activities. Therefore the regulatory body:

- Should establish or adopt regulations and guides that are sufficient in scope to cover all types of facilities and activities within the scope of its responsibilities;
- Should ensure that those responsible for facilities and activities are made aware of their prime responsibility for safety;
- Should verify and assess safety in compliance with regulatory requirements through an effective system of authorization, review and assessment, inspection and enforcement.

3.10. The regulatory body is accountable for how it discharges its responsibilities and therefore it:

- Should establish policies and standards against which it can be judged by government and other interested parties in an open and transparent manner;
- Should be able to justify and explain its judgements and decisions;
- Should incorporate a formal appeals process into the framework for safety;

– Should establish an effective mechanism for interactions with interested parties.

3.11. The State should provide for independent oversight of the regulatory body and its key decisions. This may be achieved in a number of different ways, for example by appearing before legislative committees, referral of decisions to courts of law and the appointment of an independent auditor. Such arrangements could also provide independent oversight and governance of the appeals process against regulatory decisions and actions. Further accountability can be achieved by establishing a direct reporting line from the regulatory body to the highest levels of government. Peer review systems, at national and international levels, can also provide a useful input into demonstrating accountability. The need for accountability should not compromise the regulatory body's independence in making decisions relating to safety.

PROVISION OF RESOURCES

3.12. Senior management is required to ensure that the resources[6] essential to the fulfilment of the regulatory body's functions and to the achievement of the regulatory body's objectives are identified and made available [10].

Financial resources

3.13. In order to be able to act independently, the regulatory body should be allocated sufficient financial resources and should have the authority to decide how these resources are to be used, in accordance with a graded approach.

3.14. The regulatory body should be able either to develop its own budget or, in cases where this is predetermined (e.g. by national government), to control the distribution of financial resources within its overall budget.

3.15. The funding for the regulatory body should be reviewed periodically. Attention should be paid to future changes in the type and numbers of facilities and activities that need to be regulated. This can include the introduction of new facilities, changes during the lifetime of facilities including closure and decommissioning, and waste disposal. Large changes, for example to a national nuclear power programme, should be expected to have a significant impact on the regulatory resources required. Other factors, such as the expectations of interested parties, should also be considered when reviewing regulatory body funding.

[6] Resources include individuals (the number of individuals and their competences), infrastructure, the working environment, knowledge and information, and suppliers, as well as material and financial resources [15].

Human resources

3.16. Requirement 18 of GSR Part 1 (Rev. 1) [2] states that:

> "The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to adequately perform its functions and to discharge its responsibilities."

3.17. Adequate staffing will ensure that the regulatory body has the necessary resources, competences and capabilities to reach its own independent decisions on the safety of facilities and activities. As such, attention should be paid to the education, training and continuing development, of the staff of the regulatory body in a dedicated human resources process within the integrated management system.

3.18. Where external expert support is used, the regulatory body should still ensure that sufficient internal staff are available, having the capability to determine the need for and extent of external expert support, and also to evaluate the adequacy of any advice or services provided. Responsibilities for fulfilling core regulatory functions should not be delegated. Details on staffing of, and competence management within, the regulatory body are described in Section 6.

Information and knowledge

3.19. Information and knowledge are part of the corporate memory of the regulatory body and should be managed as a key resource that is embedded in the regulatory body's processes, activities and functions (see Table A-19 in the Annex). Effective management for safety will take into account the knowledge and information resulting from both positive and negative experiences (e.g. good practices and bad practices). Examples of information and knowledge relevant for regulatory bodies include the following:

- The collective experience of the staff of the regulatory body;
- Technical expertise;
- Lessons learned from regulatory practices, e.g. techniques of assessment and inspection;
- Feedback from interested parties;
- Feedback of experience from other authorities and national and international bodies;
- Operating experience in authorized facilities and activities in the State and in other States.

3.20. Processes should be established, from the early stages of development of the regulatory body's integrated management system, to acquire, use, maintain, store and retrieve information and knowledge. These processes should be supported by specific tools and techniques, for example:

- Questionnaires, interviews and discussions, reports (special attention should be paid to the transfer of knowledge when experienced staff leave or retire from the regulatory body);
- Databases, libraries, 'knowledge portals' and archives.

Other resources

3.21. There are other types of resources necessary for the regulatory body to perform its functions and to discharge its responsibilities. These may include the following:

- Offices, including furniture, equipment and supplies;
- Computer and communications equipment, including software and network systems;
- Arrangements for conventional emergencies;
- Personal protective equipment;
- Radiation monitoring and dosimetry equipment;
- Laboratory facilities;
- Record-keeping systems;
- Support facilities;
- Means of transport.

INTERACTIONS WITH INTERESTED PARTIES

3.22. As part of a policy of openness, transparency and mutual trust, the regulatory body should establish effective working relationships with interested parties. The regulatory body may be subject to legal requirements that prescribe the provision of information to, and consultation with, interested parties (including multilateral and bilateral regulatory interactions).

3.23. Regulations and associated guides are the primary means by which the regulatory body communicates its requirements and guidance, modes of work and basis for decisions to interested parties. Therefore, in developing and subsequently reviewing regulations and guides, comments from, and the expectations of, interested parties should be taken into account.

3.24. Interested parties may have differing expectations of the regulatory body, depending on their functions, roles and interests. In order to understand and address these needs and expectations, the regulatory body should establish a process to ensure effective interactions with all interested parties. This should include the following:

- Identifying relevant interested parties and the legal requirements relevant to informing and consulting interested parties;
- Clarifying the needs and expectations of interestd parties and ensuring that these are recognized and understood;
- Evaluating these needs and expectations and determining an appropriate and balanced response;
- Deciding on a communication strategy setting out the methods and frequency of informing, involving and consulting each party as appropriate, including keeping relevant parties informed of possible radiation risks associated with facilities and activities;

- Communicating the response to relevant parties;
- Using feedback to inform regulatory policy, strategies, plans and other decisions;
- Periodically assessing the satisfaction of interested parties to determine whether their needs are being met.

3.25. The regulatory body should consider developing methods for gathering information regarding the effectiveness of its interactions with interested parties.

4. FUNCTIONS AND ORGANIZATION

INTRODUCTION

4.1. To meet its regulatory responsibilities, there are several core functions that a regulatory body should fulfil. These core functions are described in detail in Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. DS473 [4] and only a brief description is provided in this section.

4.2. In fulfilling its core functions there are also several supporting functions that should be available within the regulatory body. These supporting functions enable the implementation of the core functions, and a regulatory body could not operate satisfactorily without most of them. Core functions and supporting functions are described in separate subsections below.

4.3. In addition, management functions are necessary to enable the regulatory body to sustain an efficient and effective organization with sufficient competent staff.

4.4. The core functions, supporting functions and management functions should be organized through associated processes and should be represented in the regulatory body's integrated management system (see Section 5 and the Annex).

CORE REGULATORY FUNCTIONS

Development of regulations and guides

4.5. Requirement 32 of GSR Part 1 (Rev. 1) [2] states that:

> "The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for protection and safety upon which regulatory policies, judgments, decisions and actions are based."

4.6. 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 the regulations and guides:

- Have sufficient and appropriate scope commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach;
- Are consistent and clear;
- Are kept up-to-date;
- Are developed in consultation with interested parties.

Notification and authorization

4.7. Requirement 23 of GSR Part 1 (Rev. 1) [2] states 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."

4.8. The regulatory body should have the authority to accept and to process notifications and applications for authorization for facilities and activities within the scope of the regulations.

4.9. 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 use this information to update the register of sources, facilities and activities, as appropriate, and to decide on the level of regulatory control to be applied.

4.10. The objective of granting authorizations is for the regulatory body to exercise effective regulatory control throughout the lifetime of a facility or duration of an activity in relation to safety. The authorization process should require assurance by the applicant that it can comply with all relevant safety requirements.

Review and assessment of facilities and activities

4.11. Requirement 25 of GSR Part 1 (Rev. 1) [2] states 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 the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization."

4.12. The review and assessment process is a critical appraisal, performed by the regulatory body, of information that is submitted by the authorized party on all aspects of safety, or that comes from inspection, information on events, feedback of operating 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 a series of decisions) on the acceptability of the facility or activity in terms of safety.

Inspection of facilities and activities

4.13. Requirement 27 of GSR Part 1 (Rev. 1) [2] states 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."

4.14. In addition, inspections should be performed to allow the regulatory body to supplement or to verify information submitted by the authorized party as well as to form its own opinion on issues relevant to safety.

4.15. Paragraph 4.49 of GSR Part 1 (Rev. 1) [2] states that:

> "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."

4.16. Paragraph 4.52 of GSR Part 1 (Rev. 1) [2] further states that:

> "Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach."

Enforcement of regulatory requirements

4.17. Requirement 30 of GSR Part 1 (Rev. 1) [2] states that:

> "The regulatory body shall establish and implement 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."

4.18. Regulatory enforcement activities should cover all areas of regulatory responsibility. Enforcement actions should be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with regulatory requirements or with the conditions of the authorization.

4.19. The principal objective of enforcement is to provide a high level of assurance that the authorized party complies with all relevant safety requirements and meets the safety objectives and authorization conditions, and promptly identifies and corrects non-compliances with safety requirements. This applies at all stages of the lifetime of a facility (i.e. siting, design, construction, commissioning, operation and decommissioning or closure) or for the duration of an activity.

4.20. Enforcement actions are intended to correct or improve any aspect of the procedures and practices of the authorized party or of the facility's systems, structures and components as necessary to ensure safety. Enforcement actions may also include civil penalties and other sanctions.

Emergency preparedness and response

4.21. The roles and responsibilities for emergency preparedness and response are required to be allocated among the authorized party, response organizations and the regulatory body. While certain

roles and responsibilities in emergency preparedness and response are allocated to the regulatory body (for example, those addressed in paras 4.10-4.15 and 6.30 of GSR Part 7) [7], the government may assign the regulatory body additional roles and responsibilities in emergency preparedness and response. The precise nature of such additional responsibilities will depend on the specific legal and organizational arrangements in the State concerned. In the following text, therefore, the emergency preparedness and response functions and processes of the regulatory body are identified only in a generic manner.

4.22. As a minimum, the regulatory body:

- Should verify that on-site emergency arrangements are in place;
- Should verify that coordination with off-site response organizations is in place;
- Should establish and maintain its internal arrangements for emergency preparedness and response;
- Should discharge its assigned responsibilities in emergency response.

DS473 [4] provides further details on the regulatory body's functions and processes in respect of emergency preparedness and response.

Communication and consultation with interested parties

4.23. The regulatory body should provide information on its activities to interested parties, including the public, on a regular basis and in the event of abnormal events. Information should be factual and as objective as possible, reflecting the regulatory body's independence. The regulatory body should be as transparent as possible while respecting any requirements of commercial confidentiality and information security.

4.24. The regulatory body should, in accordance with national legislation, consult with interested parties, including the public, on its policies, regulations, guidance and operations. This requires development of an approach to meeting and discussing with the public and considering public issues and concerns regarding safety. Further details on approaches to and means of communication and consultation with interested parties are provided in DS460 [15].

SUPPORTING FUNCTIONS

4.25. There are two categories of supporting functions that enable the regulatory body to implement its core functions effectively:

- Administrative functions supporting the routine operations of the regulatory body (e.g. finance, management of documents and records, purchasing and control of equipment);
- Technical functions directly relating to the effective implementation and fulfilment of the core regulatory functions (e.g. legal support, research and development, the functions of advisory committees, external expert support, liaison with other governmental organizations, international cooperation and assistance).

Most of these functions should be represented in processes of the regulatory body's integrated management system (see Section 5).

Administrative functions

4.26. The regulatory body should have organizational units dedicated to various administrative activities, which may be divided into specific aspects, to support its core activities. The number and the size of the units will depend on the size of the regulatory body. Administrative functions include the following activities:

- General administration, such as internal planning, maintenance of buildings and equipment, operation of communication systems and physical security of the premises;
- Management of human resources, which covers recruitment and training, internal communication, arrangements for medical care, security of staff and travel arrangements;
- Financial administration, including procurement, contracting, accounting, salaries and invoicing;
- Management of documentation and records, including the preparation, storage, retrieval, access control, reproduction and distribution of documents including legal instruments, e.g. authorizations or permits;
- Computer and/or data administration, ensuring adequate computing capability for technical use (data handling, analytical computing) as well as general uses of information technology and computer security;
- Knowledge management and library services, including access to specialized publications.

Technical functions

Legal support

4.27. The regulatory body should have access to expert legal advice. The objective of legal support is to provide the regulatory body with legal advice on international obligations, the national legal framework and legislation, and development of rules, regulations and guides, for the implementation of the regulatory body's functions.

4.28. Activities typically requiring professional legal support include the following:

- The development of basic legislation;
- The development of regulations and review for compatibility with other relevant laws and regulations;
- Assisting in the development of the internal administrative procedures of the regulatory body;
- Providing legal advice in the authorization process;
- Providing legal advice on proposed enforcement actions;

- Representing the regulatory body in the event of enforcement activities involving formal legal processes;
- Assisting regulatory body staff in responding to requests for public information.

4.29. The experts providing legal support should review and advise the regulatory body regarding:

- How the regulatory body performs its regulatory responsibilities and functions;
- The adequacy of its regulations, implementing guides and procedures;
- Authorization by the regulatory body for facilities and activities;
- Enforcement actions;
- Existing and proposed safety standards, and technical and policy issues relating to the authorization of facilities and activities;
- Other matters deemed relevant by the regulatory body (e.g. contracts, matters involving cooperation with other organizations).

4.30. Since legal support is embedded in many activities of the regulatory body, the regulatory body should establish processes describing how to document the results of a legal review, as well as the criteria for the acceptance or rejection of recommendations from experts providing legal support.

Research and development

4.31. Research and development provides supporting information on the safety of the design and operation of facilities or the conduct of activities. Research and development is intended to:

- Confirm existing knowledge on specific technical matters;
- Identify any technical safety issues and resolutions;
- Improve existing scientific and technical knowledge and safety assessment methods;
- Develop technical and scientific bases to support new regulations and/or procedures of the regulatory body.

4.32. Research and development is an essential supporting function to enable the regulatory body to assess and evaluate the adequacy of the technical basis supporting its regulations and regulatory activities. Having such capabilities will enable the regulatory body to evaluate key issues that impact on safety. Organizations that perform research and development should be able to independently evaluate issues and scenarios with potential impact on safety. Regulatory activities should rely to the extent practicable on state of the art scientific and technical knowledge obtained from national and international research and development programmes. Research and development programmes in nuclear safety should be organized to maintain and continuously develop the knowledge and competence of regulatory staff.

4.33. The organizational structure of the regulatory body should take into account the need for research and development, either by the establishment of a dedicated research unit or by recruiting

staff who can define research and development needs, identify suitable external expert support organizations, initiate, coordinate and monitor the necessary work, and evaluate the results.

4.34. The regulatory body should, where appropriate, request authorized parties to carry out research and development necessary to demonstrate safety, and should assess the adequacy of the research and development methodology used and the results obtained. The regulatory body may consult with an appropriate advisory committee in its evaluation of the research and development programmes of authorized parties.

Advisory committees

4.35. Advisory committees provide the regulatory body with independent expert opinion on the adequacy of regulatory activities. Advisory committees are typically independent bodies (i.e. their members should not include staff from the regulatory body) that give advice and make suggestions to the regulatory body about safety issues.

4.36. Advisory committees can be distinguished from other forms of external expert support as their role is not to deliver technical input, but is intended to advise on overall regulatory approaches and policies.

4.37. Advisory committees should advise the regulatory body on:

- How effectively the regulatory body performs its regulatory responsibilities and functions;
- The adequacy of its regulations and guides, and procedures for such regulations and guides;
- Existing and proposed safety standards, and technical and policy issues relating to the authorization of facilities and activities;
- Other matters referred to the committee by the regulatory body.

4.38. The regulatory body may choose to give a formal structure to the processes by which expert opinion and advice are sought and provided. An effective advisory committee can provide valuable service to the regulatory body by helping to ensure that policies and regulations are clear, practical and complete, and provide a good balance between the interests of authorized parties and the needs of the regulatory body and other interested parties.

4.39. Advisory committees should report to the highest level of authority within the regulatory body. An advisory committee may consist of representatives from government departments, other national regulatory bodies, regulatory bodies of other States, scientific organizations, senior technical experts, academia, non-government organizations and authorized parties. Any advisory committee member who might have a conflict of interest on any subject under discussion should be disqualified from that discussion. Membership of an advisory committee should represent a balance of interests across various interested parties. The terms of reference of advisory committees should be clearly defined by the regulatory body, and should specify the role and responsibility of the advisory committee, its constitution and the selection criteria for its membership. Advisory committees should solicit, where

appropriate, views from the public, industry, regional and local governments, and other interested parties on regulatory matters.

External expert support

4.40. The regulatory body should have, as a minimum, adequate competence in every core function and supporting function, so that it has the ability both to formulate and to manage its requests for technical advice and to understand, evaluate and implement the advice received (see para. 3.18 and Section 6).

4.41. If the regulatory body decides to establish a dedicated technical support organization, clear limits on the degree of control and direction by the regulatory body over the work of the technical support organization should be set. This will ensure that the technical support organization has sufficient flexibility to pursue investigations to the point where it can give definitive and independent advice.

4.42. The regulatory body should establish requirements for the integrated management system to be used by the technical support organization. In some cases, the existing integrated management system of the technical support organization may be adequate, while in other cases the regulatory body should specify the requirements for the integrated management system in its contract with the technical support organization. In the case of individual experts, they should work in accordance with the regulatory body's integrated management system.

4.43. The regulatory body should establish and maintain a list of qualified external experts, as well as arrangements for engaging their services when necessary. Examples of providers of external expert support can be found in Appendix I.

Liaison with other governmental organizations

4.44. The regulatory body should interact with other governmental organizations that have regulatory responsibilities that interface with safety to ensure a consistent and effective approach. Such governmental organizations may include:

- Environmental protection authorities;
- Radioactive waste management authorities;
- Authorities responsible for public liability issues;
- Authorities responsible for nuclear security and/or the State system of accounting for and control of nuclear material;
- Authorities for planning water resources and land use;
- Authorities responsible for water and food safety;
- Authorities responsible for public and occupational health and safety;
- Fire protection authorities;
- Transport authorities;

- Law enforcement bodies;
- Bodies with responsibility for conventional or industrial safety;
- Other bodies with responsibilities for emergency preparedness and response;
- Other bodies with responsibilities relating to the release of radioactive effluents.

4.45. Special consideration should be given to cooperation with governmental organizations with responsibilities for environmental protection, nuclear security and the State system for accounting for and control of nuclear material. The arrangements for how governmental organizations will cooperate may include legislation where appropriate, and should ensure that the system of regulatory control works effectively and that timely, effective enforcement and corrective actions are taken.

4.46. Where the responsibilities of the regulatory body and other organizations interact or have an interface, liaison between these bodies should be established by means of a formal agreement specifying each body's responsibilities, the areas of interface and the means for resolving any conflicts between different requirements. It should be ensured that no conflicting requirements are placed upon an authorized party.

4.47. The regulatory body should be organized to be capable of providing governmental organizations with clear, accurate and timely information in areas relevant to its responsibilities.

4.48. To help promote a better working relationship with other organizations, the regulatory body should assign responsibilities for making arrangements for liaison to an individual or an organizational unit. Staff of the regulatory body should be made aware of the reasons for and the implications of the overlapping responsibilities and of the fact that good working relationships at all levels are necessary.

International cooperation and assistance

4.49. Requirement 14 of GSR Part 1 (Rev. 1) [2] states that:

> "The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally."

4.50. The regulatory body should, under agreements made by the government, take part in a range of international cooperation activities. Such agreements and arrangements include:

- International conventions that establish common obligations and mechanisms for ensuring protection and safety;
- Codes of conduct that promote the adoption of good practices in the relevant facilities and activities;
- The development of internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices;

- International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States;
- International and regional agreements and networking to enhance the ability of the regulatory body to fulfil its regulatory responsibilities and contribute to the global harmonization of safety standards;
- Regular multilateral and bilateral cooperation with regulatory bodies in other States, relevant national and international organizations to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections by means of sharing of knowledge and feedback of experience (e.g. by the development of networks).

4.51. The regulatory body should actively participate in international working groups to provide advice and assistance to international organizations and to other States to help develop effective regulatory bodies and to enforce rigorous safety standards for global application. Participation in such arrangements, in turn, is a valuable means of exchanging experience and benchmarking against international practice.

4.52. The safety of facilities and activities is of international concern. National authorities, with the assistance of the regulatory body as appropriate, should establish arrangements for the exchange of safety related information, multilaterally or bilaterally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote cooperation.

4.53. International cooperation by the regulatory body, arranged by means of networking and multilateral or bilateral agreements, may include exchange of information, mutual assistance in regulatory activities, staff training and staff meetings on a regular basis on specific subjects and other matters. Multilateral cooperation may involve different approaches, for example, regional approaches, approaches based on the design or type of the facilities concerned, or approaches on the basis of common problems concerning safety.

4.54. The regulatory body should also serve as the national point of contact for international systems for the exchange of safety related information and should join dedicated regional organizations in order to ensure the quality of information provided to such systems and to ensure the effective communication of information to and from authorized parties and other governmental organizations.

ORGANIZATION

4.55. In order for the regulatory body to discharge its responsibilities and perform its functions effectively, it may be appropriate to establish an organizational structure that is flexible and adaptable to different circumstances and demands. Depending on the national circumstances and in accordance

with a graded approach, the organization of the regulatory body will vary widely from State to State, and therefore the following factors should be taken into account:

- The size, number, type, nature and stage in the lifetime of existing facilities and activities;
- Future plans (e.g. for new installations and/or facilities, new technology and activities relating to new stages in the lifetime of facilities, such as decommissioning);
- The national legal framework;
- Other existing regulatory authorities;
- Expectations of interested parties;
- The availability of competences at a national level (e.g. educational institutions and technical support organizations, as applicable);
- The availability of funding.

4.56. These factors may impact the organization in terms of the regulatory functions, the structure and size of the regulatory body, the use of external expert support and competence management. Nevertheless, the organization of the regulatory body should be sufficient to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently and it should be commensurate with the results of an analysis of the factors listed in para 4.55.

4.57. The regulatory body should ensure that the responsibilities assigned to different parts of its organization are clearly defined. The organizational structure of the regulatory body may be arranged in accordance with regulatory functions (a process based organizational structure), in accordance with the technical areas to be covered, (a line organizational structure), in accordance with the facilities and activities to be regulated, or a mixture of these (a matrix or project organizational structure).

4.58. Irrespective of the organizational structure selected, attention should be paid to the distribution of expertise and required competences in organizational units and to the integration and interaction of the technical and administrative units involved in implementing the core functions and supporting functions. However, the regulatory body should use an interdisciplinary approach to the oversight concept, enabling a systemic approach in which all aspects relevant to safety are adequately considered with respect to human, technical and organizational factors and their interactions.

4.59. Irrespective of the organizational structure selected, the regulatory body should ensure that its staff members are protected from any undue influence by any interested party, especially authorized parties.

4.60. In order to be able to act effectively and to address changing circumstances and demands that arise at any time during the different stages of the lifetime of authorized facilities, the structure and composition of the regulatory body’s organization should be flexible. The need for changes may arise unexpectedly, and the regulatory body should put a process in place for managing organizational changes. This process should be established in the very early stages, of the establishment of the regulatory body since changes often take place during the initial growth of a regulatory body.

4.61. The roles, responsibilities, and lines of communication of organizational units, managers and staff should be clearly defined and assigned, in accordance with the organizational structure, to allow for the effective and efficient implementation of the core functions and supporting functions.

ROLES AND RESPONSIBILITIES OF THE MANAGEMENT

4.62. Senior management should give the highest priority to the fundamental safety objective to protect people and the environment from harmful effects of ionizing radiation [1]. Senior management has the ultimate responsibility for the effectiveness and efficiency of the regulatory body. They should provide consistent direction and oversight for the effective implementation of regulatory functions.

4.63. Requirement 4 of GSR Part 2 [10] states that:

> "Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy."

4.64. Managers at all levels should demonstrate effective leadership that seeks to continuously improve safety awareness and safety culture.

4.65. The vision, values, policies, strategies and goals of the regulatory body should be commensurate with the legal framework, the mission of the regulatory body and the needs and expectations of interested parties. The vision, values, policies, strategies and goals should be subject to regular review and revision, as necessary, depending on changes and developments in the legal system, the national nuclear programme and the expectations of the interested parties, but also considering operating experience and developments in the State and in other States.

4.66. The vision, values, policies, strategies and goals should be communicated throughout the regulatory body and also to interested parties in order to foster transparency and confidence.

4.67. Senior management is responsible for the proper functioning and, as necessary, adaptation of an appropriately structured and staffed regulatory body with sufficient competence to fulfil the regulatory functions as well as for the establishment, application, sustaining and continuous improvement of an effective integrated management system [10].

4.68. Senior management should ensure that:

- Managers develop and implement plans for their areas of responsibility that are aligned with the broader vision, values, policies, strategies,goals and plans of the regulatory body;
- Managers communicate effectively with their staff to keep them informed about the regulatory body's strategic plans and their contribution to delivering these;
- Managers provide effective supervision and oversight as well as appropriate support for their staff.

4.69. In supporting the implementation of the plans for the achievement of the regulatory body's objectives, senior management should ensure that essential resources are identified and made available. Such resources include financial resources, human resources, information and knowledge and other resources, as appropriate, as described in Section 3.

4.70. The role and responsibilities of managers of a regulatory body may not differ greatly from roles and responsibilities of managers in other organizations. Essentially, this involves managing their own organizational units in compliance with the integrated management system and in accordance with the mission, policies, strategies and plans laid out by senior management. The roles and responsibilities of managers include:

- Implementing the mission, strategy and plans;
- Identifying and developing strategies and plans for their organizational units;
- Allocating duties and responsibilities to staff in their organizational units;
- Implementing, managing, monitoring and evaluating processes in accordance with the integrated management system;
- Identifying the necessary resources for their organizational units;
- Developing a motivating work environment for staff by giving them responsibilities for challenging tasks and supporting and coaching them in case they need assistance.

4.71. It is of utmost importance that managers of a regulatory body should demonstrate a commitment to safety, as described in Section 2. All managers in a regulatory body should act as role models concerning safety awareness by demonstrating a questioning attitude and good communication. Such behaviours play an essential role in developing a strong safety culture within the regulatory body.

5. INTEGRATED MANAGEMENT SYSTEM

GENERAL

5.1. The requirements for establishing, implementing, assessing and continuously improving a management system that integrates safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, are established in GSR Part 2 [10] and Requirement 19 of GSR Part 1(Rev. 1) [2].

5.2 Paragraph 4.15 of GSR Part 1(Rev. 1) [2] states that:

> "The management system of the regulatory body has three purposes:
>
> (1) To ensure that the responsibilities assigned to the regulatory body are properly discharged;
>
> (2) To maintain and improve the performance of the regulatory body by means of the planning, control and supervision of its safety related activities;
>
> (3) To foster and support a safety culture in the regulatory body through the development and reinforcement of leadership as well as good attitudes and behaviour in relation to safety on the part of individuals and teams."

5.3. Requirement 3 of GSR Part 2 [10] states that:

> "Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety."

5.4. The integrated management system of the regulatory body is required to clearly specify its organizational structure, resources and processes [10]. A set of coherent processes and procedures should be used to help carry out the regulatory functions in an effective and efficient manner, with account taken of all internal and external requirements, such as the following:

- Requirements for safety;
- Requirements for nuclear security;
- Legal requirements;
- Quality requirements;
- Environmental requirements;
- Health and industrial safety requirements;
- Economic requirements;
- Human performance requirements;
- Requirements relating to societal expectations and the expectations of interested parties.

5.5. The integrated management system is an essential tool for ensuring the following:

- That regulatory functions are carried out in an effective and efficient manner;

- That regulatory responsibilities are adequately discharged;
- The consistency and predictability of regulatory actions;
- Continuous improvement;
- That a strong safety culture is fostered, including the promotion of an open and questioning attitude.

5.6. The integrated management system should include arrangements to ensure that the regulatory body and its staff are not subject to undue influence by any interested party, especially authorized parties.

5.7. The integrated management system should incorporate suitable mechanisms (such as verification and redundancy) to provide appropriate defence in depth for processes with significant impact on regulatory effectiveness and safety. An independent review of important decisions may be appropriate in some cases.

5.8. The effectiveness of the processes should be regularly evaluated against preset criteria. Processes that do not meet these criteria should be corrected (e.g. by means of a 'plan, do, check, act' cycle).

5.9. There are three different phases to an integrated management system: the development phase, the implementation phase and the maintenance phase, as follows:

- The development phase of the integrated management system includes the identification and definition of the processes necessary for the regulatory body to discharge its responsibilities and details and documents the content of each individual process in the context of the overall structure;
- The implementation phase of the integrated management system involves implementing the processes in a planned and systematic way across the regulatory body;
- The maintenance phase of the integrated management system involves ensuring that processes continue to be reliably applied and improved across the regulatory body.

RESPONSIBILITY AND RESOURCES FOR THE INTEGRATED MANAGEMENT SYSTEM

5.10. At each of the three phases of an integrated management system clear responsibilities should be assigned to the individuals and units involved. Leadership and oversight for the system should be assigned to an experienced member of staff. Senior management should allocate appropriate resources to develop, implement, and maintain the integrated management system, including those needed for staff training.

5.11. From the very beginning of the development phase, the regulatory body should designate a member of the staff with professional knowledge of integrated management systems as the 'management system manager', who should report directly to senior management.

5.12. The regulatory body should use a project management approach for the development and implementation of the integrated management system. The regulatory body should consider assigning a project manager to lead a team that includes staff with knowledge of regulatory responsibilities, supported by internal or, if necessary, external expertise in the design of integrated management systems. The project manager should have sufficient authority and should have direct access to the management system manager.

5.13. The roles and responsibilities of individuals involved in each process should be identified in the development phase of the integrated management system, which includes the identification and definition of the processes. For each process a process owner should be assigned.

5.14. The process owner is responsible for the management of the assigned process and should be made accountable for ensuring that the process is clearly identified, documented, reviewed, maintained and improved. Usually, this is a manager with a direct interest in the outcome of the process or who has the most resources involved.

5.15. The process owner should be assigned appropriate authority and resources to discharge his or her responsibilities; however, he or she might not have line management authority over all the staff who implement the process. In such circumstances this may lead to processes not being implemented as intended. Therefore senior management should retain oversight of the development, maintenance and implementation of processes and should take action to ensure that processes are fit for purpose (e.g. they are compatible with current priorities and resources) and effectively implemented.

5.16. As part of the maintenance phase, provision should be made for the periodic review and independent assessment of the integrated management system. An organizational entity should be established within the regulatory body with responsibility for planning and conducting independent assessments to provide assurance to senior management that the integrated management system is reliable and effective. This entity is required to be given sufficient authority to discharge its responsibilities and is required to have direct access to senior management of the regulatory body [10].

5.17. To support this organizational entity, a group of suitable individuals from different parts of the regulatory body should be appointed and trained who will form a pool of auditors from which audit teams can be assembled for specific audits. Different levels of qualification might be necessary for internal audits and for external audits. Individuals conducting independent audits should not assess their own work.

5.18. Experience has shown that it can be valuable to appoint individuals from different parts of an organization not only for audit support but for the support of the work of the regulatory body in general. Such individuals are often more familiar with the work performed in the departments and can facilitate communication concerning specific subjects or issues relating to the integrated management system or its implementation. The reporting lines of such individuals should be clearly defined.

DEVELOPMENT PHASE OF AN INTEGRATED MANAGEMENT SYSTEM

5.19. The integrated management system should be developed in line with the mission of the regulatory body, by individuals familiar with process development and project management. In most cases professional external support should be used in the development phase and implementation phase of an integrated management system.

5.20. Typical processes that fulfil the regulatory functions are the following:

- The development of regulations and guides;
- Notification and authorization and;
- The review and assessment of facilities and activities;
- The inspection of facilities and activities;
- The enforcement of regulatory requirements;
- Communication and consultation with interested parties;
- Emergency preparedness and response.

5.21. Regulatory functions supporting the core functions may be described either as stand-alone processes, or as subprocesses, or as procedures that are part of other processes. For example, the legal support process may also be used to support several core processes, such as for developing regulations and guides, issuing authorizations and conducting enforcement actions. The activities involved in using legal advice may differ depending on the core process for which they are used (see the Annex).

5.22. The structure of the integrated management system and the range of processes should be based on an analysis of the regulatory body's responsibilities. Where regulatory responsibilities are divided between more than one authority, the analysis should include the links and relationships with the activities of the various authorities involved. For the analysis of responsibilities, suitable staff should be trained in process management and analysis techniques.

5.23. The regulatory body may structure its integrated management system and its processes to best suit its needs, as long as the resulting system enables effective discharge of all its responsibilities. These responsibilities include any requirements formally agreed with interested parties, relevant requirements of the IAEA safety standards, as well as national statutory and regulatory requirements. An example of a hierarchical structure of the integrated management system documentation is given in Appendix IV.

5.24. Particular consideration should be given to: interfaces between processes within the regulatory body; and interfaces of the regulatory body's processes with processes conducted by external service providers and other external organizations, including with a parent organization.

5.25. It is convenient to group the regulatory body's processes into the following:

- Management processes: concerned with the governance and management of the regulatory body, strategic planning, the provision of resources, competence management, and evaluation and audit (see Appendix II for descriptions of generic administrative processes);
- Core processes: derived from the core functions, which relate directly to the discharge of the regulatory responsibilities such as notification and authorization, review and assessment of facilities and activities, inspection and enforcement, emergency preparedness and response (for more details on the core functions see DS 473 [4]);
- Support processes: supporting the functioning of the regulatory body, such as human resource management, financial management, purchasing, information technology and document control.

5.26. A graded approach is required to be applied throughout the integrated management system so that appropriate resources, time and attention are devoted to those processes, activities and decisions that have significant impact on regulatory effectiveness and efficiency [10]. This should take into account the nature and complexity of the processes, the impact of the performance (or non-performance) of regulatory activities, and the safety related risks and other risks that may arise (e.g. business risks, cost risks, environmental risks, legal risks, political risks, and risks associated with public perception and credibility of the regulatory body). The nature of the regulatory approach, e.g. prescriptive or performance-based, should also be considered in developing the core processes.

5.27. The experience and knowledge of the future users of the management system should be considered in developing the individual processes and procedures. An integrated management system requires the commitment of the people that fulfil tasks and responsibilities. Therefore, the regulatory body should ensure that all relevant staff are consulted and are involved in the development of the processes. The design should be such that the management system is compact, well-structured and user-friendly in order to ensure its acceptance and systematic application by all staff of the regulatory body.

IMPLEMENTATION PHASE OF AN INTEGRATED MANAGEMENT SYSTEM

5.28. In the implementation phase of the integrated management system, senior management should demonstrate commitment to the system and actively and visibly participate in the implementation. Members of senior management should be role models by being users of the system.

5.29. The implementation phase of the integrated management system involves deployment of the processes in a planned and systematic way across the regulatory body. It is often best to deploy the processes in a step by step manner to enable staff to become familiar with new ways of working in a progressive manner and to ensure that they are not overloaded with change. A series of ‘hold points’ may be necessary to ensure that significant processes are effectively embedded before embarking on further change.

5.30. Typical steps in the deployment of each process include:

- The identification of all staff involved in the process;
- Communication of the principles of an integrated management system, and the process and dissemination of the associated documentation;
- Training, briefings and workshops, where the process introduces new practices. A graded approach should be adopted commensurate with the importance and complexity of the process;
- Coaching and supervision for correct application of the process;
- Follow up inspections and audits to identify and correct any early signs of difficulties with implementation.

5.31. The process owner is the individual who has the best knowledge of the process and should play a central role in its implementation, and during this phase should collect first impressions from individuals on the suitability, usability and acceptability of the process.

MAINTENANCE PHASE OF THE INTEGRATED MANAGEMENT SYSTEM

5.32. After the integrated management system has been established and implemented, it should be used for the daily work of all individuals within the regulatory body. In this phase special care should be given to the maintenance of the integrated management system. Managers should ensure that processes, both individually and collectively, are applied reliably across the regulatory body and are improved to continually fulfil the purposes and objectives of the integrated management system.

5.33. Opportunities for improvements in the integrated management system, as well as improvements to the efficiency and effectiveness of the regulatory body's work, should be identified. Actions to improve processes and the effectiveness and efficiency of the regulatory body should then be selected, planned, implemented, adequately resourced and recorded. The maintenance phase includes audit, evaluation, and review and update of processes, including system documentation and procedures. In the maintenance phase, the process owner again plays a central role.

MEASUREMENT, ASSESSMENT, EVALUATION AND CONTINUOUS IMPROVEMENT

5.34. To achieve sustained success, managers at all levels should monitor, measure and review performance with the aim of:

- Motivating high standards of personal performance;
- Sustaining a strong safety culture;
- Learning from experience and improving performance and the integrated management system;

- Holding those with responsibilities to account for their performance;
- Demonstrating to interested parties the efficiency and effectiveness of the regulatory body and the achievement of the regulatory mandate.

Monitoring developments in the external environment

5.35. Developments in the external environment in which the regulatory body operates that may impact regulatory activities should be monitored, in order to ensure that strategies, policies, plans and activities remain relevant and effective. Such developments include the following:

- Changes in the national nuclear power programme, or in other facilities and activities;
- Changes relating to nuclear commercial developments;
- New legislation and industrial standards;
- Technological advances and lessons from research;
- Lessons from worldwide operating experience;
- Economic, societal and ecological trends;
- The experience and perceptions of interested parties, including authorized parties, and their views on regulatory performance.

5.36. Suitable methods of keeping up to date with regard to such developments should be adopted by the regulatory body. In the case of interested parties, periodic surveys seeking their views are a valuable source of information. Information on all these developments can usefully inform the improvement of policies, strategies, plans and methods of inspection and assessment.

5.37. In order to identify opportunities for improvement at the level of the integrated management system, the regulatory body should regularly exchange experiences with other similar organizations, both in the State and in other States, with emphasis on identifying good practices. International peer reviews should also be undertaken regularly.

Management oversight and supervision

5.38. Managers at all levels should regularly monitor and measure progress in the delivery of plans, strategies and budgets and should hold to account those responsible for implementation. Such measurement should be against clear goals, objectives and criteria and timescales so that it can be carried out in a fair and open manner. The aim is to reward success by confirming that work meets the necessary requirements and standards and to address weaknesses and overcome obstacles.

5.39. A set of performance indicators is a useful tool for senior management to oversee the performance of the entire regulatory body. The regulatory body should also develop indicators that provide an early warning of declining safety performance in authorized parties and which may thereby give insight into the suitability and effectiveness of the regulatory body's integrated management system.

Measurement and evaluation of the processes of the integrated management system

5.40. Paragraph 6.2 of GSR Part 2 [10] states that:

> "All processes shall be regularly evaluated for their effectiveness and for their ability to ensure safety."

5.41. Regular self-assessments, led by managers, can be used to:

- Identify and correct weaknesses that hinder the achievement of the regulatory body's objectives;
- Enhance the safety culture and the effectiveness of processes and activities;
- Assess present performance against good practices to identify opportunities for improvement;
- Identify good practices and strengths in order to improve the integrated management system.

5.42. Methods of self-assessment can include the following:

- Group discussions and brainstorming sessions;
- Coaching and observations;
- Collection and analysis (e.g. for identification of trends) of performance data;
- Benchmarking processes and activities across different parts of the regulatory body or with other organizations such as other regulatory bodies;
- Comparison with international standards, such as the IAEA safety standards.

5.43. The regulatory body should also provide convenient means for staff to suggest improvements. Suggestions should be evaluated as soon as practicable by senior management. Feedback should be given to those who provided the suggestion and should subsequently be disseminated to all staff.

5.44. Process owners should conduct periodic structured evaluations of the processes of the integrated management system in accordance with a graded approach to confirm that they are meeting expectations. Inputs to the evaluation should include, but are not limited to, the following:

- Reviews of non-conformances, to establish trends and any common problems;
- Reviews of suggestions for improvements and of difficulties with implementation, to identify problems with processes and/or inconsistent implementation across parts of the organization;
- Sampling process documents, records and products to confirm proper implementation and that process criteria are being met;
- Structured interviews with staff about the implementation of processes and procedures.

5.45. Periodic surveys of staff attitudes may be a valuable source of feedback on the state of the organizational culture of the regulatory body.

5.46. Data from the monitoring of performance should be analysed against suitable indicators. Such indicators may be output based or outcome based, and may be defined at different levels of detail across the regulatory body. Trends should be analysed and evaluated at regular intervals and should be evaluated as a part of the review of the integrated management system.

Review of the integrated management system

5.47. Paragraph 6.6 of GSR Part 2 [10] states that:

> "Senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the organization to be accomplished, with account taken of new requirements and changes in the organization."

5.48. The integrated management system review should cover all significant sources of information on performance, including the following:

- Outputs from different forms of assessment, including self-assessments of senior management itself;
- Results delivered and objectives achieved by the regulatory body and its processes and activities;
- Non-conformances and the progress and effectiveness of corrective and preventive actions;
- Feedback from operating experience, including lessons learned and good practices from other organizations;
- Opportunities for improvement.

5.49. Reviews should identify weaknesses and obstacles that could affect the effectiveness of the integrated management system and should be used to identify whether there is a need to make changes and improvements to policies, goals, strategies, plans and objectives, as well as to the processes or activities. The schedule of reviews should facilitate the timely provision of information for the strategic planning of the regulatory body. Any weaknesses should be evaluated by senior management and should be remedied in a timely manner.

Independent assessment

5.50. Plans for the conduct of audits and assessments should be prepared in accordance with a graded approach commensurate with the safety significance of the process and activity. Such plans should be reviewed and adjusted to reflect new or emerging management concerns and performance problems, as well as opportunities for improvement.

5.51. Independent assessments should be conducted regularly on behalf of senior management in order to evaluate the efficiency and effectiveness of the regulatory body. Such independent assessments could assess the following:

- The fulfillment of the regulatory mandate and the vision, mission, policies, strategies, plans and objectives of the regulatory body;
- Governance, leadership, management and organizational culture of the regulatory body;
- The adequacy of resources provided to meet requirements, policies, strategies, plans and objectives;
- The effectiveness of regulatory activity in ensuring the safe operation of facilities and conduct of activities by authorized parties.

5.52. Independent assessments may include internal audits, external audits, peer reviews and special activities such as evaluation of emergency exercises. Internal audits are the basic instrument available for the regulatory body to assess the functioning of its integrated management system processes and to investigate performance problems.

5.53. The support of external organizations may be sought to review and evaluate the leadership and integrated management system of the regulatory body, through services such as the IAEA Integrated Regulatory Review Service (IRRS), peer review by other regulatory bodies or by independent consultants, and international quality standards. Other governmental or legislative bodies could also call for evaluation of the regulatory body.

5.54. Paragraph 6.11 of GSR Part 2 [10] states that:

> "The results of self-assessments and independent assessments…shall be communicated at all levels in the organization. The results of such assessments shall be acted upon to foster and sustain a strong safety culture, to improve leadership for safety and to foster a learning attitude within the organization."

Non-conformances and corrective and preventive actions

5.55. Non-conformances should be regarded as opportunities for improvement and as such should be used as an input to the integrated management system improvement process. Senior management should foster an organizational culture that encourages individuals to identify and report non-conforming processes and outcomes of the regulatory work.

5.56. Non-conformances should be reported in sufficient detail to allow their proper review. The causes of non-conformances (and other emerging issues negatively affecting the regulatory work or safety issues) should be determined and their potential consequences should be evaluated. Trends in non-conformances and associated causes should be analysed to identify repeat occurrences, common issues and weaknesses.

5.57. Paragraph 6.3 of GSR Part 2 [10] states that:

> "The corrective actions necessary for eliminating the causes of non-conformances, and for preventing the occurrence of, or mitigating the consequences of, similar safety related events, shall be determined, and corrective actions shall be taken in a timely manner. The status and

effectiveness of all corrective actions and preventive actions taken shall be monitored and shall be reported to the management at an appropriate level in the organization."

5.58. Senior management should allocate responsibilities for monitoring and following up non-conformances until it has been verified that the agreed corrective actions have been completed, including the provision of feedback to the individuals who identified the non-conformances. Managers should be held accountable for meeting deadlines for corrective actions.

5.59. The regulatory body should take preventive actions to identify and eliminate potential non-conformances that could negatively affect the regulatory work. Preventive actions could include the following:

- Changing processes or the organizational structure;
- Retraining and re-qualifying individuals;
- Improving the organizational culture of the regulatory body;
- Changing or modifying documents;
- Improving the integrated management system;
- Enforcing requirements for documentation;
- Issuing of new documents.

Learning and continuous improvement

5.60. In accordance with the concept of a learning organization, a strategic objective of the regulatory body should be the continuous improvement of its performance. The regulatory body should systematically seek and analyse information on its performance, including the effectiveness and efficiency of the integrated management system and its processes. The regulatory body should also evaluate and continuously improve its organizational and safety culture. Improvements can be achieved:

- At the working level within a process, by those directly involved in daily activities;
- At the level of management processes under the supervision of the process owners;
- At the organizational level through organizational improvement projects under the supervision of senior management.

5.61. All proposed changes to the regulatory body, the integrated management system or the processes should be planned, coordinated and adequately resourced to avoid change 'overload'. Even small changes should be analysed with regard to actual or potential impacts on safety and on the effectiveness of the regulatory body.

5.62. Improvement plans should be decided on by senior management and adequate resources should be provided to implement these plans. Suitable project management techniques should be applied when significant changes are envisaged. Individuals involved in implementing an improvement should be provided with the necessary authority and resources. Improvement actions should be

monitored through to their completion and their effectiveness should be checked to ensure that the anticipated benefit has actually been achieved.

DOCUMENTATION OF THE INTEGRATED MANAGEMENT SYSTEM

5.63. Requirement 8 of GSR Part 2 [10] states that:

> "The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use."

5.64. The documentation of the integrated management system should be appropriate to the organization of the regulatory body. The documentation should be clear, understandable and flexible enough to accommodate changes in policy, in strategic aims and in external and internal requirements. It should also accommodate the feedback of experience from the implementation of the integrated management system and from internal and external lessons learned.

5.65. The integrated management system of a regulatory body should be described in a set of documents that need to be applied in order for the regulatory body to achieve its goals. This set of documents typically includes the following:

- An overview of the integrated management system and a description of how it complies with the requirements imposed on the regulatory body;
- The mission and values of the regulatory body;
- The expectations of senior management;
- Policy and strategy statements and plans of the regulatory body;
- A description of the structure of the regulatory body, including a description of the responsibilities, accountabilities, levels of authority and interactions of those leading and managing the organization and managing, performing and assessing work;
- A description of the regulatory body's decision making process;
- A description of the processes and procedures, as well as supporting information that explains when, how and by whom work is to be prepared, reviewed, carried out, recorded, assessed and improved;
- A structured overview (a 'process map') of all processes that illustrates the integrated management system as a whole and the interrelation and interactions of the processes;
- A description of the interfaces with interested parties and external organizations.

The structure of the documentation of the integrated management system will vary in accordance with the needs of the regulatory body. Appendix IV includes an example of a documentation structure.

5.66. For each process, the following should be identified and documented:

- The purpose, scope and objectives of the process;
- The process owner;
- The organizational units and individuals who use the process;
- The sequence of steps, activities and decision points within the process;
- The interfaces with other processes, to explain how the process fits into the integrated management system and its significance for the regulatory activity;
- The inputs to the process, including the necessary information, in accordance with an evidence based approach to regulation;
- The outputs from the process and records that should be retained;
- Performance criteria for measuring the consistency, effectiveness and efficiency of the process;
- The resources necessary and the responsibilities for maintaining the process (the process owner), and the competence requirements of those performing and managing the process;
- Mechanisms for obtaining feedback on the effectiveness of the integrated management system.

Descriptions of processes relevant to regulatory bodies are given in the Annex.

5.67. As a part of its integrated management system, the regulatory body should establish a document management system that supports its information management processes, knowledge management processes and competence management processes. The document management system should enable the storage and retrieval of all documents and records that are used and produced by the regulatory body as inputs to and outputs of the regulatory processes, including documents and records provided by authorized parties and other interested parties.

5.68. The documents and records within the document management system should be accessible to all staff authorized for their use, in accordance with national requirements concerning document classification (security and confidentiality). As part of a policy of openness and transparency, regulatory documents should, in accordance with the requirements on security and confidentiality, be made available to interested parties.

5.69. Paragraph 4.20 of GSR Part 2 [10] states that:

> "Retention times of records […] shall be established to be consistent with the statutory requirements and with the obligations for knowledge management of the regulatory body. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record."

6. STAFFING AND COMPETENCE OF STAFF

GENERAL

6.1. Requirement 18 of GSR Part 1(Rev. 1) [2] states that:

> "The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."
>
> This contributes to effective independence in regulatory decision making.

6.2. The regulatory body should have staff with expertise in a wide range of technical matters and in human and organizational factors. The stage in the lifetime and the extent of the authorized facilities and activities should be considered in deciding how these disciplines are to be represented in the regulatory body.

6.3. In order to achieve the necessary capability within the technical staff of the regulatory body, most should have an appropriate academic degree. This should be supplemented with specialized training and/or professional work experience in their specific area of work, especially relating to the facilities and activities to be regulated.

6.4. In addition to depending on the employment of sufficient staff with suitable qualifications and expertise, the effectiveness of the regulatory body will also depend on the status of its staff in comparison with those of the authorized parties and other involved organizations. Staff of the regulatory body should be appointed at such grades and with such salaries and conditions of service as would facilitate their interactions with authorized parties and reinforce the independence and authority of the regulatory body staff in conducting their work.

6.5. In order to maintain the necessary independence, the staff of the regulatory body should be as objective as possible in discharging their responsibilities. They should be open to receiving information and opinions from others, and regulatory positions and decisions should demonstrate transparency and clarity. Staff of the regulatory body should not engage in, or hold any kind of interest in, activities that may represent a conflict of interest with the performance of regulatory functions. The staff of the regulatory body should be open but also formal and professional in their interactions with authorized parties and should, at all times, maintain their integrity and independence.

6.6. The regulatory body should provide opportunities for training and career development, in order to facilitate recruitment and avoid a high turnover of staff.

STAFFING

6.7. Paragraph 4.11 of GSR Part 1 (Rev. 1) [2] states that:

"A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."

6.8. Paragraph 4.12 of GSR Part 1 (Rev. 1) [2] states that:

"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."

6.9. The staffing needs should be based on the regulatory body's core functions as listed in Section 4. Staffing requirements for other functions of the regulatory body such as emergency response and investigation of incidents are not normally day to day activities, and related responsibilities should therefore be assigned as part of the routine organizational structure.

6.10. Senior management of the regulatory body should regularly review the required functions and should determine the size and composition of the regulatory body necessary to fulfil its obligations. The appropriate size for a regulatory body will depend on a range of factors: the various types and numbers of facilities and activities; the regulatory approach adopted; and the legal arrangements in place. Staff assignments should be regularly reviewed to ensure that regulatory independence and objectivity are maintained in dealings with authorized parties.

6.11. In large regulatory bodies, staff may be assigned to a specific functional area. Alternatively, staff may specialize in particular types of facility or activity and consequently their work assignments would cover more than one functional area in the organizational structure.

6.12. The number of staff of the regulatory body and their specialized skills will also depend on decisions about the coverage of functional areas and on the extent to which the regulatory body will use external experts and/or advisory committees. Irrespective of the arrangements in place, the regulatory body should have sufficient numbers of staff with the basic knowledge, skills and attributes necessary to operate the regulatory system without depending on the immediate availability of external expert support. It should also be prepared to fulfil its pre-established role in emergency response at all times, if necessary by diverting staff from routine activities.

COMPETENCE MANAGEMENT

6.13. Paragraph 4.13 of GSR Part 1 (Rev. 1) [2] states that:

"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing

applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."

6.14. The regulatory body should establish as part of its integrated management system (see Section 5) a management process that aims to develop and maintain adequate competences to fulfil its regulatory functions, and to be an 'intelligent customer'[7] in receiving advice and making decisions based on that advice. Further information on competence management for the regulatory body can be found in Ref. [16].

6.15. The regulatory body should, through its competence management, ensure that its organization is sufficiently robust and flexible to deal with staff departures, retirements or other events, including unexpected staff changes. Succession planning should be included as part of competence management.

6.16. The competence management process may include the following sub-processes [16]:

- Analysis of competence needs:
    - Task analysis leading to determination of the necessary competences;
    - Analysis of existing competences within the regulatory body;
    - Gap analysis (personal performance review and assessment);
- Prioritization of competence needs and filling competence gaps:
    - Recruitment and human resources planning;
    - Staff training and development;
    - Management of external expert support.
- Knowledge capture and management.
- Reviews and audits of competence management and feedback.

Responsibilities for competence management

6.17. In order to develop and enhance the efficiency and effectiveness of the regulatory body, senior management should be committed to ensuring that the regulatory body has and maintains competences appropriate to its needs. Learning is a lifelong process, and management should be committed to the ongoing development of a professional, competent, versatile and motivated workforce.

6.18. The regulatory body should define the organization, levels of authority, responsibilities and accountabilities for competence management processes; an individual or a team should be appointed to be responsible for these processes.

6.19. Effective competence management necessitates the commitment and involvement of all managers and staff. Each manager should be made accountable for the competence building of their

[7] An 'intelligent customer' capability is the capability of the organization to have a clear understanding and knowledge of the product or service being supplied. The 'intelligent customer' concept relates mainly to a capability required of organizations when using contractors or external expert support.

staff. Senior management should seek to foster an organizational culture that supports individual staff members to recognize that they are also accountable for the development of their own competence and contribute to the development of the competence of the regulatory body as a whole.

Planning of competence and staffing needs

6.20. The regulatory body should have in place processes for governance and for strategic planning. A review of the functions that need to be performed, and an assessment of the size and composition of the regulatory body needed to fulfil these obligations, should be part of the strategic planning processes. These processes are applicable to both short term and long term needs for competence and staffing.

6.21. A strategic plan for developing and maintaining competence should be an output of the planning process. It should cover training and development, staffing plans, the use of external expert support and other methods of meeting competence needs, particularly to overcome competence gaps.

6.22. The regulatory body should establish a strategy to build the competence of its staff. A new regulatory body may initially need considerable reliance on external support for building competence. As the regulatory body matures, it should build its knowledge base so that it can become more self-sufficient.

6.23. As a regulatory body matures and its workforce ages, particular attention should be paid to succession planning for key managers and senior technical staff. Succession planning requires effective knowledge management as part of the competence management. Provision should be made for the capture of explicit and tacit knowledge that the regulatory body generates through its various regulatory activities, and the ready dissemination of such knowledge to its staff.

6.24. The introduction of new types of facilities or new activities, the introduction of novel technologies, the ageing of facilities or the passage of a facility to another stage of its lifetime should be considered in the planning of competences and in the adaptation of training programmes.

Competence analysis

6.25. The necessary level of competence for certain individuals with responsibilities in relation to the safety of facilities and activities may be predefined in legislation.

6.26. The competences required by the regulatory body in order to fulfil its functions should be identified by means of a systematic analysis of competence needs based on the regulatory body's function and processes (see DS473 [4]). This should take place at periodic intervals, and when necessitated by substantial changes.

6.27. The results of the competence analysis should be used to determine the regulatory body's workload and hence its resource requirements. This information may be used to develop or modify the organizational structure of the regulatory body, and also be used as a feedback for improving the competence management of the regulatory body.

6.28. The competence analysis should identify the different tasks to be performed in order to fulfil the regulatory functions. The analysis should take place at several levels: at the level of the entire regulatory body; at the level of individual organizational units; and at the individual staff level.

6.29. This analysis should consider technical competences and skills, and also 'soft skills' (see Appendix III). Staff should be able to interact with people, both within the regulatory body and in oversight interactions with authorized parties, in an effective and constructive way, to address findings adequately, to give constructive feedback and to solve conflicts.

6.30. The competence analysis then leads to a competence profile for certain tasks within the regulatory body, which in turn can be used to create the job descriptions for individual staff members and the associated selection criteria.

6.31. Competence profiles provide a strong management tool to address competence gaps. A further valuable instrument for competence management at the regulatory body is a competence model. Reference [16] gives an example of a competence model for a regulatory body. Use of a competence model enables a balanced approach to competence management and to consistency of regulatory performance. It provides a basis for assessing competence needs both for the short term and medium term, and represents a significant input into the process of developing a regulatory body that can respond effectively to internal and external changes in the environment and the associated challenges.

Competence requirements

6.32. In the following paragraphs, the competences necessary for performing regulatory functions are described. In general, these refer to the staff of the regulatory body engaged in the core regulatory functions as described in GSR Part 1 (Rev. 1) [2]). More details may be found in Ref. [16].

Human and organizational factors

6.33. Knowledge in human and organizational factors should be part of the regulatory body's competence profile. Such competences are necessary for effective oversight of issues such as safety culture, leadership, organizational and management aspects, competence development as well as relevant interfaces. They enable the regulatory body to oversee in a systemic manner, the actions and interactions of authorized parties, and specialists in such competences should be employed by the regulatory body.

6.34. As well as specialists in human and organizational factors, other staff should also have competence in human and organizational factors. This includes, for example, managers responsible for the deployment of the strategy relating to human and organizational factors, and for providing the necessary resources for its implementation; specialists who integrate the human-and-organizational-factor approach into the processes of organizations; trainers; specialists in operating experience feedback; and inspectors, in order to enable them to understand and evaluate working conditions and factors contributing to human performance. Specialists in human and organizational factors and other

staff members should cooperate in the analysis of human and organizational factors and of their relationship with the technical aspects of the work.

6.35. The regulatory body needs to understand the key characteristics and attributes of safety culture in order to ensure that the behaviour of its staff promotes and supports a positive safety culture both within the regulatory body and in authorized parties. All staff of the regulatory body should have a common understanding of the concepts of safety culture in order to develop their own safety awareness and a questioning attitude necessary for safety oriented behaviour and decision making.

Core regulatory functions

Regulations and guides

6.36. Individuals assigned to develop or revise regulations and guides should have sufficient understanding of the relevant areas. Such individuals should also have sufficient knowledge of other existing regulations and guides, to ensure consistency and compatibility between them. The workload can be accommodated by assigning specialists from other functional areas or by making use of specially selected committees or groups of consultants.

6.37. An organizational unit, whether permanent or temporary, that is tasked with producing regulations and guides should have access to staff with:

- Experience of the activities being regulated;
- Experience of regulatory enforcement;
- Knowledge of the regulatory framework;
- Knowledge of the procedures for producing regulations and guides;
- Legal expertise and knowledge of the legal basis for regulations.

6.38. Staff responsible for the development and revision of regulations and guides should be capable of coordinating the work of specialists from various disciplines. As part of their activities, they should review developments in national and international regulations and guides on a broader level to gain awareness of such developments and should take account of them accordingly in new regulations and guides.

Authorization

6.39. Staff of the regulatory body should be capable of issuing an authorization that complies with all legislative requirements. They should possess a good working knowledge of the various regulations and guides applicable in their area of work, and should have a strong understanding of the design and operation of the facility or activity they are authorizing. They should be able to understand the results of review and assessment and should be capable of leading public consultations, if applicable. Authorization is normally performed by senior and experienced staff.

Review and assessment

6.40. Staff of the regulatory body should be capable of performing reviews and making independent judgements. They should possess a good working knowledge of the various regulations and guides applicable in their area of work, and should have a strong understanding of the design and operation of the authorized facility or activity they are assessing and knowledge and experience in the use of safety assessment techniques and tools.

Inspection

6.41. Regulatory inspection differs somewhat from other regulatory functions in that the principal activity takes place at the authorized facility or where the authorized activity occurs. Regulatory inspection involves interviewing individuals, observing and evaluating activities, reviewing records and, where appropriate, making decisions and providing recommendations. All inspectors should be able to evaluate and discuss safety related issues with staff of the authorized party and its contractors. Inspectors should be able to interview individuals effectively to obtain the relevant information, and should be able to review and evaluate logbooks, records and other documents to identify non-compliance with regulatory requirements or with any conditions specified in the authorization.

6.42. Staff who are assigned to inspect major facilities and activities (e.g. the manufacture of components and the commissioning and initial operation of facilities) should have sufficient relevant work experience, preferably in facilities and activities of a type similar to those they will be assigned to inspect. As part of their functions, inspectors are routinely involved in compliance assurance activities.

6.43. Inspectors should also have a thorough knowledge and a good understanding of the regulations and guides that are relevant to the authorized facility or activity and have experience in their application. Inspectors should be aware of the safety case for the facility or activity, in particular of the important safety systems and procedures and the limits and conditions for safe operation, in order to gain the respect of the staff of the authorized party.

6.44. Inspectors should be experienced and capable of working without direct supervision, and should have the necessary skills so as to be able to represent the regulatory body adequately without being drawn into the authorized party's decision making process.

Enforcement

6.45. Staff of the regulatory body should be capable of performing reviews and making independent judgements, and on the basis of this deciding upon and initiating enforcement actions due to non-compliances in a facility or activity. They should possess a good knowledge of the regulatory body's enforcement policy, requirements, processes and procedures and related guides. They should also know whether and what support is needed, as well as whether corrective measures proposed by the authorized party are adequate.

Emergency preparedness and response

6.46. Staff of the regulatory body working in the area of emergency preparedness and response should have the competence to review, assess and make judgements in line with the appropriate regulations and independent of the authorized party on the adequacy of on-site emergency arrangements and to evaluate certain emergency exercises. Regulatory body staff should also be able, directly in cooperation with relevant off-site authorities or indirectly through the established national coordinating mechanism, to assess the coordination and integration of on-site emergency arrangements with off-site emergency arrangements. Staff having duties in emergency preparedness and response should have the necessary qualifications, skills and training to establish and maintain the necessary arrangements (such as plans, procedures, exercises and training programmes, tools, communication means and equipment) to fulfil the functions assigned to the regulatory body in emergency response.

Communication and consultation with interested parties

6.47. Staff working in this area should be able to engage in effective dialogue, representation and interaction with all interested parties (e.g. authorized parties, colleagues, media and the public) through committed listening, speaking, writing and delivery of presentations, understanding potential sources of bias and delivering meaningful messages. They should be able to talk effectively in small groups and to large audiences, to respond appropriately to questions, and to provide factual answers consistent with the regulatory body's views as well as to communicate complex issues clearly.

Supporting functions

Legal support

6.48. The regulatory body should have competence available to provide legal support for its regulatory functions. This includes knowledge of the laws and decrees relating to the facilities and activities to be regulated, other relevant laws and decrees, and an ability to apply legal provisions and knowledge regarding the powers and authority of the regulatory body and its staff. In addition, the staff providing legal support should be familiar with conventions and treaties to which the State is a party as well as the nature and content of relevant IAEA safety standards.

Research and development

6.49. The regulatory body should have adequate internal competence to define relevant research issues, to specify the research activities necessary and to identify appropriate institutions that could conduct research and development.

6.50. The regulatory body should be able to keep track of the research and development activities and to evaluate the quality and suitability of the results.

Administrative support

6.51. The regulatory body should have adequate competence to provide administrative support for its regulatory functions. This can be done by dedicated individuals or organizational units. The number

of individuals or the size of the unit will depend on the size of the regulatory body (see also Section 3).

External expert support

6.52. The regulatory body should have competence to decide which of its activities need support from external organizations (e.g. consultants, research institutes and dedicated support organizations) and to establish criteria for the service(s) needed, as well as to evaluate the outcome (it should be an 'intelligent customer', see Appendix I).

6.53. The staff of the regulatory body should be able to coordinate and manage the activities of the regulatory programme that are performed with the assistance of consultants or dedicated support organizations. Some staff should have experience in technical programme management or project management. Furthermore, some staff of the regulatory body should have appropriate management experience and technical experience to be able to assess and judge the effective coordination and management of large engineering companies and quality assurance programmes.

Collaboration with national and international organizations

6.54. The regulatory body should establish and maintain collaboration and good working relationships with other governmental, professional and private organizations at the national and international levels. For this reason, staff of the regulatory body should have up to date knowledge of the responsibilities and structures of these organizations and should maintain contacts with their staff.

Documentation for competence management

6.55. Documents and records should be kept and managed in accordance with security and confidentiality requirements and with the provisions of the management system. Documentation for competence management may include the following:

- Documented competence requirements for each task and profile;
- Job descriptions;
- Individual competence development plans and performance reviews;
- Records of competences possessed by individuals;
- Staff certification;
- Records of training provided and training activities;
- Outsourcing and external expert support;
- Recruitment procedures and records;
- Records of reallocation of individuals within the organization.

Measurement, assessment and improvement

6.56. The processes for competence management are part of the integrated management system and should therefore be evaluated as described in Section 5. Inputs for the evaluation can be found in Ref.

[16]. The evaluation of these processes provides feedback that can be used to identify improvements in the following aspects of the training and development programme:

- Effectiveness of training and development;
- Delivered training;
- Individual performance;
- Recruitment, reorganization and outsourcing;
- Reviews and audits.

6.57. Assessment relating to competence management should take place at several levels: the individual staff level; the level of individual organizational units; and at the level of the entire regulatory body.

6.58. At the level of organizational units and the regulatory body as a whole, performance assessment may make use of metrics such as the effectiveness and achievements of training and it should be based on sound judgement. Self-assessment and independent peer reviews are well established techniques that may contribute to these assessments.

6.59. Senior management should assess arrangements for competence management in the regulatory body and how competence management contributes to the achievement of its goals, in order to seek opportunities for improvement. Any changing circumstances and challenges should be examined, including reorganization, assignment of new regulatory functions, recruitment of new staff, changes in the activities of authorized facilities, new stages in the lifetime of authorized facilities, and technological developments.

METHODS FOR ACQUIRING COMPETENCE

Recruitment

6.60. The recruitment strategy within a regulatory body will depend on a number of factors. These factors are likely to change with time and the regulatory body will need to review the strategy periodically to establish whether it is still appropriate. Education and training, work experience, demonstrated competence, and expert or specialist knowledge are important considerations in selecting individuals to staff the regulatory body.

6.61. Staff of the regulatory body should demonstrate a high safety awareness and a questioning attitude in fulfilling their duties. These attitudes should already be considered in the recruitment process and later during initial and continuing training as part of the safety culture programme.

6.62. The general experience of States with established regulatory bodies is that they can recruit individuals with the required academic qualifications and years of relevant work experience. However, unless recruitment is from another regulatory body, it is unlikely that they can recruit

individuals with the specific knowledge, skills and attitudes necessary for conducting regulatory functions.

6.63. If new graduates, or individuals from disciplines unrelated to facilities and activities, are recruited, more extensive training programmes should be implemented to establish appropriate competence in scientific and technological knowledge.

6.64. It is inevitable that all new staff will need some training even if they have the technical competences needed by the regulatory body. This is because it is necessary to instil in new recruits the organizational culture of the regulatory body and provide them with the competences specific to the work of the regulatory body. Part of the overall strategy may also be to move staff to different posts within the regulatory body where they may also acquire additional competences through appropriate training.

6.65. The regulatory body should have a programme for capturing, retaining and transferring knowledge of staff leaving the regulatory body.

6.66. To maintain the effective independence of the regulatory body, special consideration should be given when individuals are recruited from authorized parties. The regulatory body should ensure that staff operate professionally and within their remit in relation to safety. When recruiting staff from authorized parties, consideration should be given to ensuring that they are not placed in roles that might compromise the effective independence of the regulatory body or create conflicts of interest. The regulatory body should have a process for identifying and addressing conflicts of interest.

6.67. In order to remain competitive with other potential employers, to both attract and retain staff, the regulatory body should address factors such as the following:

- Salaries and conditions of service, including pensions;
- Status and authority;
- Personal and professional development opportunities (beyond training);
- Post retirement opportunities;
- Physical working conditions, including office location.

Filling competence gaps

6.68. On the basis of a gap analysis and the identification of short term and long term priorities, the regulatory body should implement a programme for addressing any competence gaps. Managers may decide to acquire competence by training and development for existing staff, by reallocating existing competence within the regulatory body to fill gaps, by recruiting, by participating in knowledge networks, by tutoring or by outsourcing.

Training

6.69. The most common method used to acquire competences is training. The regulatory body should have the following in place:

- A training policy;
- Budgetary provisions for training;
- Processes (as part of the integrated management system) to establish training and development programmes that take into consideration the gaps that exist between the existing and required competences.

6.70. The training requirements for regulatory staff should be based on the functional areas of the regulatory body. One of the objectives of training is to develop the knowledge, skills and attitudes of the staff of the regulatory body in order to widen their appreciation of the work being undertaken by themselves as well as others. Basic elements of a training programme for a regulatory body are listed in Appendix III.

6.71. Each member of staff should be provided with an individual training and development plan relating the requirements of their job with the individual's knowledge, skills and attitudes. The plans should be based on the individual competence analysis (see paras 6.25 to 6.32), and should be reviewed and updated regularly to identify the training required to maintain or acquire new knowledge and skills. This is particularly important if there is a job change, or to address significant changes in the law, processes or other matters.

6.72. The individual training and development plans should ensure that new staff receive an adequate overview of the regulatory environment and of the work they will be performing. This should include an introduction to the law, legal powers, policies, procedures, organizational culture and internal guidance of the regulatory body. New staff should be assigned only limited tasks and should work under supervision until they have completed an initial period of their training and an evaluation of their performance has been made.

6.73. In training, special emphasis should be given to behavioural aspects in order to ensure the effective independence of the regulatory body. The competence of staff is a necessary element in achieving effective independence in decision making by the regulatory body. Regulatory body staff should act in accordance with the values of the regulatory body at all times and should remain focused on safety irrespective of their personal views.

6.74. Training should contribute to an individual and collective commitment to safety. The staff of the regulatory body should have a common understanding of the key aspects of safety and safety culture within the regulatory body. Training should foster responsibility, accountability and ownership for safety, should make staff aware of the risks and hazards relating to their work, and should provide them with an understanding of potential consequences of their work. Training should encourage a questioning and learning attitude, should foster the free reporting of concerns and should discourage complacency at all levels in the regulatory body with regard to safety.

6.75. Refresher training should be given, as required, to maintain knowledge and to draw attention to important changes in the law, procedures, technology or other matters. Developmental training, both technical and non-technical, should also be provided to prepare staff for job changes and promotions.

6.76. The training programme of the regulatory body should consist of a combination of self-study, formal university level instruction and occupational or technical training courses, workshops and seminars (provided by the regulatory body itself, by academic or professional organizations, by regulatory bodies of other States or by the IAEA), participation in scientific and technical events and on the job training in the State or abroad. Staff may be seconded to another regulatory body to help in their development and to gain experience. The development of the necessary competence for the regulatory control of facilities and activities should also be facilitated by the establishment of, or participation in, centres where research and development work and practical applications are carried out in key areas for safety.

6.77. In cases where the training programmes available in the State are insufficient, arrangements for training should be made with other States or with international organizations. International exchange of information should be a part of continuing professional development, in order to obtain new ideas for further development.

6.78. The organization of training will depend on the size and resources of the regulatory body. External support for training may be needed in particular by newly established regulatory bodies.

6.79. The administration of training should be formalized and responsibilities should be assigned within the regulatory body. For an effective and systematic approach to training, the regulatory body should consider the establishment of a training unit, either as part of the regulatory body or with the assistance of specialized institutes. The regulatory body should arrange for its staff to have access to laboratories and other facilities that have the necessary equipment to teach specific techniques.

6.80. Efforts commensurate with the size of the regulatory body should be made to develop a systematic approach to the training of staff in order to ensure consistency in the conduct of regulatory activities, including the application of quality assurance principles to training. This should provide a logical progression: from the identification of the competences necessary to perform a job; through the design, development and implementation of training to achieve these competences; to the subsequent evaluation of the training. Reference [16] provides an overview of competence management for regulatory bodies including training methods and types (classroom based training, distance learning, on the job training) and, in addition, a detailed description of developing a systematic approach to training.

6.81. Training involves substantial human and financial resources. The regulatory body should therefore carefully specify and justify its training programme, include the training costs in its budget, and should ensure that the programme is adequately put into effect. There is often pressure to reduce or delay training because of other, short term needs. Although such circumstances cannot be avoided

entirely, the regulatory body's management should ensure that they do not unduly disrupt the training programme.

6.82. Training alone cannot ensure the necessary competence. Necessary work experience, mentoring, continuing professional development and refresher training should be included in competence development plans for individuals. Staff of the regulatory body should be encouraged to make a habit of continuing professional development throughout their careers, as part of a philosophy of 'lifelong learning'. As part of its training and development plans, the regulatory body should encourage such development by providing opportunities for staff to take appropriate courses, to visit facilities and organizations, and to participate in conferences. Managers can take such development activities into account when making decisions on job assignments and promotions. In some States, professional engineering and scientific institutions require members to undertake continuous professional development to maintain their members' accreditation.

Participation in knowledge networks

6.83. An important method for acquiring knowledge and developing competence is the participation in knowledge networks. The IAEA and other international organizations, and professional bodies and associations, facilitate networking, exchange of information and mutual learning based on good practices and experience from different States.

6.84. The regulatory body can benefit from participation in knowledge networks at the national, regional or international level. National knowledge networks may involve technical support organizations, professional bodies and educational institutions. Regional networks have also proved to be very effective in sharing information and training.

Use of external expert support

6.85. If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities, it should seek advice or assistance, as appropriate, from external experts as described in Appendix I. In this case, the regulatory body should have the necessary competence to evaluate the work of the external expert (it should be an intelligent customer).

APPENDIX I EXTERNAL EXPERT SUPPORT

PURPOSE AND USE OF EXTERNAL EXPERT SUPPORT

I.1. The regulatory body is required to have the required competences to perform its functions [2]. It may, however, be necessary for the regulatory body to use the services of external experts or a technical support organization.

I.2. The need for external expert support may arise because of:

- Unexpected applications or demands combined with a lack of internal resources (number of specialists or specific competences);
- A need to build up specific internal competences;
- A specific project for which special additional competences are needed;
- A need for a second opinion;
- Permanent outsourcing of certain activities (e.g. complex, specialized or infrequent activities).

EXAMPLES OF EXTERNAL EXPERT SUPPORT

I.3. Examples of external expert support providers include:

- Advisory bodies: many governments and regulatory bodies appoint external experts in the form of an advisory committee to give advice on overall regulatory approaches and policy.
- Expert panels: a regulatory body may appoint external experts to a panel to give advice on technical and/or policy issues.
- Dedicated technical support organizations: some States have established arrangements for particular independent organizations to dedicate part of their resources to assisting the regulatory body. Such organizations are separate from the regulatory body and undertake to maintain a proven capability and provide support as necessary.
- Government laboratories or research centres: can conduct experimental investigations, analysis or verification.
- Legal organizations: can review legal documents and assist in legal enforcement actions.
- Other governmental organizations.
- International and regional organizations.
- Regulatory bodies of other States: can be consulted, which can be particularly useful when designs or regulatory procedures utilized in one State are considered in another.
- Standards organizations, quality assurance organizations and professional bodies.
- Engineering or service organizations: in many States, engineering or service organizations provide services in technical, engineering and scientific fields.

- Certified testing and analytical services: can conduct environmental, workplace or individual monitoring.
- Academic institutions: can provide advice on a range of scientific, technical and engineering issues.
- Individual experts, including recent retirees from the regulatory body: can be a useful source of advice.
- Financial organizations: can provide advice on matters such as the financial status of an applicant, the appropriateness of investments of decommissioning funds or potential financial conflicts of interest.

INTELLIGENT CUSTOMER

I.4. The regulatory body should have sufficient technical knowledge (‘intelligent customer’) to identify problems, to determine whether it would be appropriate to seek assistance from an external expert support organization, to manage and supervise the external expert support while the advice is being developed and, at the end of the process, to understand, evaluate and use any relevant advice from external organizations or experts.

SPECIFICATION OF THE WORK

I.5. The regulatory body should establish the objective, scope and schedule of the work required as part of the contracting process. The regulatory body should also determine the level of expertise necessary to perform the work, the deliverables expected from the external experts and the expected standards.

I.6. As stated in para. 4.42, the regulatory body should establish requirements for the integrated management system to be used by the technical support organization. In some cases, the existing integrated management system of the technical support organization may be adequate, while in other cases the regulatory body should specify the requirements for the integrated management system in its contract with the technical support organization. In the case of individual experts, they should work in accordance with the regulatory body’s integrated management system.

SELECTION OF A PROVIDER OF EXTERNAL EXPERT SUPPORT

I.7. The regulatory body should ensure that external experts are chosen on the basis of their expertise and experience in the relevant field. The regulatory body should specify requirements for the selection of external experts and should ensure that the successful bidder meets these requirements.

I.8. Choices of provider are best made by comparing tenders from several competitive bids. National laws may prescribe competition rules for tendering such contracts.

I.9. External experts should be chosen on the understanding that they will provide impartial advice. The regulatory body should confirm that other activities of the external experts will not give rise to any bias in the advice given; the potential for any such conflict of interest should be minimized.

I.10. When selecting providers of external expert support, the regulatory body should take the following into account:

- The external expert's processes and systems should meet the standard of, and be compatible with, those of the regulatory body.
- Providers of external expert support should be able to demonstrate technical competence to the standards specified by the regulatory body.
- There should be no actual conflicts of interest. In case of a potential or perceived conflict of interest, the situation should be discussed with all involved parties and managed.
- Providers of external expert support should be able to conduct their work within the time frame specified by the regulatory body, which should be commensurate with the scope of the work.
- Providers of external expert support should be able to prepare and deliver specific documentation as required containing its formal advice and rationale.
- The documentation provided should be accurate and relevant and should be sufficient to allow the regulatory body to judge the quality of the work.
- When the use of advice from experts in other States is considered, the regulatory body should be aware that the use of translation services in a highly specialized technical area could lead to misunderstandings.

MANAGEMENT OF CONTRACTS

I.11. The regulatory body should provide adequate management, supervision and oversight of the work of the provider of external expert support using appropriate contractual arrangements. There should be regular contact between the provider of external expert support and the regulatory body.

I.12. The frequency of contacts and meetings will depend on the extent of the work to be performed, the knowledge the regulatory body has of the provider of external expert support and the time frame for the expected results. Those individuals from the regulatory body supervising the work should:

- Fully understand the need for an external expert's services and the context in which the work is performed;
- Know what is required and how the work will be used;

- Specify the objective, scope and requirements of the work so that the product meets the needs;
- Set the time frame for delivery of the work, if appropriate divided into key stages or milestones;
- Provide any information that could be useful to the external expert;
- Understand the expected outcome;
- Not inappropriately influence the outcome of the work or the advice from the external expert or allow any other body to do so, in order that the external expert advice reflects unbiased technical opinion;
- Supervise the work in accordance with the regulatory body's procedures and technically review it when necessary;
- Ensure regular interaction with the provider of external expert support and facilitate interaction with other parties when necessary.

I.13. The regulatory body should be aware of situations where the provider of external expert support will need to interact with authorized or interested parties. Such interactions should also be subject to approval of the regulatory body. It should be made clear to all parties that the regulatory body has approved the interaction and that the regulatory body retains its responsibilities and makes the final decision. Such interfaces should be properly controlled by the regulatory body. A provider of external expert support should not be allowed to make comments or take actions that might be construed as regulatory requests or requirements. For this reason, all such interfaces should be supervised by an appropriate representative of the regulatory body.

I.14. The regulatory body should keep sufficient records so that the advice it receives from external providers can be traced and audited, including how different professional views were addressed.

I.15. Work carried out for the regulatory body should be made available to the public in accordance with legislation and regulations governing public access to information consistent with the needs for security and confidentiality.

REVIEW OF WORK

I.16. The regulatory body should evaluate the work performed by the provider of external expert support in accordance with the objective and scope of work specified at the outset. After the work is completed, the regulatory body should consider the advice received and should determine whether and how it is to be used. The regulatory body should also use the evaluation to assess the suitability of the external expert for future work.

I.17. The regulatory body should be fully responsible for the decisions made on the basis of recommendations submitted by external expert organizations.

Independence

I.18. The provider of external expert support should be able to form and express a technical judgement that is: based on safety related criteria; takes into account the latest scientific and technical knowledge and experience; and is impartial and free from commercial, financial and other pressures from interested parties. The provider of external expert support should not be bound to directives from any other organization regarding the results of its work. Moreover, the experts' judgement should be based solely on technical knowledge, on results of analyses and on applicable regulatory requirements and guidance and should in no case be biased by political opinion. Technical competence and the safety culture of the provider of external expert support contribute to the impartiality of the technical advice.

I.19. An important element in ensuring impartiality in the advice provided is the development and implementation of adequate arrangements to avoid conflicts of interest. All situations should be analysed early in the process for potential or perceived conflicts of interest. Actual conflicts of interests should be eliminated, while potential and perceived conflicts of interest should be addressed. Activities that can be undertaken include the following:

- Verifying that the provider of external expert support has mechanisms in place such as a code of ethics and an organizational structure that promotes a strong safety culture and detects and avoids conflicts of interest.
- Verifying that the organizational structure of the provider of external expert support and its internal procedures provide functional and personal separation to ensure effective independence between units carrying out work for the regulatory body and units carrying out similar work for authorized parties or other organizations. The links between such units should be carefully monitored.

I.20. If neither of the above can be verified, an alternative opinion from other providers of external expert support should be sought and, if there is any doubt, legal advice should be obtained.

I.21. The provider of external expert support should make rigorous, demonstrable arrangements to maintain the required independence and should clearly indicate to the regulatory body any actual, potential or perceived conflicts of interest. Any changes in staff that might affect independence should be discussed with the regulatory body before they are made. Conflicts of interest may potentially occur in a variety of cases, including the following:

- When a financial tie (e.g. through a stockholder or through funding) exists between an external expert or organization and the nuclear industry (e.g. a licensee, a designer or a vendor);

- When the external expert or organization is part of, or is closely linked to, an organization that has been assigned responsibilities in relation to the promotion of nuclear technologies;
- When there may be a conflict of national interest or commercial interest;
- When the external expert or organization is providing support on the same or closely related issues to potential licensees, designers or vendors in the State or in other States;
- When the external expert or organization is involved in research and development activities in collaboration with other interested parties.

I.22. In all cases, the requirement to assess for conflicts of interest should be clearly specified and the process for managing and monitoring any identified conflict of interest should be thoroughly documented. This can be done by including appropriate clauses in the contract between the regulatory body and the provider of external expert support, or in another appropriate document, depending on the legal framework for obtaining external expert support.

Technical competence

I.23. The regulatory body should ensure that the provider of external expert support possesses the necessary technical competence. Technical competence is the ability to evaluate and to apply the latest scientific knowledge and state of the art technology. In general, the technical qualifications and experience of external experts should be equivalent to or exceed those of the staff of the regulatory body performing similar tasks. The provider of external expert support should be able to demonstrate understanding and competence in the assigned area through a range of independent activities previously performed in relevant areas.

I.24. The provider of external expert support should have access to (directly or through subcontractors) the necessary tools (e.g. computer codes, reference data), standards and expertise to accomplish the task.

I.25. For an individual expert, the regulatory body can verify that the expert has already provided similar external expert support in a satisfactory way or is recommended by other experienced experts.

I.26. For an academic expert, a publication list is a useful additional tool, and documented research activities should indicate skills and knowledge that are adequate and suitable for the task to be assigned. Certification or professional accreditation can demonstrate continued competence in the expert's specialized area.

I.27. For an organization that has a well-established reputation as a provider of external expert support to a regulatory body, there is still a need to build and maintain competence. Competence can be demonstrated by the following:

- The existence of a strategy for training the provider's own staff and implementing this training in its technical field of competence;

- Involvement in an ongoing up to date research and development programme in its field of competence;
- Development of technical tools and equipment (including software and key scientific developments);
- Access to operating experience information from authorized parties;
- Technical cooperation with other similar bodies;
- Experience gained in performing safety related tasks in the State and in other States;
- Bilateral cooperation with the regulatory body, covering areas such as: exchange of experience, sharing of skills and organization of activities relating to familiarization with operating procedures and documentation of authorized parties;
- International activities aimed at research analyses, participation in international activities relating to safety and other areas of cooperation;
- Results from self-assessments and assessments by a national body or international peer reviews.

Management system

I.28. Any potential provider of external expert support should adhere to basic management requirements. GSR Part 2 [10] establishes the general requirements for the integrated management system. See also para. I.6.

Confidentiality

I.29. The organization providing external expert support may have to manage several types of confidential information, including nuclear security related sensitive information, protected information, and proprietary information.

Nuclear security related sensitive information

I.30. In most States, the management of nuclear security related sensitive information is controlled at the government level, and the verification of the trustworthiness of every organization and individual requiring access to such information is required. Such information can only be transmitted to a provider of external expert support (or its subcontractors) in accordance with relevant government requirements.

Proprietary information

I.31. An applicant or authorized party may be required by the regulatory body to provide proprietary information, including information of commercial value, to the regulatory body. If such information is to be shared with a provider of external expert support, the regulatory body should first inform the owner of the proprietary information of its intention to do so. At the same time, the regulatory body should establish arrangements with the provider of external expert support for maintaining the confidentiality of this information. The regulatory body should make the provider of external expert

support aware of the existence of any confidential proprietary information and of its scope, restrictions on its use, and the organizations to which it may be disclosed. The regulatory body should verify that the provider of external expert support has management rules, procedures and organizational conditions in place to protect this type of information.

Safety culture

I.32. The provider of external expert support should provide the requisite technical support in accordance with the regulatory body's policy on safety culture, and should raise with the regulatory body any safety concerns regarding the work. The regulatory body should address any such concerns raised by the provider of external expert support. In this regard, the regulatory body should develop a process for addressing different professional views.

APPENDIX II GENERIC PROCESSES OF THE INTEGRATED MANAGEMENT SYSTEM

DOCUMENT CONTROL

II.1. Documents are written policies, process descriptions, and procedures used to communicate information. They are part of the documentation of the integrated management system and provide written instructions for performing a specific task.

II.2. Forms associated with procedures, that need to be filled in during regulatory activities e.g. inspections, are also documents, and they are used to capture data or information from performing a task associated with a procedure.

II.3. A document control process should be established for the preparation, review, approval, issuing, distribution, revision and validation (where appropriate) of documents essential to the management, performance and assessment of work. An electronic document management system can be used to aid in document control and management.

II.4. The responsibilities of each participating organizational unit or individual should be defined in the document control process.

II.5. Senior management (or an appointed individual, e.g. the process owner) should identify the need for documents and should provide guidance to the organizational units and individuals preparing them so that they are prepared in a consistent manner. The guidance should cover the status, scope and content of the documents, and the policies, standards and codes that apply to them. It should also explain the need for the feedback of experience. Documents, and changes to documents, should be distributed to, and should be made available at, the location where the activities described in the documents are conducted.

II.6. The process for document control should explain the following:

- How to prepare documents;
- How to review documents and confirm their acceptability;
- How documents at different levels are to be subject to approval;
- How to issue and distribute documents;
- How to control any temporary documents;
- How documents are to be modified or changed;
- How to suspend or cancel documents;
- How to control documents from sources outside the regulatory body;
- How to archive documents.

II.7. Document control for processes and procedures should ensure identification and availability of the current versions. Changes to documents should be reviewed and recorded, and should be subject to the same level of approval as the documents themselves.

CONTROL OF PRODUCTS

II.8. The products of the regulatory body can be regarded as the outputs of regulatory activities. Typically, for a regulatory body, products include documents that relate to the discharge of core functions and supporting functions and their related processes, for example:

- Review and assessment reports;
- Inspection and audit reports;
- Regulations, policies and guides;
- Authorizations (including draft authorizations);
- Certificates of approval (e.g. for transport, operating personnel, or regulatory body staff);
- Enforcement action (e.g. notices, directions, orders and reports);
- Documentation of the integrated management system;
- Plans (e.g. plans for strategic regulatory activities and training);
- Communications with interested parties (e.g. annual reports, financial reports, seminars, decision letters, requests for information, research and development reports and contributions to international and national cooperation);
- Public information (e.g. press releases, web sites and material for conferences);
- Regulatory recommendations in support of decision making;
- Internal communications to staff;
- Results of analyses of operating experience and external events.

II.9. Products of the regulatory body should be controlled in accordance with the requirements of the integrated management system. In some instances the products will be controlled by generic requirements of the integrated management system; in other cases, the requirements for control of a product may be embedded within specific processes. For example, the inspection process may establish the way in which inspection reports will be structured and reviewed.

CONTROL OF RECORDS

II.10. The regulatory body will have to keep extensive records of its work and its interactions with authorized parties and interested parties. This includes all the incoming documents as well as documents created by the regulatory body itself.

II.11. Records are generated when written instructions in procedures are followed; i.e. after data, information, or results are recorded (for example, onto a form), it becomes a record, in paper or electronic form.

II.12. The integrated management system of a regulatory body should ensure that relevant records are collected, processed and retained for specified periods. National legislation may also set out requirements relating to record management. These requirements should be identified and addressed within the regulatory body's integrated management system.

II.13. In order to facilitate the control of records, an index system should be established that allows the reliable and unique categorization of records. In many cases the index is structured in accordance with facilities, activities and processes.

II.14. The process for control of records should ensure that records:

- Are categorized;
- Are registered upon receipt;
- Are readily retrievable;
- Are indexed and placed in their proper locations in the files of the record facility with the retention times clearly specified;
- Are stored in a controlled and safe environment;
- Are stored in appropriate storage media;
- Remain unchanged under normal circumstances.

II.15. The regulatory body should ensure that all records are indexed, filed, stored and maintained in facilities that allow their retrieval when necessary. The records should be accessible at all times during the specified retention periods. Access to locations where records are retained should be controlled. Consideration should be given to storing documents that may be necessary in emergency conditions at a location away from the facility.

II.16. The management and retention of records should take into account the sensitivity of the recorded information, giving due regard to confidentiality, security, distribution, routeing and notification, availability to interested parties, search and retrieval, and destruction.

II.17. Records should be readily retrievable to support and justify decision making. However, access to records should be limited to individuals authorized for the use of the records in accordance with requirements concerning security, privacy and confidentiality.

PURCHASING

II.18. The regulatory body will need to purchase products and services that support the delivery of their regulatory functions. Purchasing of all such activities, services and products may be subject to

general procurement requirements established by government organizations. These requirements, and any others which are put in place by the regulatory body, should be set out in the regulatory body's integrated management system.

COMMUNICATION

II.19. Information relevant to safety, health, environmental, security, quality and economic related goals should be communicated to individuals in the regulatory body and, where necessary, to other interested parties.

II.20. The regulatory body should adopt a communications policy in order to promote effective sharing of information with all interested parties. The regulatory body should establish the information that it needs to communicate both within the regulatory body and to external organizations. It should also identify the information that it seeks from such external organizations in order to discharge its mandate effectively.

II.21. Regulatory decisions, and decisions that affect the operation of the regulatory body, should be based on accurate and up-to-date information that has been reviewed and approved. Such information needs to be communicated effectively within the regulatory body. The internal communications policy should promote sharing of relevant up-to-date information, and should enable staff to work effectively and efficiently. Management of the regulatory body should systematically identify the information that needs to be communicated to its staff, and the formal channels of communication within the regulatory body should be defined. Suitable methods of communication should be identified and used to ensure that the necessary information is made available in a timely manner.

II.22. Communication is a two-way process and management should actively seek and listen to feedback from staff, incorporating their input into decisions about the operation of the regulatory body. When communicating information, staff within the regulatory body should be mindful of the need to protect certain types of information, such as commercially sensitive data, security related information, and personnel data.

II.23. Communication with external organizations and groups may be required by legislation governing the operation of the regulatory body. The regulatory body may also identify the need for additional communications with external organizations. Management of the regulatory body should systematically identify the information that needs to be communicated to, and sought from, external interested parties, and the formal channels of communication to accomplish this should be defined. Suitable methods of communication should be identified and used to ensure that the necessary information is made available in a timely manner.

MANAGING ORGANIZATIONAL CHANGE

II.24. The regulatory body should put in place a process for managing organizational change, for changes made in response to external or internal initiatives. The process should ensure that the potential impact of proposed changes on the effectiveness of the regulatory body is systematically assessed. Changes should not be implemented without adequate review and should be modified (e.g. by means of compensatory measures) if they impact negatively on the effectiveness with which the regulatory body discharges its mandate.

MEASURING AND TEST EQUIPMENT

II.25. Activities for inspection, testing, verification and validation of any equipment to be used by the regulatory body should be completed before acceptance, implementation or operational use of such equipment. The tools and equipment used for these activities should be of the proper range, type, accuracy and precision.

II.26. If regulatory activities involve the use of measuring and testing equipment, a process for the control, and where necessary calibration, of tools, gauges, instruments and other measuring and test equipment should be established.

II.27. Calibration should be performed using certified equipment traceable to a recognized standard or to another documented basis where no standards exist. A documented system for the control of out of calibration equipment, including identification and evaluation of the impact of the use on previous measurements since the last calibration date, should be established.

APPENDIX III ELEMENTS OF A TRAINING PROGRAMME FOR THE REGULATORY BODY

III.1. The training programme should impart trainees with knowledge of:

- Principles of nuclear, radiation, waste and transport safety;
- Radiation and industrial safety;
- Relevant legislation;
- Human and organizational factors;
- Safety culture;
- Site characterization;
- Facilities and systems (design, operation and maintenance, including surveillance methods);
- Accident analysis;
- Emergency preparedness and response;
- Safety assessment;
- Decommissioning of facilities;
- Radioactive waste management, including disposal;
- Quality assurance and organizational matters;
- Nuclear security.

III.2. Depending on the tasks to be performed, it may be necessary additionally to impart knowledge of:

- Physics;
- Nuclear engineering;
- Systems engineering;
- Electrical engineering;
- Mechanical engineering;
- Civil engineering;
- Radiation protection;
- Chemistry;
- Biology;
- Behavioural sciences;
- Ergonomics;
- Medicine;
- Geology;
- Law;
- Communication;
- Administration;

III.3. Furthermore, knowledge of regulatory policies and processes should be included:

- Links between legislative aspects and implementation of regulatory functions;
- Regulatory policy and its objectives;
- Regulations and use of regulatory guides;
- Authorization stages and procedures, including the purpose and content of supporting documentation;
- Internal guidance and procedures of the regulatory body;
- Methods of review and assessment;
- Inspection techniques;
- Enforcement procedures.

III.4. The training programme for professional knowledge and skills should include the following:

- Knowledge of regulatory control;
- Review and assessment skills;
- Inspection skills;
- Knowledge from job specific training;
- Knowledge from on the job training.

III.5. Communication and management skills should also be included:

- Oral communication;
- Effective writing;
- Interviewing;
- Negotiation;
- Leadership;
- Project management;
- Teamwork;
- Decision making;
- Dispute resolution;
- Languages;
- Use of computers;
- Public information.

III.6. Continuous professional development should be provided, covering:

- Refresher training;
- Further personal development.

III.7. In addition, training should be provided on information exchange and international cooperation.

APPENDIX IV STRUCTURE OF INFORMATION IN THE INTEGRATED MANAGEMENT SYSTEM

IV.1. A three level structure of information promotes clarity and avoids repetition by establishing the amount of information and the level of detail appropriate to each type of document and by using cross-references between specific documents at the different levels. A typical three level structure consists of:

- Level 1: An overview of how the regulatory body and its integrated management system are designed to meet its policies and objectives;
- Level 2: A description of the processes to be implemented to achieve the policies and objectives and the specification of which organizational unit is to carry them out;
- Level 3: Detailed instructions and guidance that enable the processes to be carried out and specification of the individual or unit that is to perform the work.

LEVEL 1

IV.2. Level 1 should provide an overview of the policies and objectives of the regulatory body and should describe how the integrated management system addresses the requirements that apply to the regulatory body's work. The information at this level of the integrated management system should be the senior management's primary means of communicating to individuals the expectations of management, their strategies for success and the methods for achieving the regulatory body's objectives.

IV.3. Information on the following should be provided at this level:

- The vision, mission and goals of the regulatory body;
- Policy statements of the regulatory body;
- Organizational structure;
- Levels of authority and responsibilities and accountabilities of senior management and organizational units;
- Structure of the integrated management system documentation;
- An overview of the regulatory body's processes;
- Responsibilities of owners of the processes;
- Arrangements for measuring and assessing the effectiveness of the integrated management system.

IV.4. Senior management in the regulatory body should ensure that level 1 information is distributed to all individuals with responsibilities for implementation, and that the contents are effectively understood and implemented.

LEVEL 2

IV.5. This level of information contains the process descriptions and provides specific detail on which activities should be performed and which organizational units or individuals should carry them out. This level of information should also contain a process map of the integrated management system providing an overview of the interactions between processes.

IV.6. The process descriptions typically contain the following sections:

- Purpose: Why does the document exist? The specific objectives of the document should be stated clearly and concisely;
- Scope: What actions are addressed by the document and who is supposed to use it? The type of work and situations to which the document applies should be defined. The boundaries of application of the document should be stated;
- Responsibilities: Who is responsible for the document (the process owner);
- Details: How is the work to be conducted? This information may take the form of a flow chart or process map describing the sequence of actions necessary to accomplish the work. The text should be simple and direct. Approved numbering and nomenclature for job titles and documents should be used. The details section of a document should describe what is to be done, typically by providing the following information:
    - Planning and scheduling considerations, to ensure that work is dealt with safely, systematically and efficiently;
    - Administrative and technical information;
    - Work steps and actions to be carried out;
    - Responsibilities and authorities;
    - Interfaces;
    - Lines of communication both within and outside the regulatory body;
    - Any cross-references between the document and other documents, including working documents at level 3.
- Definitions and abbreviations: What words or acronyms are used in the document that may not be commonly understood? Such terms and any jargon that may cause confusion should be defined and clearly explained;
- References: Would other documents be of use to those who have to use the document? If so, the specifications, standards or other documents that are cited in the text and which may provide additional information to users should be listed. If documents are referenced in part, the page and paragraph numbers should be stated;
- Records: Which records are necessary to conduct the work and which ones need to be retained after the work has been completed? The records that are necessary to demonstrate that the tasks specified in the document have been accomplished should be identified;

– Appendices (where applicable), if additional information is necessary.

IV.7. To avoid unnecessary detail, cross-reference should be made to level 3 information, such as supporting guidance or detailed working documents.

LEVEL 3

IV.8. Level 3 information consists of a wide range of documents to prescribe the specific details for the performance of tasks by individuals or by small functional groups or teams. The type and format of documents at this level can vary considerably, depending on the application involved. The primary consideration should be to ensure that the documents are suitable for use by the appropriate individuals and that the contents are clear, concise and unambiguous, whatever the format.

REFERENCES

[1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[3] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. DS473, IAEA, Vienna (in preparation).

[5] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, PREPARATORY COMMISSION FOR THE COMPREHENSIVE NUCLEAR-TEST-BAN TREATY ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, UNITED NATIONS OFFICE FOR THE COORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Safety Infrastructure for a Nuclear Power Programme, IAEA Safety Standards Series No. SSG-16, IAEA, Vienna (2012).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary, IAEA, Vienna (2007).

[8] 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, IAEA, Vienna (2011).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14, IAEA, Vienna (2011).
[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).
[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Convention on Nuclear Safety, Legal Series No. 16, INFCIRC/449, IAEA, Vienna (1994).
[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, IAEA International Law Series No. 1, IAEA, Vienna (2006).
[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Code of Conduct on the Safety of Research Reactors, IAEA, Vienna (2006).
[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Code of Conduct on the Safety and Security of Radioactive Sources, IAEA, Vienna (2004).
[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA, Vienna (in preparation) (DS460).
[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Managing Regulatory Body Competence, Safety Reports Series No. 79, IAEA, Vienna (2014).

ANNEX

PROCESS DESCRIPTIONS

This Annex presents examples of process descriptions that could be used in an integrated management system for a regulatory body.

MANAGEMENT PROCESSES

A-1. Tables A-1 to A-6 indicate the purpose, inputs, process, outputs, interfaces and performance criteria for the management processes of the regulatory body.

TABLE A-1. POLICY MAKING

Purpose	To describe how senior management develops the policies of the regulatory body, which are necessary for discharging the regulatory mandate.
Inputs	1. External demands for change or improvement arising from political or legislative change impacting on the regulatory mandate; 2. Internal information on performance and regular policy reviews identifying potential areas for improvement in policy.
Process	1. Review and analysis of relevant information requirements and lessons learned; 2. Development of policy options based on evidence and involvement of relevant experts; 3. Consultation with regulatory body staff and interested parties; 4. Impact and cost-benefit assessment of proposals; 5. Refinement of proposals into new policies; 6. Development of specific proposals for approval by senior management, including implementation plans.
Outputs	1. Policies that are: focused on outcomes; evidence based; take account of national and international expectations; aligned with other regulatory and other government policies; 2. Practical implementation and communication plans and criteria for the future evaluation of impact and effectiveness.
Interfaces	1. Governance; 2. Process management; 3. Performance management; 4. Communication and consultation.
Performance criteria	1. Achievement of targets in policy making; 2. Achievement of policy implementation deadlines; 3. Achievement of evaluation criteria.

TABLE A-2. PROCESS MANAGEMENT

Purpose	To manage all processes to ensure they are systematically and consistently developed, and implemented and maintained in a controlled and integrated fashion.

Inputs	1. List of key processes; 2. Document hierarchy of the integrated management system; 3. Legal and regulatory requirements, guidance and procedures, applicable government requirements or national legislation (e.g. records retention and control); 4. Corrective actions and adjustments resulting from performance management activities; 5. Existing processes that need to be streamlined and documented; 6. Senior management directions and expectations; 7. Feedback and review comments from staff and other interested parties.
Process	Develop an individual process: 1. Establish the scope of the process. 2. Prepare and map the process. 3. Identify the purpose, roles and responsibilities, process description, inputs, outputs, records, key interfaces, and resource implications, (e.g. IT tools, and competence and training requirements). 4. Specify control points and performance indicators. 5. Identify references. 6. Document the process, which may include: a. Procedures; b. Work instructions; c. Criteria and guides (e.g. a writing guide); d. Standard forms, templates and checklists. 7. Validate the process (‘desktop review’). 8. Approve the process. Implement an individual process: 1. Plan the implementation; 2. Deploy the process; 3. Verify initial performance of the process and identify and implement corrective actions, as necessary. Maintain an individual process: 1. Execute the process; 2. Review performance and assessment results; 3. Address any identified process improvement opportunities; 4. Modify the process (as necessary). Control documents and records associated with or generated by the process: 1. Review and approve documents and records; 2. Manage and retain documents and records (interface with the information management process).
Outputs	1. Process documents; 2. Documents and records generated by the process; 3. Resource implications for each process.
Interfaces	1. Information management process; 2. Purchasing process (e.g. requirements for IT tools); 3. Competence management process.

Performance criteria	1. Adequacy, effectiveness and efficiency of the integrated management system including all its processes.

TABLE A-3. PERFORMANCE MANAGEMENT

Purpose	To measure the effectiveness and efficiency of the regulatory body and its activities.
Inputs	1. Progress with strategy, objectives and plans; 2. Key performance indicators; 3. Self-assessment reviews; 4. Process performance information; 5. Internal audit review reports; 6. International peer reviews; 7. Information from operating experience feedback; 8. Staff suggestions; 9. Results of surveys of interested parties.
Process	1. Identify accountabilities and reporting responsibilities at each level of the regulatory body. 2. Identify frequencies of monitoring, review and reporting at each level of the regulatory body. 3. Identify performance objectives, criteria and key performance indicators that can be used to demonstrate effectiveness, efficiency, and process 'health'. (Process 'health' includes such things as: throughput time for each process; resources allocated and used by each process; backlogs and delays in processes; consistency of application of a process, e.g. timeliness specifications are met; standards for assessing the consistent application of judgment and discretion within a process; numbers, nature and trends of non-conformances). 4. Analyse and synthesize information to identify key issues and significant aspects relating to the performance objectives and criteria. (Present the right information, in the right way at the right time and in the right place for evaluation). 5. Compare information with performance objectives and criteria to determine the performance 'gap'. 6. Decide what to do to address the performance gap, including initiating further studies or analyses (e.g. root cause analysis) to understand the reasons for the gap and identifying appropriate, prioritized corrective actions and adjustments. 7. Plan and implement corrective actions, including adjustments to strategy, programme and plans.
Outputs	1. Results from applying performance assessment methodologies; 2. Corrective action plans.
Interfaces	1. Governance; 2. Policy making; 3. Planning; 4. Communication and consultation.
Performance criteria	1. Timeliness and adequacy of monitoring and review activities.

TABLE A-4. GOVERNANCE

Purpose	To provide the strategic direction and oversight of the regulatory body to ensure it fulfils its regulatory mandate, consistent with the expectations of interested parties.
Inputs	1. National and international developments among interested parties; 2. Internal information on the performance of regulatory activities.
Process	1. Senior management takes the lead, supported by advisers. 2. Link the external demands and expectations of interested parties with the internal operations of the regulatory body. 3. Clarify which responsibilities, powers and decisions are reserved for senior management, and which are delegated to others. 4. Set out the cycle of activities by which senior management plans, monitors and reviews: (a). The relevance of the vision, mission and values (typically every 3 to 5 years); (b). The effectiveness of the strategy, policy, plans and performance; (c). The effectiveness of the structure of the regulatory body (typically annually); (d). The implementation of programmes and plans and supervision of the activities of management (typically several times within a year e.g. monthly or quarterly). 5. Identify the information needs relevant to each activity, commensurate with the significance of the topic or issue in scope. 6. For each activity (or event or meeting): (a). Collect relevant information and provide to participants in advance of the meeting, event or activity. (b). Ensure adequate: (i). Consideration of information relative to its significance; (ii). Discussion and debate; (iii). Consideration of options where appropriate; (iv). Clear decisions and actions which can be implemented. (c). After each meeting, event, or activity, provide appropriate notes, records or reports and communicate these to interested parties.
Outputs	1. Mission, vision and values; 2. Strategic direction, policies, programmes, plans, priorities; 3. Budget, structure, roles and responsibilities; 4. Performance reports.
Interfaces	1. Policy making; 2. Planning; 3. Performance management; 4. Communication and consultation.
Performance criteria	1. Timeliness of governance activities; 2. Effectiveness and efficiency of regulatory body.

TABLE A-5. PLANNING

Purpose	To establish and maintain a strategic plan supported by detailed operational work plans to optimize planned activities, delivery timelines and the use of resources, in order to achieve the desired regulatory outcomes.
Inputs	1. Results of regulatory performance; 2. Expectations of interested parties; 3. Changes in regulated facilities, activities and programmes; 4. Research and development.
Process	Strategic plan: 1. Analyse and document relevant regulatory challenges for the coming multi-year period; 2. Establish priorities using a graded approach; 3. Assess available resources; 4. Draft the strategic plan with objectives, outcomes, resources and timelines. Operational work plan: 1. Extract relevant information from strategic plan; 2. Draft detailed work plans identifying the: scope; objectives; key interfaces; various tasks involved and who is responsible for these tasks; work schedule, resources and competences needed; regulatory requirements associated with the work; work controls; and expected deliverables.
Outputs	1. A strategic plan; 2. Detailed work plans as necessary; 3. Allocation of necessary resources.
Interfaces	1. Training and competence management; 2. Performance management; 3. Communication and consultation; 4. All core processes.
Performance criteria	1. Capture all of the relevant circumstances for the regulatory body during the coming three years; 2. Provision of relevant priorities for the regulatory body; 3. Engagement of all managers and relevant staff; 4. Optimization of resources; 5. Planning completed within set time limits.

TABLE A-6. MANAGEMENT OF CHANGE

Purpose	To manage change in response to external or internal initiatives and to minimize the risks to performance.
Inputs	1. Proposed changes to strategy, policy, organization or process.
Process	1. Identify changes which may impact on performance; 2. Assess or filter changes to identify those changes with significant potential impact; 3. Graded systematic assessment of change and potential impact on strategy, policy, structure, capability and competence of staff, and processes; 4. Impact or cost-benefit assessment of change; 5. In consultation with relevant interested parties, develop a proportionate and

	progressive change plan that includes milestones and controls to exploit opportunities and to minimize the risks of change, and which is aligned with other plans; 6. Develop a monitoring scheme and success criteria for the implementation of the change plan and the review of its effectiveness; 7. Obtain agreement on the change plan at appropriate management level.
Outputs	1. Proportionate change implementation plan with monitoring scheme and success criteria; 2. Plan for the evaluation of the assessment of the effectiveness of the change.
Interfaces	1. Governance; 2. Policy making; 3. Planning; 4. Communication and consultation with interested parties
Performance criteria	1. Proportionate change plan prepared before change is commenced; 2. Implementation of change plan to time and cost; 3. Evaluation of change completed on time.

CORE PROCESSES

A-2. Tables A-7 to A-13 indicate the purpose, inputs, process, outputs, interfaces and performance criteria for the core processes of the regulatory body. More information and requirements relating to the functions supported by these processes can be found in DS473 [A-1].

TABLE A-7. DEVELOPMENT OF REGULATIONS AND GUIDES

Purpose	To develop and maintain the regulations and guides that define the regulatory requirements and expectations applicable to the regulated facilities and activities.
Inputs	1. Legal mandate of the regulatory body to issue regulations and guides; 2. Government instructions on the process for developing regulations; 3. New developments in international safety standards and industrial standards; 4. New developments in technology, research and development and operational lessons learned; 5. Identification of needs for new regulations or guides in a specific area; 6. Identification of needs to revise existing regulations or guides.

Process	1. Analyse and determine the need for new or updated regulations or guides, and their scope; 2. Establish a project to develop the regulations or guides; 3. Review relevant international safety standards and industrial standards; 4. Draft new regulations or guides; 5. Review the draft within the regulatory body, including an expert legal review; 6. Consult with interested parties, including the public; 7. Consult with advisory committees, as appropriate; 8. Revise the draft to take due account of any comments received, and conduct final legal review; 9. Formally decide to adopt the regulations or guides; 10. Publish, and implement a strategy for communicating this to all relevant parties. 11. Provide a means of disseminating and distributing copies of the regulations and guides; 12. Inform and train staff in the new regulations or guides.
Outputs	1. New or revised regulations and guides.
Interfaces	1. Review and assessment of facilities and activities; 2. Inspection of facilities and activities; 3. Enforcement of regulatory requirements; 4. Operating experience feedback; 5. International cooperation; 6. Communication and consultation with interested parties.
Performance criteria	1. Production completed with planned resources and within set time limits; 2. Successful communication with interested parties; 3. New or revised regulations shown to provide benefits for interested parties.

TABLE A-8. NOTIFICATION AND AUTHORIZATION

Purpose	To take action on notifications and to make decisions on requests for authorizations, in line with legal and regulatory requirements.
Inputs	1. Legal and regulatory requirements, guidance and regulatory procedures specific to notification and authorization; 2. Application for an authorization; 3. Notifications submitted to the regulatory body; 4. Demonstration of safety in support of an application for authorization (e.g. safety assessment); 5. Outputs of other regulatory processes (e.g. review and assessment, inspection); 6. Operating performance of the applicant, including its safety history and compliance history.
Process	1. Extract relevant information from all inputs; 2. Verify completeness of notification or of the application for authorization; 3. Require applicant for authorization to submit a safety assessment commensurate with the risk; 4. Require applicant for authorization to submit additional safety related

	information, if necessary; 5. Conduct review and assessment to support the authorization process; 6. Conduct verification activities (e.g. on-site inspection), as appropriate; 7. Make a decision on the application for authorization, specifying any necessary limits and conditions and controls on the authorized party's subsequent activities; 8. Formally record and document the decision and basis for decision, as appropriate; 9. Issue an authorization or refusal.
Outputs	1. Authorization document (including limits, conditions, controls); 2. Decision and basis for decision.
Interfaces	1. Review and assessment of facilities and activities; 2. Inspection of facilities and activities; 3. Document control; 4. Communication and consultation.
Performance criteria	1. Issuing of authorization completed with planned resources and within set time limits; 2. Successful communication with the applicant or authorized party and, where appropriate, the public.

TABLE A-9. REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES

Purpose	To review and assess technical and other information relating to safety, in order to verify the adequacy of the proposed safety measures as part of the authorization process, and determine whether the facility or activity complies with regulatory requirements and the authorization.
Inputs	1. Legal and regulatory requirements, guidance and regulatory procedures specific to review and assessment; 2. Application forms and other documents submitted in support of applications for authorizations; 3. Technical and other documents required to assess compliance with the regulatory requirements and the authorization; 4. Feedback on operating experience; 5. Developments in international standards and research; 6. Outputs of other regulatory processes (e.g. inspection results, previous reviews and assessment results).
Process	Review and assessment to support the authorization process: 1. Extract relevant information from inputs; 2. Establish a review and assessment plan (identify key issues and tasks, milestones, and assigned resources, both internal and external); 3. Conduct review and assessment activities; 4. Collect and integrate assessment results, and request additional information if necessary; 5. Document the conduct of the review and assessment and the results; 6. Propose authorization conditions; 7. Provide feedback to the authorization process.

	Review and assessment to support regulatory oversight: 1. Extract relevant information from inputs; 2. Establish a review and assessment plan (identify key issues and tasks, milestones, and assigned resources, both internal and external); 3. Request additional technical and other documents, if necessary; 4. Conduct review and assessment activities; 5. Document the conduct of the review and assessment and the results; 6. Provide feedback information for other regulatory processes.
Outputs	1. Reports and documents covering review and assessment results, proposed conditions for authorization.
Interfaces	1. Authorization and notification; 2. Inspection of facilities and activities; 3. Enforcement; 4. Event reporting; 5. Document control; 6. Communication and consultation.
Performance criteria	1. Review completed with planned resources and within set time limits; 2. Successful communication with the applicant or authorized party and other interested parties.

TABLE A-10. INSPECTION OF FACILITIES AND ACTIVITIES

Purpose	To inspect facilities and activities of the authorized parties to verify they are in compliance with regulatory requirements and the conditions specified in authorizations.
Inputs	1. Legal and regulatory requirements, guidance and regulatory procedures specific to inspection; 2. List of licensed facilities and activities and the relative risk posed by each; 3. Relevant authorizations and issues or concerns for follow up; 4. Safety performance of the authorized parties, including results of regulatory inspections; 5. Strategic directions and plans; 6. Reports of incidents and events; 7. Outputs of other core regulatory processes.
Process	Develop overall programme for inspection of facilities and activities: 1. Identify key aspects (see GSR Part 1 (Rev. 1) [A-2]) to be included in the baseline inspection programme, as appropriate to the type of facility and activities; 2. Identify priorities and safety significant targets for the programme; 3. Allocate inspection resources across facilities and activities in proportion to the relative risk posed by each, taking into account safety performance, results of regulatory inspections, and the number and nature of outstanding issues; 4. Make provisions for reactive inspections. Develop specific inspection plans for individual facilities and activities:

	1. Prepare inspection plan for different types of facility and activity, including objectives and outcomes, number and type of inspections, method(s), resources, and schedules and timetables. 2. Prepare plans for each individual inspection, including objectives, resources, sets of questions, method of conducting inspection and collecting data, identification of non-compliances, inspection report, and communicate the report to the authorized party. Individual inspections can be performed both announced and unannounced. Develop procedures for inspections, covering all facilities and activities under regulatory control. Develop procedure for reactive inspections: 1. Assess unplanned situations or incidents against relevant inspection selection criteria and decide if a reactive inspection is necessary; 2. For each reactive inspection, select objectives consistent with the nature and significance of the incident or event; 3. Within the context of the overall inspection plan for the facility or activity and licensee performance, assign resources, prepare sets of questions, verify access arrangements and analyse relevant documents; 4. Conduct inspection and data collection, prepare inspection report and communicate to the authorized party; 5. Record findings and follow-up.
Outputs	1. Programme of inspection of facilities and activities; 2. Inspection plan for individual facilities and activities; 3. Report(s) of inspection, findings, conclusions on non-compliance, correspondence and communication to authorized party; 4. Inspection records.
Interfaces	1. Authorization and notification; 2. Enforcement of regulatory requirements; 3. Document control; 4. Communication and consultation.
Performance criteria	1. Degree of completion of planned inspection programme; 2. Number of, and reason for, additional announced and unannounced inspections; 3. Number of enforcement cases.

TABLE A-11. ENFORCEMENT OF REGULATORY REQUIREMENTS

Purpose	To identify and apply the appropriate action to ensure and encourage compliance with regulatory requirements.
Inputs	1. Applicable laws, regulations, standards and codes; 2. Enforcement policy; 3. Authorization (e.g. licence, certificate or permit); 4. Inspection findings (from both planned and reactive inspections); 5. Review and assessment results; 6. Compliance history;

	7. Operating experience and feedback.
Process	1. Assess the significance of a non-compliance by considering the following criteria: (a). The number (or recurrence) of non-compliances; (b). The (actual or potential) safety consequences; (c). The severity of the non-compliance, and the degree to which it was intentional; (d). The impact on risk intervals in risk monitors or the increase in conditional risk, and acceptance criteria, if applicable. 2. Select the appropriate enforcement action(s), which may include one or more of: recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization; 3. Apply enforcement using an associated procedure for the selected enforcement action and with clear documentation of the facts, findings and the basis for the enforcement action; 4. Confirm that the authorized party has effectively implemented any necessary corrective actions. If necessary consider further enforcement action.
Outputs	1. Enforcement actions; 2. Record of completion of corrective actions.
Interfaces	1. Review and assessment of facilities and activities; 2. Authorization and notification; 3. Inspection of facilities and activities; 4. Legal support; 5. Document control; 6. Communication and consultation.
Performance criteria	1. Number of different kinds of enforcement cases (there are expected to be only a small number of serious cases if an effective regulatory regime is being applied); 2. Time for issuing of enforcement decision after finding the non-compliance; 3. Number of appeals.

TABLE A-12. EMERGENCY PREPAREDNESS

Purpose	To effectively respond to a nuclear or radiological emergency.
Inputs	1. Legal and regulatory provisions regarding emergency preparedness and response, including international obligations; 2. National radiation emergency plan; 3. Authorized parties' emergency plans; 4. Internal emergency plan of the regulatory body; 5. Developments, experiences and lessons identified in the area of emergency preparedness and response, both in the State and in other States; 6. International cooperation.
Process	1. Analyse national requirements and arrangements to be made for emergency preparedness and response by the regulatory body; 2. Develop the necessary arrangements identified in the analysis (for example

	by developing procedures, supplying tools and equipment and assigning facilities); 3. Identify the necessary staff knowledge and skills to effectively discharge the regulatory body's functions in emergency preparedness and response; 4. Develop and implement suitable staff training programme and exercise programme that take into account the needs of authorized parties and other relevant interested parties, as well as national and international requirements; 5. Evaluate the effectiveness of training and exercise programmes; 6. Provide feedback to staff involved in planning and response; 7. Periodically review and revise the emergency arrangements, and also when significant changes to any process inputs are made.
Outputs	1. Up-to-date emergency plan and procedures; 2. Verification that internal emergency arrangements are realistic and provide for the effective discharge of the functions assigned to the regulatory body; 3. Improved staff skills and arrangements of the regulatory body; 4. Feedback to facilitate improvements in the arrangements for emergency preparedness and response.
Interfaces	1. Planning; 2. Inspection of facilities and activities; 3. Coordination with other national authorities and authorized parties; 4. International cooperation.
Performance criteria	1. Demonstrated performance of regulatory body functions in emergency planning and response in relation to expectations.

TABLE A-13. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Purpose	To inform and consult interested parties about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.
Inputs	1. Scientifically based information about radiation risks associated with facilities and activities; 2. Legal and regulatory provisions regarding protection of the public; 3. Regulatory body's integrated management system; 4. Regulatory decisions.
Process	1. Develop a communication and consultation plan, including the strategies and methods for communicating regulatory activities, judgements and decisions to interested parties including the public; 2. Develop information material on radiation risks and on requirements to protect the public, which are understandable to the general public; 3. Identify regulatory requirements, judgements, decisions and processes to be communicated to the public; 4. Identify information on incidents in facilities and activities to be communicated to the interested parties; 5. Analyse and select the most efficient means to reach and interact with the public. Examples include printed information material, web sites, exhibitions, meetings with interested parties, visits to schools and local organizations;

	6. Periodically review and update outreach material.
Outputs	1. Information provided (or available) to interested parties; 2. Conduct of meetings with interested parties; 3. Responses to issues raised by the public and media.
Interfaces	1. Core processes 2. Legal support
Performance criteria	1. Satisfaction of the public and media.

PROCESSES TO SUPPORT CORE REGULATORY FUNCTIONS

A-3. Tables A-14 to A-17 indicate the purpose, inputs, process, outputs, interfaces and performance criteria for the processes of the regulatory body supporting the core regulatory functions. The related supporting technical functions are described in Section 4 of this Safety Guide.

TABLE A-14. LEGAL SUPPORT

Purpose	To provide legal advice to the regulatory body in connection with the development of regulations, regulatory judgments and decision making such as enforcement decisions.
Inputs	1. National legal structures and arrangements; 2. Draft regulations and guides; 3. Draft authorization documents; 4. Draft inspection reports; 5. Draft regulatory statements, judgements and decisions.
Process	It may be that this is not an explicit process; however, in some processes a statement may appear to seek or to consult legal advice. For each core process, the legal advice process may be different.
Outputs	1. Expert legal advice; 2. Legal advice for regulations and guides; 3. Legal advice for authorization documents; 4. Legal advice on enforcement activities.
Interfaces	1. Authorization and notification; 2. Development of regulations and guides; 3. Enforcement of regulatory requirements.
Performance criteria	1. Number of contestations to authorizations issued; 2. Number of contestations to regulations issued; 3. Number of contestations to enforcement actions.

TABLE A-15. RESEARCH AND DEVELOPMENT

Purpose	To identify research and development needs in support of the regulatory functions and to conduct the research and development with its own resources or by engaging

	external expert organizations.
Inputs	1. Questions on safety that are not yet resolved; 2. Questions from international collaboration; 3. Questions that may arise from operating experience or from new technological developments.
Process	1. Identify the research needs; 2. Conduct a literature search; 3. Contact institutions (e.g. scientific or regulatory institutions, universities, the IAEA) for additional information; 4. Specify the research to be done; 5. Specify the acceptance/success criteria; 6. Start the purchasing process; 7. Monitor project delivery; 8. Evaluate quality of deliverables and check against original specifications; 9. If necessary, start iterations with the support organization; 10. When deliverables are acceptable, conclude the purchasing process; 11. Document the outcomes and review the process, and look for improvements.
Outputs	1. Research and development report; 2. Answers to research questions and issues.
Interfaces	1. Review and assessment of facilities and activities; 2. External expert support.
Performance criteria	1. Quality of deliverables; 2. Delivery of outputs within agreed timescales; 3. Internal resources utilized compared with planned resources

TABLE A-16. EXTERNAL EXPERT SUPPORT

Purpose	To identify and obtain technical or other expert professional advice or services in support of the regulatory functions in accordance with the specified standards.
Inputs	Any regulatory function for which external support is requested.
Process	1. Identify the required external expert support (in terms of objectives, scope, timeline and milestones); 2. Develop the specifications; 3. Identify possible support organizations; 4. Start the purchasing process; 5. Monitor project delivery; 6. Evaluate quality of deliverables and check against original specifications; 7. If necessary, start iterations with the support organization; 8. When deliverables are acceptable, conclude the purchasing process 9. Document the outcomes and review the process, and look for improvements.
Outputs	1. Specified project deliverables.
Interfaces	1. All core processes; 2. All other processes to support core regulatory functions.

Performance criteria	1. Quality of deliverables; 2. Numbers of iterations with the support organization; 3. Delivery of outputs within agreed timescales; 4. Internal resources needed compared with external resources.

TABLE A-17. INTERNATIONAL COOPERATION

Purpose	To engage in international cooperation in accordance with multilateral or bilateral agreements, including international conventions, as well as the preparation of international standards and the provision of regulatory assistance. To exchange experience and gain information on unfamiliar regulatory activities.
Inputs	1. Questions; 2. Experience; 3. Obligations of international conventions and codes of conduct.
Process	1. Identify the subject areas on which cooperation is required; 2. Identify the institutions, organizations or States that may contribute to the subject; 3. Contact the corresponding institution, organization or State; 4. Define the form of contact and collaboration; 5. Obtain an agreement with the institution, organization or State; 6. Identify the responsible staff members to contact the institution, organization or State; 7. Develop a collaboration plan; 8. If necessary, start the purchasing process; 9. Start the cooperation; 10. Regularly check the effectiveness of the collaboration and the need for continuing the collaboration.
Outputs	1. Protocols; 2. Reports; 3. Meeting minutes.
Interfaces	1. Purchasing; 2. Communication and consultation with interested parties.
Performance criteria	1. Results achieved as a consequence of international cooperation.

PROCESSES TO SUPPORT THE ORGANIZATION

A-4. Tables A-18 to A-26 indicate the purpose, inputs, process, outputs, interfaces and performance criteria for the supporting processes of the regulatory body. These processes are not specific to a regulatory body. The generic administrative processes are also described in Appendix II of this Safety Guide.

TABLE A-18. HUMAN RESOURCES MANAGEMENT

Purpose	To ensure that the regulatory body has sufficient competent and qualified staff to

	discharge its responsibilities.
Inputs	1. Safety Reports Series No. 79 [A-3]; 2. Regulatory body organization chart.
Process	1. Periodically evaluate the regulatory body's staffing needs; 2. Apply subprocesses such as: (a). Recruitment; (b). Induction of new staff (education and training); (c). Staff development (including appraisals, continuous professional development and refresher training); (d). Staff departures and retirement.
Outputs	1. Regulatory body with sufficient competent and qualified staff; 2. Succession plan for key staff.
Interfaces	1. Planning; 2. Finance; 3. Knowledge management (staff departures and retirement); 4. Training and competence management; 5. External expert support.
Performance criteria	1. Percentage of staff fully qualified for position; 2. Number of positions vacant; 3. Amount of time a position remains unfilled.

TABLE A-19. KNOWLEDGE MANAGEMENT

Purpose	To ensure that knowledge relevant for the activities of the regulatory body is acquired, stored, preserved and distributed, i.e. in general, managed as a very valuable resource of the regulatory body.
Inputs	1. Any information relevant for the regulatory body to discharge its responsibilities and to fulfil its functions. Special attention should be paid to the tacit knowledge that forms part of the experience of individuals (staff departures, retirements).
Process	1. Periodically identify the regulatory body's information needs; 2. Periodically review the existing knowledge base; 3. Identify needs for update of information; 4. Compare with existing knowledge base and identify gaps; 5. Identify and access internal and external sources of information and capture the necessary information to fill the gaps (essential for retirements and departures); 6. Convert information to knowledge of use to the regulatory body: 7. Store the information adequately and safely; 8. Ensure easy retrieval; 9. Inform the concerned individuals about changes and updates.
Outputs	1. Knowledge base; 2. Comprehensive collection of up-to-date information.
Interfaces	1. Planning; 2. Human resources management (staff departures and retirement);

	3. Training and competence management; 4. Research and development; 5. External expert support; 6. International cooperation.
Performance criteria	1. Accuracy and currency of information; 2. Completeness of knowledge base; 3. Ease of access to relevant information; 4. Positive feedback of users.

TABLE A-20. TRAINING AND COMPETENCE MANAGEMENT

Purpose	To develop and maintain adequate competence for the staff of the regulatory body.
Inputs	1. Functional and organizational structure of the regulatory body; 2. Job descriptions; 3. Human resources plan; 4. Previous evaluation of staff performance.
Process	Depending on the size and the structure of the regulatory body, the processes relating to training and competence management may vary. Some details are provided in Section 6. The concept of a systematic approach to training is detailed in Ref.[A-3].
Outputs	1. Training programmes; 2. Qualified and competent staff.
Interfaces	1. Human resources management; 2. Knowledge management.
Performance criteria	1. Implementation of training programmes; 2. Periodic evaluation of staff performance.

TABLE A-21. DOCUMENT CONTROL

Purpose	To ensure that the integrated management system documents used by the regulatory body remain relevant, updated, available, understandable, unambiguous, user friendly and readily accessible (by means of adequate preparation, review, approval, issue, distribution, use and revision of documents).
Inputs	1. Existing integrated management system (list of documents); 2. List of functions and tasks to be performed by the regulatory body; 3. Changes in legislation; 4. Changes in standards; 5. Changes in the regulatory body; 6. Changes in external expert support organizations; 7. Changes in interested parties.
Process	Used periodically or on demand of users. 1. Compare input data with existing documentation. 2. Regularly identify important activities (processes) performed by the

	regulatory body that are not documented yet (in the form of process descriptions, procedures and forms). 3. Regularly identify needs for modifications in documents (caused by e.g. changes in legislation, organization and changed modes of collaboration). 4. Use a subprocess for drafting or modifying documents: (a). Collect necessary information; (b). Draft new or modified document using templates and writers' guide; (c). Review of the draft (by different people), test user friendliness (may need iterations); (d). Approval of the draft by authorized people; (e). Inform the staff about changes in documentation (if necessary, do training); (f). Issue new document; (g). Distribute new document; (h). Archive old documents. 5. Regularly identify obsolete documents, take them out of circulation and archive them.
Outputs	1. Comprehensive set of up-to-date documents.
Interfaces	1. All other processes.
Performance criteria	1. Positive feedback of users; 2. Completeness of process descriptions and forms.

TABLE A-22. CONTROL OF PRODUCTS[8]

Purpose	To identify the products of the regulatory body and to ensure that the products meet legal requirements and standards as well as other requirements of the integrated management system.
Inputs	1. Information relating to regulatory documents and decisions; 2. Information relating to the integrated management system.
Process	3. Define the necessary information to develop the product (as a subprocess of other processes: core functions and functions supporting core functions); 4. Screen the available information for relevance and completeness; if necessary, collect more information; 5. Perform the task (a core function or function supporting core functions); 6. Draft the regulatory product; 7. Expert review of draft product; 8. Finalize the product; 9. Approval of the product by the relevant parts of the regulatory body.
Outputs	1. Regulatory products.
Interfaces	1. All other processes.

[8] Products of the regulatory body are internal and external documents, including regulatory reports, decisions, regulations and guides. Control of products means in this case assuring that the documents produced by the regulatory body are comprehensive, complete, reviewed and approved based on the relevant legal requirements and standards applicable to the work of the regulatory body.

Performance criteria	1. Number of iterations to finalize the product; 2. Satisfaction of the interested parties; 3. Timeliness of delivery.

TABLE A-23. CONTROL OF RECORDS

Purpose	To ensure that relevant records are collected, processed and retained for specified periods and that the records are reliable, complete, identifiable and easily retrievable.
Inputs	1. Structure of the document management system (archive); 2. All types of records (incoming documents, outgoing documents, internal documents such as reports, protocols and notes).
Process	1. Register all documents (incoming, outgoing, internally produced) according to the structure of the document management system. 2. Process documents based on relevant document and records classification. 3. Subprocess for registration and archiving: (a). Register and process all records; (b). Distribute copies of the records to concerned users; (c). Respect confidentiality and security rules; (d). Archive original record according the structure of the document management system. 4. Subprocess for retrieval.
Outputs	1. Well-structured archive; 2. Easy access to records in a reliable and timely manner for concerned users.
Interfaces	1. All other processes. Note: At a regulatory body, most of the processes create records as a product. So, most of the processes use the control of records as subprocess.
Performance criteria	1. Comprehensiveness of archive; 2. Easy and timely access to relevant information.

TABLE A-24. PURCHASING[9]

Purpose	To ensure that suppliers or products are selected on the basis of specified criteria and their performance is evaluated.
Inputs	1. Requirements for products or services.
Process	1. Specify the required product or service. 2. Define acceptance criteria. 3. Identify appropriate potential providers. 4. Identify if cost of product or service is within the budget. If not, look for additional financial resources or redefine priorities. 5. Call for bids for the product or service (respect legal constraints). 6. Collect and evaluate the bids.

[9] Purchasing is a process common to every organization. There are no specific issues related to a regulatory body.

	7. Select the supplier (respect legal constraints). 8. If necessary create, sign and countersign the contract. 9. Commission the product or service. 10. After delivery, evaluate the delivered product or service, compare with specifications and acceptance criteria; if not acceptable, either iterate or take other appropriate actions. 11. If acceptable, authorize the payment and close the contract.
Outputs	1. Products and services meeting the specifications and acceptance criteria.
Interfaces	1. Planning; 2. Finance; 3. Subprocess for many processes within the integrated management system.
Performance criteria	1. Satisfactory products and services (within specifications); 2. Timely delivery of products and services; 3. Cost of product or service within budget.

TABLE A-25. MEASURING AND TEST EQUIPMENT[10]

Purpose	To ensure that measuring and test equipment used in regulatory activities is adequate and appropriate for the purpose, well maintained and properly calibrated.
Inputs	1. Information from suppliers; 2. Requirements for calibration of measuring and test equipment: range of the instrument, admissible tolerance, calibration frequency, authorization for calibration, methods for calibration and documentation.
Process	Adequacy of measuring and test equipment: 1. Periodically review the adequacy of measuring and test equipment; 2. If measuring and test equipment is outdated, look for adequate new equipment; 3. If needed, start purchasing process. Calibration of measuring and test equipment: 1. Periodically review the calibration of measuring and test equipment; 2. If calibration date is close, start calibration, respect the necessary criteria; 3. After successful calibration, note the calibration date and the date for next calibration on the measuring and test equipment; 4. Enter calibration date and the date for next calibration into database.
Outputs	1. Adequate measuring and test equipment with up-to-date calibration.
Interfaces	1. Measuring and test processes; 2. Purchasing.
Performance criteria	1. Measuring and test equipment adequate and calibrated.

[10] Most of the production or surveillance industries need test equipment. There are no specific administrative issues concerning test equipment of the regulatory body.

TABLE A-26. FINANCE[11]

Purpose	To plan and account for the financial resources necessary to deliver the regulatory mandate, in accordance with the national laws and standards.
Inputs	1. Strategies and plans; 2. Identified financial needs; 3. Available resources.
Process	1. Main process: periodically create the budget and provide the necessary financial resources; 2. Subprocesses: financial control, book-keeping.
Outputs	1. Budget; 2. Adequate financial resources for the regulatory body to discharge its responsibilities; 3. Well balanced income and expenses.
Interfaces	1. Planning; 2. Human resources management; 3. Purchasing.
Performance criteria	1. Adequate financial resources available; 2. Well balanced income and expenses.

REFERENCES TO THE ANNEX

[A-1] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. DS473, IAEA, Vienna (in preparation).

[A-2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[A-3] INTERNATIONAL ATOMIC ENERGY AGENCY, Managing Regulatory Body Competence, Safety Reports Series No. 79, IAEA, Vienna (2014).

[11] This process is not specific for a regulatory body and may very largely depend on the structure and the financial provisions of the regulatory body as well as the legal and governmental system.

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