

# **IAEA SAFETY STANDARDS**

**for protecting people and the environment**

**STEP 8:** Soliciting  
comments by Member  
States

## **ORGANIZATION, MANAGEMENT AND STAFFING OF A REGULATORY BODY FOR SAFETY**

**DRAFT GENERAL SAFETY GUIDE**

**GSG XXX (DS472)**

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# 1. INTRODUCTION

## BACKGROUND

1.1. Regulation is essential to ensure safety for all facilities and activities that give rise to radiation risks. The existence of a legally based, independent, fully resourced and technically competent regulatory body is a fundamental element outlined in Principle 2 of the IAEA's Fundamental Safety Principles, SF-1 [1]. This principle is reinforced and further defined as a requirement in the Safety Requirements on Governmental, Legal and Regulatory Framework for Safety, GSR Part 1 [2]. Some of the content of this Requirements document is also included in the Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 3 [3].

1.2. Increasingly, the intention has been to bring together IAEA Safety Standards which deal with similar aspects of safety. Thus the Safety Fundamentals covered all facilities and activities and, similarly, GSR Part 1 [2] was not restricted in its coverage. This Safety Guide will maintain the approach by providing guidance on the organizational structure, management and staffing of regulatory bodies ensuring the control of all facilities and activities<sup>1</sup>, and in so doing promote a more consistent approach to organizational aspects and to resources needed. Clear consistent guidance 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 needed between various regulatory authorities, in order to facilitate co-ordination and co-operation.

1.3. This Safety Guide supersedes the following Safety Guides: Organization and Staffing of the Regulatory Body, 2002 (GS-G-1.1); Regulatory Control of Radiation Sources, 2004 (GS-G-1.5) (part of); Use of External Experts by the Regulatory Body, 2013 (GSG-4) and Management Systems for Regulatory Bodies (DS113).

1.4. Most of the supporting Safety Guides in this field were over ten years old and needed to be reviewed, and in some cases only covered a subset of the facilities and activities. To be able to include such a wide range of facilities and activities it is necessary to apply a graded approach so that the degree of regulatory control and requirements varies in a manner appropriate for the risks associated with the various facilities and activities. This graded approach has been increasingly used within IAEA Safety Standards so that the similarities of the requirements can be emphasised rather than the differences.

1.5. Organizational and managerial aspects have proven of fundamental importance for regulatory bodies to be able to perform their functions in all circumstances. This is one of the lessons learned

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<sup>1</sup> Facilities and activities, a general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other activity or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources. See GSR Part 1 footnote 4 for more complete definitions.

from the Fukushima Daiichi accident. This Safety Guide covers organizational structure, management and staffing of regulatory bodies ensuring the control of all facilities and activities, to support them in carrying out their responsibilities and functions in an independent manner taking into account the need for a graded approach in accordance with national circumstances and facilities and activities that give rise to radiation risks.

1.6. This Safety Guide has been developed in parallel with IAEA Safety Guide DS473 [9], covering the technical aspects of a regulatory body's core functions and associated core processes. It is strongly recommended that the two Safety Guides are treated as complementary guidance.

1.7. The information in these Safety Guides is intended to be mainly used by regulatory bodies but can be also useful for governments who are developing a regulatory framework for radiation and nuclear safety. It will also assist authorised parties and others dealing with radioactive materials in understanding the fundamental organizational and functional aspects of regulatory control for all facilities and activities that give rise to radiation risks.

1.8. This Safety Guide is also intended for States embarking on a new nuclear programme or significantly extending an existing programme, already having an existing regulatory system for other radiation facilities or activities. These 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 programme can be found in the IAEA Safety Guide SSG-16 [10].

## OBJECTIVE

1.9. The objective of this Safety Guide is to provide practical guidance and recommendations to regulatory bodies on their organizational structure, management and staffing to support them in carrying out their responsibilities and functions in an independent manner, taking into account the need for a graded approach in accordance with national circumstances and with radiation risks associated with facilities and activities.

1.10. The core functions are those described in GSR Part1 [2] and GSR Part 7 [4]:

- Development of regulations and guides;
- Notification and authorization, including licensing procedures;
- Regulatory review and assessment;
- Regulatory inspection;
- Enforcement;
- Emergency preparedness and response;
- Communication and consultation with interested parties.

The regulatory core functions and their interactions, as well as the associated core processes, are described in detail in the Safety Guide DS473 [9].

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

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

1.12. This Safety Guide offers guidance on how to organize and staff a regulatory body in order to fulfil its regulatory functions in an effective and efficient manner. Also it offers guidance on how an integrated management system should be set up and implemented, in order to have: 1) core processes that help the regulatory body to perform its core functions; and 2) management and support processes that are necessary to run the regulatory body.

## SCOPE

1.13. This Safety Guide covers the organizational and managerial aspects of regulatory bodies of fundamental importance for the regulatory core functions to be performed in all circumstances, thus promoting a more consistent approach to organizational aspects and to resources needed. This will allow the regulatory body to have an integrated and overall view of facilities and activities. In particular, this is to be ensured not only by the technical dimensions but also by the cultural, organizational and individual aspects (Human and Organizational Factors), supporting strong regulatory effectiveness, supplemented by a questioning attitude and self-reflection on its own culture and on the influences on the authorized parties.

1.14. The terminology used in this Safety Guide involves a limited number of terms for simplicity and economy. The term “organization” depicts a social unit of people that is structured and managed to meet a need or to pursue collective goals. All organizations have a management structure that determines relationships between the different activities and the members, and subdivides and assigns roles, responsibilities, and authority to carry out different tasks. The term “authorized party” is used in this Safety Guide to indicate the person or organization responsible for an authorized facility or an authorized activity, whether they are a licensee, registrant, operator or operating organization. Interested parties, also known as stakeholders or concerned parties, are those individuals or organizations concerned with safety and the regulatory body’s decisions. Interested parties include,

among others, the general public, such as people residing in the vicinity of facilities and activities; elected officials and governmental authorities at the national, regional and local level; national and local non-governmental organizations; regulated industry and its employees, trade unions, and suppliers; professional and academic organizations; news media; and neighbouring countries. Also, on grounds of simplicity and economy, the term “safety” is used throughout to mean “radiation and nuclear safety” and similarly “operation of facilities and conduct of activities” is used to cover all practices and applications of radioactive and nuclear materials.

1.15. The scope of this Safety Guide is limited to the regulation of radiation and nuclear safety and does not extend to nuclear security. Where nuclear security is mentioned in this document it is only to remind the reader that nuclear security aspects need to be considered through an appropriate interface, especially for crisis management. Guidance on addressing nuclear security aspects can be found in the Nuclear Security Series publications: Nuclear security recommendations on physical protection of nuclear material and nuclear facilities [7] and Nuclear Security Recommendations on Radioactive Material and Associated Facilities, [8] and supporting guidance.

## STRUCTURE

1.16. Section 2 of this Safety Guide sets out the generic characteristics of a regulatory body with responsibility for safety while Section 3 focuses on the traits of a management for safety. Section 4 discusses the organizational aspects that provide for the implementation of the core and support regulatory functions. Section 5 outlines the characteristics of an integrated management system, necessary for an effective and efficient regulatory body, and Section 6 addresses the topics of staffing, qualifications and competencies, which should be considered in order for regulatory bodies to effectively perform their functions and to discharge their responsibilities. Appendices I, II and III give more detailed guidance on the use of external expert support, examples of generic management processes and basic elements of a regulatory body training programme, while Annexes I and II provide an overview of the structure of an integrated management system and generic process descriptions respectively.



## 2. GENERIC CHARACTERISTICS OF A REGULATORY BODY

### INTRODUCTION

2.1. Preparing a set of organizational values helps to guide the behaviors of all staff to create a strong safety culture which is in line with the regulatory body's mission. Regulatory values should incorporate the following characteristics:

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

2.2. In performing its functions, it is important that the regulatory body has a systemic and holistic view so it can properly interact with all interested parties, including government, authorized parties and the public.

### INDEPENDENCE

2.3. The need for regulatory independence is affirmed in the Convention on Nuclear Safety, the Joint Convention on the Nuclear Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the Code of Conduct on the Safety of Research Reactors, the Code of Conduct on the Safety and Security of Radioactive Sources and in the IAEA Safety Requirements GSR Part 1 [2] and focuses on the separation of the regulatory body from the promoters of nuclear technology. The primary reason for this separation is to ensure that regulatory judgements can be made, and enforcement actions taken, without any pressure from interests that may conflict with safety.

Furthermore, the credibility of the regulatory body in the eyes of the general public depends in large part upon whether the regulatory body is regarded as being independent from the organizations it regulates, as well as independent from government agencies or industry groups that promote nuclear technologies.

2.4. It is recognized that a regulatory body cannot be absolutely independent in all respects of other parts of government: it must function within a national system of laws and budgets, just as other governmental bodies and private organizations must do. Nevertheless, for the regulatory body to have credibility and effectiveness, it should have effective independence in order to be able to make the necessary decisions in respect of the radiation protection of the people and the environment. At the same time, the need for independence of the regulatory body does not imply that it ought to have an adversarial relationship with authorized parties or with any other party. The following paragraphs provide a more detailed discussion of a number of aspects of regulatory independence.

### **Political aspects**

2.5. GSR Part 1 [2] states that, in order “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”.

2.6. However the regulatory body remains accountable to parliament and government, as well as to the general public with regard to effectively and efficiently fulfilling its mission to protect workers, the public and the environment from radiation hazards. Such means of ensuring accountability may be: establishing a direct reporting line to the highest levels of government, as well as undertaking regular audits and peer reviews.

### **Legislative aspects**

2.7. 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.

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

2.8. Where regulatory responsibilities for safety are divided, the legislation should establish clear lines of authority and responsibility so as to avoid gaps or overlaps. Therefore the regulatory authorities

should formally establish a system of liaison and working procedures so as to ensure an appropriate degree of co-ordination and co-operation between regulatory bodies sharing responsibilities.

2.9. Although the regulatory responsibilities may be divided among several authorities for specific safety aspects, having a single authority with regulatory responsibilities for all aspects of safety offers advantages with regard to legally specifying and clearly allocating regulatory responsibilities and avoids gaps or overlaps.

### **Financial aspects**

2.10. 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 should not depend on fines or penalties collected from licensees, nor should it be decided by or be subject to the approval of those parts of the government which are responsible for exploiting or promoting nuclear technologies.

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

2.12. Specific provisions to fund the regulatory body should be established through implementing legislation or through the national fiscal process. How this is best accomplished will depend on a number of considerations and factors, including:

- National precedents for funding other 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 regulatory body functions;
- How the regulatory body is structured, including its use of in-house and outsourced competencies.

2.13. However, an open and transparent system of auditing and governance of the regulatory body's funding should be in place. Review and approval of the regulatory body's budget should only be performed by governmental agencies that are effectively neutral to the development, promotion or operation of facilities and activities. This provides additional assurance for the independence of the regulatory body.

### **Competence aspects**

2.14. The independence of a regulatory body's decision making depends heavily on the competence of its staff. The regulatory body should have sufficient technical expertise in the areas relevant to its safety mission. 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. In order to maintain independence, the following types of competence are needed:

- Competence in the relevant scientific and technological areas;
- Competence with regard to the installations, organizations and activities of the licensees;
- Competence in applying the regulatory processes 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 Chapter 6 Staffing and competence of staff.

2.15. 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. It is essential to underline that advice obtained is independent and it does not relieve the regulatory body of its assigned responsibilities. As further detailed in section “Provision of resources”, the regulatory body should acquire, manage, maintain and preserve knowledge and information for building and maintaining adequate core competencies. This should be performed in the frame of a coherent process within the regulatory body’s integrated management system, further addressed in Chapter 5 Integrated management system, with the objective to make informed decisions as well as to obtain the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants. The external expert support may be provided in several ways, as described in further details in Appendix I External support.

### **Aspects of communication and consultation with interested parties**

2.16. The credibility of the regulatory body to the general public depends in large part upon whether the regulatory body can demonstrate it is independent of the organizations that it regulates as well as independent of governmental organizations and industry groups that promote nuclear technologies.

2.17. As such, the regulatory body should have the authority and the obligation to establish provisions for appropriate means of communication with the 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. Informing and consulting interested parties and the public should be done by means of a transparent, open and constant communication process.

### **International aspects**

2.18. A systematic program for professional reviews and audits of regulatory performance is a useful tool to promote independence in decision making by the regulatory body. This should include

participation in various types of international professional co-operation exercises and external peer reviews, either of a specific regulatory activity or of the regulatory body as a whole.

## COMMITMENT FOR SAFETY

2.19. The protection of the people and the environment from any hazard due to ionizing radiation is the main focus of the regulatory body. In doing so, the view of the regulatory body should cover all aspects of a facility or activity including its organization and its staff. The regulatory body should have a holistic approach in discharging its responsibilities, taking into account all aspects of Individuals, Technology, and Organization (ITO) and their respective interactions.

2.20. Every member of the regulatory body should exhibit a strong commitment to safety. This commitment can be achieved by developing and fostering a strong safety culture within the regulatory body as further described in section 3.2 Safety culture.

## ACTING IN THE PUBLIC INTEREST

2.21. The prime responsibility for safety rests with the authorized parties. The regulatory body should ensure that its actions do not take the prime responsibility from the authorized parties.

2.22. While this responsibility of the regulatory body is defined by legislation, expectations of the public may go beyond legal requirements. In order to maintain its authority and credibility the regulatory body should establish and maintain arrangements for effective communication 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 for collection of concerns and questions from the public;
- Information channels specifically addressed for public information, etc.

2.23. Information collected from public questions and proposals should be carefully analysed and dealt with in a professional manner. Response to the public should be performed in a timely manner. The information collected may also be used in the regulatory body's working modes, regulations, guides and procedures where appropriate and not in contradiction with the regulatory body's mandate.

## OPENNESS, TRANSPARENCY AND PREDICTABILITY

2.24. Regulatory requirements, regulations and guides should be clear and unambiguous, and should be written in a manner that can be understood by the authorized parties. A strong communication with all interested parties enables the regulatory body to take into account all the different perspectives and expectations and to consider them in the basis for establishing or modifying the regulatory framework.

2.25. The regulatory body should assure that regulations and requirements are applied in a consistent, transparent, balanced and predictable manner. The regulatory body should apply policies to establish and cultivate principles that promote proportionality, transparency and consistency, and the broad sharing of information and ideas in the conduct of the work.

2.26. Transparency and openness towards the general public enhances confidence and trust in the working modes of the regulatory body.

## COMMITMENT FOR CONTINUOUS IMPROVEMENT

2.27. The nuclear programme, technologies, rules and regulations, expectations from the public etc. change with time. The regulatory body's organization, staff, competences and knowledge as well as the integrated management system should adapt to these changes.

2.28. The regulatory body should have a questioning attitude regarding its functions and activities, and the activities of authorized parties. This requires a continuous improvement process for the regulatory body. This process is covered in section Measurement, assessment, evaluation and continuous improvement.

### 3. MANAGEMENT FOR SAFETY

#### LEADERSHIP FOR SAFETY

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

- Promoting a systemic/holistic approach to safety that embraces all ITO interactions;
- 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 safety policy, vision, strategy, plans and objectives, whereby safety is paramount, overriding all other priorities;
- 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 and 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. This shall include capabilities for leadership in severe or unexpected situations;
- 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 employees to achieve safety in their work and seek their active involvement in improving safety performance including the consideration of staff's input in safety related decisions;
- Demonstrating commitment to the establishment, implementation, assessment and continuous improvement of the integrated management system by actively seeking information on performance within their area of responsibility, 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 readiness to challenge acts or conditions which are inconsistent with the values of the regulatory body;
- Identifying and remedying pressures and conflicts which inhibit the discharge of responsibilities and functions;

- Creating a working environment that allows employees to feel responsible for their work and develop their competences. This may be achieved 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. The regulatory body should have a good safety culture to ensure that all staff members are committed to give safety the highest priority in all activities.

3.3. Desired and expected attitudes and behaviors, (including those of possible external experts or technical support organizations), that promote a strong safety culture should be defined and communicated throughout the entire regulatory body.

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

3.5. Five major characteristics of a strong safety culture are defined as follows:

- 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.

These characteristics should permeate the entire regulatory body, so that individuals show a questioning attitude, feel responsible and are supported in identifying safety concerns.

3.6. A good safety culture does not grow by itself, nor can it be controlled but it can be influenced. The role model of leaders, their behaviour and commitment to safety influence the attitudes and behaviours of individuals. Therefore, a good safety culture needs the strong commitment and engagement of the senior management with the support of the integrated management system.

3.7. Attitudes and behaviors that support a good safety culture include:

- 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 and feedback for identified problems and suggestions for improvement;



- The regulatory body continuously seeks to develop and improve safety and the safety culture;
- Encourage a questioning and learning attitude and to discourage 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 risks and hazards relating to the potential consequences of regulatory activities. All factors that might impact upon safety must be taken into account during the regulatory body's decision-making process.

3.8. The regulatory body should establish and maintain a programme to develop, to foster and to evaluate its safety culture. This may be facilitated by installing a permanent internal working group that oversees the safety culture development. Such a development 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. A regulatory body has the responsibility to assure that the public and the environment are protected from hazards of ionizing radiation. Therefore the regulatory body should:

- Have regulations and guides in place for all types of facilities and activities that are included in the scope of the national framework for safety;
- Ensure that the facilities and activities are in compliance with these national requirements and that the authorized parties are aware of their prime responsibility for safety.

3.10. The regulatory body is accountable for how it discharges this responsibility. This means that the regulatory body should:

- Have policies and standards against which it can be judged by government and other interested parties in an open and transparent manner;
- Be able to justify and explain its judgements and decisions; and,
- Have an effective mechanism for interested party interactions.

3.11. The State should provide for independent oversight and governance of the regulatory body and its key decisions. This may be achieved in a number of different ways, for example by the establishment of a Commission or Management Board. Such arrangements could also provide independent oversight and governance of an appeals process for actions and decisions made by regulatory staff. A method of ensuring accountability in some States is the establishment of a direct reporting line from the regulatory body to the highest levels of government. Peer review systems,

national or international, can 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 should ensure that the resources<sup>2</sup> 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.

### **Financial resources**

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

3.14. The regulatory body's funding program should be reviewed periodically. Special attention should be paid to upcoming changes in the national nuclear program, such as the introduction of new facilities, life cycle changes including closures, decommissioning and waste disposal as well as changes in the public's expectations.

3.15. The regulatory body should be able to either develop its own budget or – in the case of strong dependency or national restrictions – to influence the budgetary conditions of the regulatory body's funding.

### **Human resources**

3.16. The regulatory body should 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 in an efficient and effective manner.

3.17. Adequate staffing is an important issue to give the regulatory body the necessary resources, competence and capabilities to develop its own independent decisions on the safety of facilities and activities. As such, special attention should be paid to the development, education and training of the regulatory body's staff in a dedicated human resources process.

3.18. Where external expert support is used, special attention should be made that sufficient internal staff is available, having the capability to determine the need and extent for using external expert support, as well as being able to evaluate the adequacy of information received from external expert

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<sup>2</sup> Resources includes individuals, infrastructure, the working environment, information and knowledge, and suppliers, as well as material and financial resources [5].

support. Responsibilities for core regulatory functions cannot be delegated. Details on staffing and the competence management of the Regulatory Body are described in Chapter 6 Staffing and Competence of Staff.

### **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 (II-21. Knowledge management in Annex II).

3.20. Dedicated processes should be established to acquire, use, maintain, store and retrieve information and knowledge, from the early stages of development of the regulatory body's integrated management system. These processes should be supported by specific adequate tools and techniques, tailored for the present and anticipated needs of the regulatory body. Examples include:

- Capture and transfer: questionnaires, interview, informal discussions, reports (special attention need the transfer of tacit knowledge in the case of retirements and leaves);
- Storage and retrieval: databases, libraries, portals, archives.

3.21. An effective management for safety should take into account the knowledge and information resulted from both positive and negative experiences (e.g. good practices and less effective practices). Examples of information and knowledge relevant for regulatory bodies include:

- Collective experience of the regulatory staff;
- Technical expertise;
- Lessons learned from regulatory practices, e.g. Techniques of assessment and inspection;
- Feedback from interested parties;
- Experience from other authorities and national and international bodies;
- Operational experience of national and international authorized facilities and activities.

3.22. Such information and knowledge represent an integral part of the management for safety and are used in support of regulatory processes. Competence management, in particular, benefits from the information provided by the knowledge management process. This topic is of special importance for a regulatory body and is detailed in section Competence Management.

### **Other resources**

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

- Offices, including furniture, environmental equipment and office supplies;
- IT and communications equipment, including software and network systems;
- Emergency arrangements;

- Personal protective equipment;
- Regulatory measuring and testing equipment, plus laboratories;
- Records systems, including filing and libraries;
- Support facilities;
- Transportation.

## INTERACTIONS WITH INTERESTED PARTIES

3.24. Regulatory bodies have a number of interested parties, including their own staff and other groups within government, the industry, the media and the public, as well as residents living close to facilities. In some cases there may be legal requirements which prescribe the provision of information and consultation. As part of a policy of openness and transparency and in order to secure the continued confidence and trust of all parties, regulatory bodies should establish effective working relationships with the interested parties.

3.25. Regulations and guides represent a powerful mean to communicate the regulatory body's opinions, modes of work and basis for decisions to interested parties. Therefore, in developing regulations and guides, the opinion and needs of interested parties should be considered.

3.26. Each interested party will have differing expectations of the regulatory body according to their functions, roles and interests. In order to understand and address these needs and expectations the regulatory body should establish a process securing effective interactions with all interested parties. A suitable process of 'interested party relations' would include:

- Identifying all relevant interested parties and legal requirements relevant to informing and consulting interested parties;
- Clarifying their needs and expectations of the regulatory body and ensuring that these are recognized and understood;
- Evaluating these needs and expectations and determining an appropriate and balanced response by the regulatory body;
- 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 interested party satisfaction to judge how well the regulatory body is meeting interested party needs.

3.27. The measurement of interested party satisfaction essentially involves gathering information about interested parties' perceptions of the role and performance of the regulatory body. The results of the analysis should provide an input to the continuous improvement process of the regulatory body.

## 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 DS 473 and only a brief description is provided below for completeness.

4.2. In fulfilling its core functions there are also several supporting functions that should be available within the regulatory body. These supporting functions are necessary enablers in fulfilling the core functions, and a regulatory body could not operate satisfactorily without most of them. Core 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. All these functions should be organized in their associated processes and should be represented in the regulatory body's integrated management system (see Chapter 5 Integrated Management System and Annex II Process Descriptions).

### FUNCTIONS OF THE REGULATORY BODY

#### **Core regulatory functions**

##### *Development of regulations and guides*

4.5. The main objective of the regulations and guides is to specify the principles, requirements and associated criteria for protection and safety upon which regulatory policies, judgments, decisions and actions are based, within the legal framework.

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:

- Provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach;
- Are consistent and comprehensive;
- Are kept up-to-date; and
- Involve consultations with the interested parties.

### *Authorization and notification*

4.7. 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 that the applicant can fulfil its safety obligations; demonstration of staff competence, where appropriate; and demonstration of safety by the applicant. These aspects should be subject to suitable review and assessment by the regulatory body before the authorization is issued. In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities.

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

4.9. The regulatory body should have the power to accept and process notifications and applications for authorisation for any use and handling of radioactive material.

### *Review and assessment of facilities and activities*

4.10. The regulatory body reviews and assesses 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 should be performed prior to authorization and during the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.

4.11. The review and assessment process is a critical appraisal, performed by the regulatory body, of information submitted by the authorized party or which comes from inspection, information on events or other specified reports (Periodic Safety Reviews, monthly and annual reports, etc.) to demonstrate the safety of the facility or activity. Review and assessment are undertaken in order to enable the regulatory body to make a decision or series of decisions on the acceptability of the facility or activity in terms of safety. The process consists of examining the authorized party's submissions on all aspects relating to the safety of the facility or activity. The review and assessment process should include checks on the site and elsewhere to validate the claims made in the submissions.

### *Inspection of facilities and activities*

4.12. Requirement 27 of GSR Part 1 [2] requires that “The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.” In addition, inspections should be performed to allow the Regulatory Body to supplement or to verify information submitted by the authorized parties as well as to build up its own opinion on safety relevant issues.

4.13. GSR Part 1 [2] makes it clear that the regulatory inspection should not 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.

4.14. GSR Part 1 [2] further requires that the 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 operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections.

### *Enforcement of regulatory requirements*

4.15. Requirement 30 of IAEA Safety Standards GSR Part 1 [2] requires that the regulatory body 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.

4.16. 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, authorized conditions and requirements.

4.17. The principal objectives of enforcement (in conjunction with inspections) are to provide a high level of assurance that all activities performed by the authorized party at all stages of the authorization process and all stages during the lifetime of a facility or activity (siting, design, construction, commissioning, operation and decommissioning or closure) have been executed safely and meet the safety objectives and authorization conditions.

4.18. Enforcement actions are intended to modify or correct any aspect of an authorized party’s procedures and practices or of a facility’s systems, structures and components (SSC) as necessary to



ensure safety. Enforcement actions may also include the imposition or recommendation of civil penalties and other sanctions.

### *Emergency preparedness and response*

4.19. The roles and responsibilities in emergency preparedness and response (EPR) are to be allocated among authorized party, response organization and the regulatory body. While certain roles and responsibilities in emergency preparedness and response are valid for any regulatory body, the government may assign the regulatory body additional roles and responsibilities in emergency preparedness and response but their precise nature will depend on the specific legal and organisational arrangements in the Member State. In the following text, therefore, it is only possible to identify the necessary functions and processes that the regulatory body should perform, in relation to these roles and responsibilities, in a generic manner.

4.20. Functions and processes that the regulatory body should perform are:

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

See DS473 [9] for further details on the regulatory body's EPR functions and processes.

### *Communication and consultation with interested parties*

4.22. The regulatory body should provide information concerning its activities to the interested parties including the public, both on a regular basis and in relation to 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 complying with requirements of commercial confidentiality and information security. Public information should be managed by experts in the field so as to ensure that the information provided is clear and comprehensible. The establishment of a specialized public information unit should be considered.

4.23. 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, discussing and considering public issues and concerns regarding safety.

## Supporting functions

4.24. 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, equipment purchasing and control) and,
- Technical functions directly related to the effective implementation and fulfilment of the core regulatory functions. (e.g. legal support, research and development, external expert support, advisory committees, international cooperation)

Most of these functions should also be represented in processes of the regulatory body's integrated management system.

### *Administrative functions*

4.25. The regulatory body should have organizational units dedicated to various administrative activities, often 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 security of the premises;
- Personnel administration (human resources management), which covers recruitment and training, internal communication, arrangements for medical care, security of personnel, travel arrangements and so on;
- 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. authorisations, permits;
- Computer and/or data administration, adequate computing capability for technical use (data handling, analytical computing) as well as general IT uses and IT-security;
- Preservation of 'corporate memory', knowledge management and library services including access to specialized publications;

### *Legal support*

4.26. The regulatory body by its nature is engaged in activities that involve meeting legislative requirements and so may require professional legal support. The objective of legal support is to provide the regulatory body with legal advice on international obligations, national legislation and development of rules, regulations and guidance documents, for the implementation of the regulatory body's core functions.

4.27. Activities typically requiring professional legal support include, but are not limited to:

- Development of basic legislation;
- Development of regulations and review for compatibility with relevant laws and other 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 the technical units and public information officers, if designated, in responding to requests for public information.

4.28. The 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 guidelines and procedures;
- Authorization by the regulatory body for facilities and activities;
- Enforcement actions;
- Existing and proposed safety standards, and technical and policy issues related to the authorisation of facilities and activities; and,
- Other matters deemed relevant by the regulatory body (e.g. Contracts, cooperative matters).

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

### *Research and development*

4.30. Research and development provide supporting information in regard to the safety of the operation of a facility or the conduct of activities and should be performed under a systemic view, considering ITO aspects.

4.31. Research and development is intended to:

- Confirm existing knowledge;
- Identify any technical issues and resolutions;
- Improve existing scientific and technical knowledge; and,
- Develop technical bases to support new regulations and/or operational procedures.

4.32. Research and development is an essential supporting function that is needed to enable the regulatory body to assess and evaluate the adequacy of the technical basis supporting its regulations and regulatory activities. These capabilities will enable the regulatory body to evaluate key significant issues that impacts safety. The organisation which performs 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 the scientific and technical state of the art which results both from national and international research and development programmes. Research and development programmes in nuclear safety should be organised to maintain and continuously develop the knowledge and competency of regulatory personnel.

4.33. The organizational structure of the regulatory body should reflect the need for research and development, either by the establishment of a research unit or by recruiting staff who can define research and development needs, determine the appropriate external expert support organisation, initiate, coordinate and monitor the necessary work, and evaluate the results.

4.34. The regulatory body should request authorized parties to carry out the research and development necessary to produce an adequate body of knowledge to demonstrate safety. In addition, the authorized party's research and development methodology and results should be assessed by the regulatory body for adequacy. The regulatory body may consult with an appropriate advisory committee for the evaluation of the research and development programme.

#### *Advisory committees*

4.35. Advisory committees provide the regulatory body with independent expert opinion on the adequacy of the regulatory activities to maintain safety. Advisory committees are typically independent<sup>3</sup> bodies of experts having the power or right to give advice and make suggestions about what should be done to maintain safety for authorized facilities and activities.

4.36. Advisory committees should 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. The advisory committees should advise the regulatory body on:

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<sup>3</sup> "Independent" means that the members are not staff of the regulatory body.

- Reviewing how the regulatory body performs its regulatory responsibilities and functions;
- The adequacy of its regulations as well as the implementing guidelines and procedures for such regulations;
- Existing and proposed safety standards, and technical and policy issues related to the authorisation of facilities and activities; and
- Other matters referred to the committee by the regulatory body.

4.38. The regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body. A well founded advisory committee can render 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. The advisory committee should report to the highest level of authority within the regulatory body. It may consist of representatives from government departments, other regulatory bodies, regulatory bodies of other States, scientific organizations, senior technical experts, academia, non-government organizations and authorised parties. Membership of the advisory committee should represent a balance of interests across various sectors of interested parties. The regulatory body should clearly define terms of reference which specify the role and responsibility of the advisory committee, its constitution and the selection criteria for its membership. The advisory committee 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, at a minimum, adequate competence in every core and supporting function, so that it has the ability both to formulate and manage its requests for technical advice and to understand, evaluate and implement the advice.

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

4.42. Where the regulatory body uses a technical support organization or consulting company, the regulatory body should establish the requirements for the integrated management system to be used. In some cases, the existing TSO or company integrated management system may be adequate, while in other cases, the regulatory body should use the contract to establish the requirements for the integrated management system to be used. In the case of individual experts, the expert should conform to 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 needed. Examples of support providers can be found in Appendix I.

#### *Liaison with other governmental organizations*

4.44. The regulatory body should interact with other governmental organisations that have regulatory responsibilities which 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 for nuclear security and/or safeguards;
- Authorities for planning water resources and land use;
- Water and food consumption authorities;
- Authorities responsible for public and occupational health and safety;
- Fire protection authorities;
- Transport authorities;
- Law enforcement bodies;
- Entities or bodies with responsibility other aspects of safety;
- Other bodies with responsibilities for emergency preparedness and response; and,
- Other bodies with responsibilities for limits on releases of radioactive effluents.

4.45. In preparing legislation, special consideration should be given to the establishment of a system of strict regulatory control for environmental protection and safety, nuclear security and materials accounting. The arrangements for how governmental organisations 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 organization's responsibilities, the areas of interface and the means of resolving any conflicts between different requirements. It should be ensured that no conflicting requirements are placed upon an authorized party.

4.47. 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. All staff members 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.

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

### *International cooperation*

4.49. Requirement 14 of GSR Part 1 states that the government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation 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 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;
- 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 abilities of the regulatory body to fulfil its regulatory responsibilities and contribute to the global harmonization of safety standards;
- Regular multilateral and bilateral cooperation with relevant national organizations that enhance safety by means of harmonized approaches as well as increased quality and effectiveness of safety reviews and inspections through knowledge and experience sharing (e.g. by developing networks).

4.51. The regulatory body should participate in international activities through international multilateral conventions and agreements. In some cases this is through a government mandate. In addition the regulatory body should also seek international cooperation through multilateral and bilateral agreements with other regulatory bodies and other organisations.

4.52. The regulatory body should actively participate in international working groups to provide

advice and assistance to international organizations and other States to help develop effective regulatory bodies and enforce rigorous safety standards for global applications. Participation in these institutions, in turn, are a most valuable means to exchange experience and to benchmark own ideas against international practice.

4.53. 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.

4.54. 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 regular staff meetings on specific subjects and other matters. Multilateral cooperation may involve different approaches, for example, regional approaches, multilateral approaches based on the design or type of the facilities concerned and approaches on the basis of common problems concerning safety.

4.55. The regulatory body should also serve as the contact body 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 these systems and to ensure the communication of information to and from authorized parties and other governmental organizations.

## ORGANIZATION

4.56. The regulatory body should be provided with adequate resources and the necessary authority to discharge its responsibilities. Therefore, it may be appropriate to establish an organizational structure that is flexible and adaptable to different circumstances and demands. Depending on the national circumstances, the organization of the regulatory body will vary widely from State to State, depending on the following factors:

- Magnitude and maturity of the existing facilities and activities;
- Magnitude of future plans (new installations and/or facilities, new technology, lifecycle activities e.g. decommissioning);
- National legal framework;
- Other existent regulatory authorities;
- Expectations of interested parties;
- Availability of competences at national level (education institutions, potential TSOs); and,
- Availability of funding.



4.57. These factors may impact the organization in terms of: regulatory functions, structure, size, use of external expert support, competence management. Nevertheless, the organization of the regulatory body should 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 the analysis of the factors mentioned above.

4.58. The regulatory body should ensure that the different parts of its organisation have a clear delineation of their specific responsibilities. The organisational structure of the regulatory body may be based e.g. according to regulatory functions (process-based organization), according the technical areas to be covered (e.g. in a line-organization), according the facilities and activities to be oversight or a mixture of these (matrix organization or project organization). Nevertheless, it should allow for the integration and interaction among the various technical and administrative units in the implementation of the activities associated with the core and supporting functions.

4.59. Regardless of the selected structure, attention should be paid to the distribution of expertise and required competences in organisational units. However, it should be emphasized that the regulatory body uses an interdisciplinary approach to the oversight concept, enabling the regulatory body to implement a systemic approach and adequately consider all aspects relevant to safety with an integrated view to ITO and their interactions.

4.60. The structure and composition of the regulatory body's organization should be flexible 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 need for changes may arise unexpectedly, therefore, in order to allow flexibility; the regulatory body should have a process in place for managing organizational changes. This process should be established in the very early stages of the regulatory body since changes take place often during the growth of a regulatory body.

## ROLES AND RESPONSIBILITIES OF THE MANAGEMENT

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

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. The senior management team or board of a regulatory body has the ultimate responsibility for the effectiveness and efficiency of the regulatory body. They should establish and execute an effective process to provide consistent direction and oversight for an effective implementation of the regulatory functions

4.63. In order to gain the acceptance of their authority by the staff, managers at all levels should demonstrate effective leadership that continuously improves safety awareness and safety culture (see Section Leadership for safety in Chapter 3).

4.64. Senior management should establish and maintain the vision, values, policies, strategies and goals of the regulatory body commensurate with the legal framework, its mission and the needs and expectations of interested parties. Vision, values, policies, strategies and goals should be subject to regular review and modifications – if needed – depending on developments of the legal system, evolution of the nuclear programme, expectations of the interested parties, but also considering national and international operational experience and developments.

4.65. 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.

4.66. Senior management is responsible for the establishment, maintenance and change of an appropriately structured and staffed regulatory body with sufficient competence to fulfil the regulatory functions as well as for the development, implementation, maintenance and review of an effective integrated management system.

4.67. In order to keep the regulatory body efficient and effective, senior managers should ensure that:

- Managers develop plans for their delegated areas of responsibility which are aligned with the strategies and plans, and that these are implemented;
- All managers communicate effectively with their staff to keep them informed about the regulatory body's strategic plans and their contribution to delivering; and,
- Managers provide effective supervision and oversight as well as appropriate support for their staff.

4.68. In support to the implementation of the plans for the achievement of the regulatory body's objectives, senior management should ensure that the essential resources are identified and made available. Types of resources include financial, human, information/knowledge and other resources, as appropriate, as described in Chapter 3 Management for safety.

4.69. The role and responsibilities of managers of a regulatory body may not differ essentially from roles and responsibilities of managers in other companies. 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 the senior managers. The roles and responsibilities of managers include:

- Implementing the mission, strategy and plans;
- Identifying and developing strategies and plans for own organizational unit;
- Allocating duties and responsibilities to staff in own organizational unit;

- Implementing, managing, monitoring and evaluating own processes, according to the integrated management system;
- Identifying required resources for own organizational unit;
- Developing a motivating work environment for the staff in giving them responsibilities for challenging tasks and supporting and coaching them in the need of assistance.

4.70. There is one characteristic that stands out for managers of a regulatory body: their commitment to safety and to other characteristics of the regulatory body, as described in chapter 2 Generic Characteristics of a regulatory body, should be well pronounced and visible. All managers in a regulatory body should act as role models concerning safety awareness in demonstrating a questioning attitude and good communication. These attitudes play an essential role in developing a good safety culture within the regulatory body.

## 5. INTEGRATED MANAGEMENT SYSTEM

### GENERAL

5.1. The requirements for establishing, implementing, assessing and continually improving an integrated management system, integrating safety, health, environmental, security, quality, societal and economic elements, are in the IAEA Safety Requirements no. GS-R-3 “The Management System for Facilities and Activities” [5].

5.2. The integrated management system of the regulatory body is a set of coherent processes and procedures that control the fulfilment of the regulatory functions in an effective and efficient manner, considering all internal and external conditions. The processes of an integrated management system should coherently reflect all internal and external requirements, such as:

- Safety;
- Nuclear security;
- Legal;
- Quality;
- Environment;
- Health and industrial safety;
- Social;
- Economic;
- Expectations of interested parties.

5.3. Senior management has the ultimate responsibility for the integrated management system, since this system is an essential tool to ensure:

- Regulatory functions are carried out in an effective and efficient manner;
- Regulatory responsibilities are adequately discharged;
- Consistency and predictability of regulatory actions;
- Continuous improvement;
- Fostering a strong safety culture;
- Promotion of an open and questioning attitude.

5.4. The development, implementation, maintenance and improvement of the integrated management system need substantial resources – human, financial, information, others. Senior management should ensure that these resources are made available.

5.5. For the continuous improvement of the integrated management system, the effectiveness of the processes should be regularly evaluated against preset criteria. Processes that do not meet these criteria should be corrected (plan, do, check, act).

5.6. Three different phases can be differentiated when an integrated management system is developed and set up: the development phase, the implementation phase and the maintenance phase.

5.7. The development phase can be divided in two stages. The first stage includes the identification and definition of the processes necessary for the regulatory body to discharge its responsibilities. The second stage details and documents the content of each individual process in the context of the overall structure.

5.8. The implementation phase of the integrated management system involves rolling out the processes in a planned and systematic way across the regulatory body. This includes training for the whole staff, selective training of users of specific processes and distribution and kick-off the use of the integrated management system. Considering the availability of resources for the implementation, it is advisable not to implement the system as a whole, but to start with certain pilot processes and later complement them with the rest of the system. Coaching for certain users may be advisable.

5.9. The maintenance phase of the integrated management system should ensure 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 phase in the life of an integrated management system it is necessary to assign clear responsibilities to the individuals and units involved. Leadership and oversight for the system should be assigned to a senior staff member. Senior management should assign responsibilities and allocate appropriate resources to develop, implement, and maintain the integrated management system, including for the training to be provided.

5.11. In the very early phase of the development of the integrated management system, the regulatory body should designate a member of the staff with professional knowledge of integrated management systems as a “system manager” to manage all activities concerning the integrated management system and to report to the corresponding senior staff member.

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 assign a project

manager to lead a team including staff with knowledge of regulatory responsibilities, supported by internal or – if necessary – external expertise in integrated management system design. The project manager should have sufficient authority and should have direct access to the senior manager responsible for the integrated management system.

5.13. The roles and responsibilities of individuals involved in each process should be identified during the first phase of developing an 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 accountable for ensuring the process is clearly identified, documented, reviewed, maintained and improved. Usually, this is a manager with direct interest in the outcome of the process or has the most resources involved.

5.15. The process owners should be assigned appropriate authority and resources to discharge their responsibilities; however, they may not have line management authority over all the staff who implements the process. In these circumstances this may lead to processes not being implemented as intended. It is therefore essential that senior management retain oversight of process development, maintenance and implementation and take action to ensure that processes are fit for purpose (e.g. it is 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 the responsibility for planning and conducting the independent assessments to provide assurance to senior management that the internal arrangements for leading and managing the organisation are reliable and effective. This entity should have sufficient authority to discharge its responsibilities and should have direct access to the top manager of the regulatory body.

5.17. To support this responsible audit entity, the regulatory body should appoint and train a group of suitable individuals from different parts of the regulatory body to form a pool of auditors from which audit teams can be assembled for specific audits. Depending on whether audits are conducted internally or externally, different levels of qualification might be needed. 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 system in general. These people are often closer to the work performed in the departments and can facilitate the communication concerning specific subjects/issues of the integrated management system or its implementation. Their reporting line 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 people familiar with integrated management systems process development and project management. In most cases, it is advisable to use professional external support during the development and implementation phase of an integrated management system.

5.20. Typical processes to fulfil the regulatory functions are:

- Development of regulations and guides;
- Authorization and notification;
- Review and assessment of facilities and activities;
- Inspection of facilities and activities;
- Enforcement of regulatory requirements;
- Communication and consultation with interested parties;
- Emergency Preparedness and Response.

5.21. Regulatory functions supporting the core functions may either be described as stand-alone processes, as subprocesses or as procedures as part of other processes. e.g. The Legal advice process may also be used for other core processes, such as for developing regulations and guides, issuing authorizations and also for enforcement actions. The activities in using legal advice may differ depending on the core process they are used for. See Annex II

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. For the analysis of responsibilities, suitable staff should be trained in process management and analysis techniques.

5.23. A 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 include any requirements formally agreed with interested parties and the relevant requirements of the IAEA safety standards, the national statutory and regulatory requirements. An example of a hierarchical structure of the integrated management system documentation is given in Annex I.

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

5.25. 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.

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

- Management processes, concerned with the governance and management of the regulatory body strategic planning, provision of resources, competence management, and evaluation and audit (see Appendix II for descriptions of generic management processes);
- Core processes - derived from the core functions, which relate directly to the discharge of the regulatory responsibilities such as 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 [10]); and,
- Support processes, which support the functioning of the regulatory body such as human resource management, financial management, purchasing, IT, document control, etc.

5.27. A graded approach should be adopted as appropriate throughout the integrated management system so that appropriate resources, time and attention are devoted to those processes, activities and decisions which have significant impact on regulatory effectiveness and efficiency. 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 and other risks that may arise (e.g. business risks, cost, environment, legal, political, public perception and credibility of the regulatory body). Also the nature of the regulatory approach, e.g. prescriptive or performance-based, should be considered in developing the core processes.

5.28. An integrated management system lives through the people that fulfil tasks and responsibilities. Therefore, the regulatory body should ensure that those people are consulted and involved in the development of the processes. The experience and knowledge of the future users of the integrated management system should be considered in developing the individual processes and procedures. It is advisable to design a compact, well-structured and user-friendly integrated management system in order to ensure its acceptance and systematic application by all members of the regulatory body.

## IMPLEMENTATION PHASE OF AN INTEGRATED MANAGEMENT SYSTEM

5.29. During the implementation phase of the integrated management system, senior management should demonstrate its commitment to the system and have a presence during the implementation. They should be role models by being users of the system.

5.30. The implementation phase of the integrated management system involves rolling out the processes in a planned and systematic way across the regulatory body. It is best to stage the roll out of processes to enable staff to become familiar with new ways of working in a progressive manner and ensure that they are not overloaded with change. A series of 'hold points' in roll out may be necessary to ensure that significant processes are effectively embedded before embarking on further change.



5.31. Typical steps in the roll out include:

- Identification of all staff involved in the process;
- Communication – dissemination of integrated management system principles, the process and associated documentation;
- Training, briefings, workshops, where the process introduces new practices. A graded approach should be adopted to match 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.

5.32. During the rollout, the process owner plays a central role. The process owner is the individual who has the best knowledge of the process and, during this phase of roll-out, should collect first impressions on the suitability, usability and acceptability of the process.

## MAINTENANCE PHASE OF THE INTEGRATED MANAGEMENT SYSTEM

5.33. 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. During this phase special care should be given to the maintenance of the integrated management system. Management should ensure that processes, both individually and collectively, are applied reliably across the regulatory body and improved to continually fulfil the purposes and objectives of the integrated management system.

5.34. Opportunities for improvements in the integrated management system, as well as improvements to the efficient and effective discharge of the regulatory body's work, should be identified and actions to improve processes and the regulator's effectiveness and efficiency should be selected, planned, resourced and recorded. This phase includes audit, evaluation, process review and update, including system documentation and procedures. In this phase again, the process owner plays a central role.

## MEASUREMENT, ASSESSMENT, EVALUATION AND CONTINUOUS IMPROVEMENT

5.35. To achieve sustained success, managers at all levels should monitor, measure, review performance as a basis of:

- Motivating for 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; and
- Demonstrating to interested parties the efficiency and effectiveness of the regulatory body and the achievement of the regulatory mandate.

### **Monitoring the external environment**

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

- Changes in the national nuclear programme;
- Changes to nuclear commercial developments;
- New legislation and standards;
- Technological advances and lessons from research;
- Lessons from worldwide operational experience;
- Economic, social and ecological trends;
- Experience and perceptions of interested parties, including authorized parties, and their views on regulatory performance.

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

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

### **Management oversight and supervision**

5.39. Managers at all levels should regularly monitor and measure progress with the delivery of plans, strategies and budgets and 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.

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

### **Measurement and evaluation of integrated management system processes and behaviours**

5.41. Integrated management system processes should be periodically measured and evaluated to confirm that they are operating as expected and delivering the expected standards of efficiency and effectiveness. Additionally, observing behaviours can contribute to the improvement of safety culture.

5.42. Regular self-assessments, led by managers, can usefully 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; and,
- Identify good practices and strengths in order to improve the integrated management system.

5.43. Methods of self-assessment can include:

- Group discussions and brainstorming sessions;
- Coaching and observations;
- Collection, analysis and trending 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.

5.44. The regulatory body should also provide convenient tools for the whole staff for suggesting 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.

5.45. Periodic structured measurement and evaluation of integrated management system processes in a graded approach by process owners can be used to confirm that they are operating as expected and delivering to expected standards of efficiency and effectiveness. Mechanisms of measurement include:

- Reviews of reported non-conformances to establish trends and any common problems;

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

5.46. Periodic surveys of staff attitudes and behaviours may be a valuable source of feedback on the state of the culture of the regulatory body.

5.47. All monitoring data should be analyzed against suitable indicators. Suitable indicators may be output- or outcome-based, and may be defined at different levels of detail across the regulatory body. Trends in indicators should be analyzed and evaluated at regular intervals and evaluated as a part of the integrated management system reviews.

### **Integrated management system review**

5.48. Periodic reviews of the integrated management system should be conducted by senior management to ensure the suitability and effectiveness of the system and its ability to effectively achieve the objectives of the regulatory body. The integrated management system review should cover all significant sources of information on performance, including:

- Outputs from different forms of assessment, including self-assessments of the 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; and,
- Opportunities for improvement.

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

### **Independent assessment**

5.50. Plans for the conduct of audits and assessments should be prepared in a graded approach matched to the safety significance of the process and activity. They should be reviewed and adjusted to reflect new or emergent 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 fulfillment of the regulatory mandate and the vision, mission policies, strategies, plans and objectives;
- Governance, leadership, management and culture of the regulatory body;
- The adequacy of resources provided to meet requirements, policies, strategies, plans and objectives; and,
- The effectiveness of regulatory activity in securing safe operation by authorized parties.

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

5.53. External organizations may be used to review and evaluate the regulatory body's leadership and integrated management system using services such as the IAEA 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. The results of assessments should be communicated in an open and transparent manner, consistent with the applicable security and confidentiality rules. The results of the independent assessments should be evaluated as soon as practicable by senior management and necessary actions taken to ensure improvements and to promote a learning attitude within the regulatory body.

### **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 a 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 proper review. The causes of non-conformances (and other upcoming issues negatively affecting the regulatory work or safety

issues) should be determined and their potential consequences evaluated. Non-conformances and associated causes should be trended to identify repeat occurrences, common issues and weaknesses.

5.57. Corrective actions for eliminating the causes of non-conformances and actions to prevent similar issues shall be determined, prioritized and implemented in a timely manner on the basis of their significance. The status and effectiveness of corrective and preventive actions shall be monitored and reported to management at an appropriate level in the regulatory body.

5.58. Senior management should allocate responsibilities to monitor and follow 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 due dates for corrective actions.

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

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

5.60. Senior management should also be involved in the resolution of difficult issues and should provide a process for resolving professional differences of opinion.

## **Learning and continuous improvement**

5.61. In line 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 analyze information of its performance, including improvement of 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 management process level under the supervision of the process owner;
- At the corporate level through organizational improvement projects under the supervision of senior management

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

5.63. Improvement plans should be decided by senior management and provided with adequate resources. Suitable project management techniques should be applied for significant changes. 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 checked to ensure that the anticipated benefit has in fact been achieved.

## DOCUMENTATION OF THE INTEGRATED MANAGEMENT SYSTEM

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 implementation and from internal and external lessons learned.

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

- An overview on 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;
- 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 organisation and managing, performing and assessing work;
- A description of the regulatory body decision making process;
- A description of the processes and procedures as well as supporting information that explain when, how and by whom work is to be prepared, reviewed, carried out, recorded, assessed and improved;
- A structured overview (‘process map’) of all processes that shows the totality of the integrated management system 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 according to the needs of the regulatory body. Annex I includes an example of a documentation structure.

5.66. For each process, the integrated management system should identify and document:

- The purpose, scope and objectives of the process;
- The process owner;
- The organizational units or individuals who must use the process;
- The sequence of steps, activities and decision points within the process, as well as the individuals and organizational units involved in the execution of the process;
- The interfaces with other processes to explain how the process fits into the integrated management system and its significance with the regulatory activity;
- The inputs to the process including the necessary information consistent with an evidenced based approach to regulation;
- The outputs of the process and records that should be retained;
- Performance criteria for the process to establish a basis for measuring process consistency, effectiveness and efficiency;
- The resources necessary and 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.

5.67. Suitable checks and balances, challenge and redundancy within the process should ensure appropriate ‘defence in depth’ for processes with significant impact on regulatory effectiveness and safety. Independent review of important decisions may be appropriate in some cases. The latitude within which discretionary decisions can be made should also be clear so that adequate parameters for controlling the process are set. Where necessary, arrangements should be established for the resolution of conflicts in professional decisions.

5.68. As a part of its integrated management system, the regulatory body should establish a document management system that supports its information, knowledge and competence management processes. This documentation system should allow for storing and retrieving all documents and records that are used and produced by the regulatory body as inputs and outputs of the regulatory processes, including documents and records delivered by authorized parties and other interested parties.

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



5.70. Retention times of records should be established to be consistent with the statutory requirements and knowledge management obligation of the regulatory body. The media used for records should 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[2] states: “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 allows the regulatory body to be effectively independent from undue influence in its 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 phase and scale 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 regulatory staff should have an academic degree. This should be supplemented with specialized training and/or professional work experience in their specific area of work, especially related to the facilities and activities to be regulated.

6.4. In addition to working in an appropriate legal framework and employing 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 that of the staffs of both the authorized parties and the other organizations involved. Staff members of the regulatory body should be appointed at such grades and with such salaries and conditions of service as would facilitate their regulatory relationships and reinforce their authority.

6.5. In order to keep the necessary distance and independence, regulatory body staff should be as objective as possible in discharging their responsibilities. They should be open to receiving information and opinions from others, and their regulatory positions and decisions should demonstrate transparency and clarity. Regulatory staff should not engage in, or hold a financial interest in, activities that may be the cause of a conflict of interest with the performance of regulatory functions. The regulatory staff should be formal and open but not familiar in their interactions with authorized parties.

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. In order to fulfil its functions effectively and efficiently, the regulatory body should establish a human resources plan that states the number of staff necessary and the essential competence (knowledge, skills and attitudes) for them to perform all the necessary regulatory functions. This plan should cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence. It includes also a strategy to compensate for the departure of qualified staff (succession planning, knowledge management).

6.8. The staffing needs are assessed based on the regulatory body's main functions as listed in Chapter 4. Staffing requirements for other functions of the regulatory body such as emergency response and investigation of incidents and accidents are not normally day to day activities, and related responsibilities should therefore be assigned according to where they best fit in the larger units of the organizational structure.

6.9. Senior management of the regulatory body should regularly review the functions that are required to be performed and should determine the size and composition necessary for the regulatory body to be able to fulfil its obligations. The appropriate size for a regulatory body will depend on a range of factors: the various types and the number 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 is maintained in dealings with the authorized bodies.

6.10. In larger regulatory bodies, staff may be assigned to perform within a specific functional area. Alternatively, staff may specialize in particular kinds of practices and consequently their work assignments would cover more than one functional area in the organizational structure.

6.11. The number and the specialized skills of the regulatory staff will also depend on decisions about the coverage of functional areas and on the extent to which the regulatory body will use consultants and/or advisory committees. In any event, the regulatory body should have sufficient numbers of staff with the basic skills 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, despite the fact that some staff may be in the field conducting inspections or unavailable for personal reasons.

## COMPETENCE MANAGEMENT

6.12. GSR Part 1 [2], in Requirement 18, goes on to state: "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. 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.”

6.13. The regulatory body should establish as part of its integrated management system (see chapter 5) a management process which acts to develop and maintain adequate competencies to fulfil its regulatory functions and to be an intelligent customer to receive advice and to make decisions based on that advice. Useful guidance can be found in the Safety Reports Series 79 “Managing the Competence of the Regulatory body” [11].

6.14. The regulatory body should, through its competence management, ensure that its organization is sufficiently robust and flexible to deal with departures, retirements or other events including unexpected staff changes. It should include succession planning.

6.15. As described in SRS 79 [11], the competence management process may include the following typical sub-processes:

- Competence needs analysis;
  - Task analysis leading to required competence;
  - Gap analysis;
  - Prioritization and choosing ways of filling gaps.
- Human resources management;
  - Succession planning and recruitment;
  - Management of organizational change (reallocation of duties within the organisation or replacement of staff members);
  - Personal development plan;
  - Personal performance review and assessment.
- Training and development;
  - Establishment of training and development plans;
  - Delivery of training and development activities;
  - Evaluation of training and development activities.
- Management of outsourcing (external expert support);
- Knowledge capture and management;
- Reviews and audits of competence management and feedback.

### **Responsibilities for competence management**

6.16. In order to develop and enhance the regulatory body’s competence to achieve its mission objectives with efficiency and effectiveness, senior management should be committed to ensuring that the regulatory body has and maintains competences appropriate to its needs. In particular, since

learning is a lifelong process, the management should be committed to the ongoing development of a professional, competent, versatile and motivated workforce.

6.17. The regulatory body should define the organization, levels of authority, responsibilities and accountabilities for competence management processes and a person, or team, should be appointed to be responsible for these processes. Competence management should be part of the integrated management system of the regulatory body.

6.18. The commitment and engagement of competence management requires the involvement of all managers and staff. Each manager should be made accountable for all aspects of the competence building of their staff and senior managers should seek to foster an culture which supports individual staff members to recognize that they are 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**

6.19. A regulatory body should have an overall governance and strategic planning process. A review of the functions that are required to be performed and a determination of the size and composition of the regulatory body needed to fulfil its obligations should be part of this strategic planning process. This process is applicable to both short term and long term needs.

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

6.21. A new regulatory body should adopt or define a strategy to build the competence of its staff. In the early stages, the initial organizational structure could necessitate considerable reliance on other bodies to provide technical expertise and advice. As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient.

6.22. 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 needs well-established knowledge management as part of the competence management. Knowledge management should make provisions for the capture of explicit and tacit knowledge that the regulatory body generates through its various regulatory activities, and make this knowledge readily available to its staff.

6.23. The introduction of new types of facilities or new activities, the introduction of novel technology, the ageing of facilities or the passage of a facility to another phase of its service life should be considered in the planning of competences and in the adaption of training programmes.

## **Competence analysis**

6.24. The competences required by the regulatory body in order to fulfil its functions should be identified by a systematic analysis based on the regulatory body's function and processes (See DS473 [9]).

6.25. The result of the competence analysis should be used to determine the regulatory body's workload and resource requirements. Whilst this information may be used to develop or modify the organisational structure, it should also be used as a feedback to the regulatory body competence management.

6.26. The analysis identifies 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 subdivisions, and at the personal level. These assessments should take place at periodic intervals and when substantial changes necessitate them.

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

6.28. This analysis leads to the 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 selection criteria.

6.29. It should be emphasized that not only "technical" skills are considered in this analysis, but also what is often termed as "soft skills" (see list in Appendix III, Communication and management skills). Staff must be able to interact with people (within the regulatory body as well as in oversight interactions with licensees) in a constructive way, to address findings adequately, to give constructive feedback, to solve conflicts etc.

6.30. Competence profiles provide a powerful management aid to address competence gaps. A valuable instrument for competence management at the regulatory body is a competence model. Safety Report Series 79 gives an example of a competence model for regulatory bodies. It enables a balanced approach to competency and consistency of regulatory performance. It suggests a basis for assessing competence needs both for the near and medium future. It is a significant input into the process of developing an effective regulatory body that responds to internal and external environments and the associated challenges.

## **Competence requirements**

6.31. In the following paragraphs, the competences necessary for performing regulatory functions are discussed. In general, the recommendations on competences refer to the regulatory staff engaged in

the core regulatory functions of developing regulations and guides, authorization, review and assessment, inspection and enforcement, emergency preparedness and response and communication and consultation (Note: core regulatory functions as described by DS462 - Revision through addenda of GSR Part 1 [2]). More details may be found in the Safety Reports Series 79 “Managing the Competence of the Regulatory body”.

### *Human and organizational factors*

6.32. Knowledge in human and organizational factors (HOF) should be part of the regulatory body’s competence profile. These competences are needed for oversight on issues such as safety culture, leadership, organizational and management aspects, competence development as well as aspects of human system interfaces. They enable the regulatory body to oversee in a systemic manner, the actions and interactions of authorized parties.

6.33. It is advisable that beside human and organizational specialists also additional members of the staff bear HOF competence. For example, managers who should ensure the deployment of the HOF strategy and attribute the means for its implementation, process specialists who can integrate the HOF approach into organizations processes and especially trainers, operational experience specialists and inspectors in order to enable them to understand and evaluate working conditions and factors contributing to human performance. It should also be stressed that HOF specialists and these other staff members should cooperate in the analysis of HOF aspects and of their relationship with the technical aspects.

6.34. 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 itself and with the authorised parties. These competences are also needed to develop and to improve the regulatory body’s own safety culture. All members of the regulatory body should have a common understanding of the concepts of safety culture in order to develop their own safety awareness and interrogating attitude necessary for safety oriented behaviour and conservative decision making.

### *Core regulatory functions*

#### Regulations and guides

6.35. Persons assigned to develop or revise regulations and guides should have a sufficient understanding of the relevant areas. These persons should also have sufficient knowledge of existing regulations and guides to ensure consistency and compatibility between them. The workload in this functional area can be adjusted by assigning specialists from other functional areas to prepare

regulations and guides for which specialized technical experience and knowledge are required or by making use of groups of consultants.

6.36. A unit, whether permanent or temporary, producing regulations and guides should have access to personnel with:

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

6.37. Personnel 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 regulations and guides on a broader level to gain awareness of such developments.

### Authorization

6.38. Regulatory body personnel 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 be capable of leading public consultations, if applicable. Authorization is normally performed by senior and experienced staff.

### Review and assessment

6.39. Regulatory personnel 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. A small number of personnel who work in this functional area may be recruited with little or no work experience.

### Inspection

6.40. 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, interviewing people, observing and evaluating activities, reviewing records and, where appropriate, making decisions and 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 people to obtain all the relevant information available, and should be able to review and evaluate logbooks and other documents to detect potential problems. In addition, personnel who are assigned



to inspect major activities (manufacture of components, 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 the function they are performing, inspectors are routinely involved in compliance assurance activities. The 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. The 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. Moreover, 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

6.41. Regulatory personnel should be capable of deciding upon and initiating enforcement actions due to non-compliances in a facility or activity (such as those identified in other regulatory processes or due to events), of performing reviews and of making independent judgements. They should possess a good knowledge of the regulatory body's enforcement policy, requirements, processes and procedures and related guides. They should also know if and what support is needed as well as when corrective measures proposed by the authorized party are adequate.

### Emergency preparedness and response

6.42. Regulatory personnel should be able to review, assess and make independent judgements on the adequacy of on-site emergency arrangements and to evaluate emergency exercises. Regulatory personnel should also be able, directly in cooperation with relevant off-site authorities or indirectly through the coordinating mechanism, to assess the coordination and integration of on-site emergency arrangements with those off-site. The regulatory body should have necessary arrangements (such as plan, procedures, exercise and training programmes, tools, communication means, equipment) to fulfil its assigned functions in emergency response including, where applicable, those for assessing the emergency situation and its potential development. The staff having duties in emergency response should have necessary qualifications, skills and training to perform their duties.

### Communication and consultation with interested parties

6.43. 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 or delivery of presentations, understanding potential sources of bias of people and delivering meaningful messages. Among other things they should be able to talk effectively in small groups and with 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

6.44. The regulatory body should have competence available to provide legal support to its regulatory functions. This may include knowledge of the laws and decrees relating to facilities and activities to be regulated, other relevant laws and decrees, ability to apply legal provisions and knowledge on powers and authority of the regulatory body and its staff. In addition the legal support should be familiar with conventions and treaties to which the State is a party as well as the nature of IAEA Safety Standards.

#### Research and Development

6.45. The regulatory body should have internal competences to define relevant research issues, to specify the research activities needed and to identify appropriate research institutions that may conduct research and development.

6.46. The regulatory body should be able to follow the research and development activities and to evaluate the quality and suitability of the results.

#### Administrative support

6.47. The regulatory body should have adequate competences 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 should depend on the size of the regulatory body (see also Chapter 3 Management for safety).

#### External expert support

6.48. The regulatory body should have competence to decide which of its activities need support from external organizations (consultants, research institutes, dedicated support organizations, etc.) and to be able to set criteria for the service needed and to evaluate the outcome.

6.49. The staff of the regulatory body should be able to coordinate and manage activities of the regulatory programme which are performed with the assistance of consultants or dedicated support organizations. Some staff should have experience in technical programme management or project management. Furthermore, it is desirable for some members of the regulatory body to have appropriate management experience and technical experience to be able to assess and judge the effective coordination and management of large engineering concerns and quality assurance activities.

## Collaboration with national and international organizations

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

## **Documentation for competence management**

6.51. Documents and records should be kept and managed in line with confidentiality. This may include:

- Documented competence requirements for each task and profile;
- Job descriptions;
- Individual competence development plans and performance reviews;
- Competences possessed by individuals;
- Staff certification;
- Records of training provided and training activities;
- Outsourcing and external expert support;
- Recruiting;
- Reallocation of people within the organisation.

## **Measurement, assessment and improvement**

6.52. The processes for the competence management are part of the integrated management system and are therefore evaluated with the same means as described in section “Measurement, Assessment, Evaluation and Continuous Improvement”. The evaluation provides feedback that can facilitate training and development programme improvements. Inputs for the evaluation can be found in the Safety Reports Series 79 “Managing the Competence of the Regulatory body”.

- Effectiveness of training and development;
- Delivered training;
- Personal performance;
- Recruitment, reorganisation and outsourcing;
- Reviews and audits.

6.53. Assessment relating to competence management should take place at several levels: the personal level, the level of individual organizational subdivisions and at the level of the entire regulatory body.

6.54. At the level of units and the regulatory body as a whole, performance assessment may make use of metrics such as the effectiveness and achievement of training and may be based on sound

judgement. Self-assessment and independent peer reviews are well established techniques which may contribute to these assessments.

6.55. Senior management should assess competence management in the regulatory body and the achievement of its goals in order to seek opportunities for improvement. The changing circumstances and challenges should be examined. These includes in particular: reorganization, assignment of new regulatory functions, recruitment of new staff, changes in authorized facilities' activities, the life-cycle of regulated installations, technological development etc.

## METHODS FOR ACQUIRING COMPETENCE

6.56. Having established a gap analysis and the associated short and long term priorities the regulatory body should implement a programme for addressing the 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. Each regulatory body will have differing views on the mixture to use.

### **Recruitment**

6.58. The recruitment strategy within a regulatory body will depend on a number of factors. These factors are likely to change with time and hence the regulatory body will need to review the strategy periodically to establish whether it is still appropriate and viable. Work experience, demonstrated competence, expert or specialist knowledge are an important consideration in selecting personnel to staff the regulatory body..

6.59. The general experience of States with established regulatory bodies is that they can recruit personnel 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 personnel with the specific knowledge, skills and attitudes necessary for conducting regulatory functions.

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

6.61. However, it is inevitable that all new staff will need training even if they have the technical competences needed by the regulatory body. This is because it is necessary to instil in such recruits the culture of the regulatory body and establish in them some of the competences specific to the work of the regulatory body. Similarly, part of the overall strategy may be to move staff to new posts where they may also need to acquire additional competences through appropriate training.

6.62. Members 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.

6.63. Regulatory bodies should have a programme for capturing, retaining and transferring knowledge of personnel leaving the regulatory body.

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

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

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

## **Training**

6.66. The most common method to acquire competences is training. The regulatory body, depending on the number and complexity of the State nuclear programme, should have:

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

6.67. The training requirements for regulatory personnel should be based on the functional areas that have been mentioned in previous sections of this document. 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 regulatory body's training programme are listed in Appendix III.

6.68. 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 discussed in section Competence analysis. They 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.

6.69. The individual training and development plans for new staff should ensure that they 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, 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 the initial period of their training and an evaluation of their performance has been made.

6.70. 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 at all times act in accordance with the values of the regulatory body and remain focused on safety irrespective of their personal views.

6.71. 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, make staff aware of the risks and hazards related to their work, and provide them with an understanding of potential consequences of their work. Training should encourage an inquiring and learning attitude, foster the free reporting of safety concerns and discourage complacency at all levels in the regulatory body with regard to safety.

6.72. Refresher training should be given, as required, to maintain knowledge, especially if there is a job change, and to draw attention to important changes in the law, procedures, technology or other matters. Lastly, there is developmental training, both technical and non-technical, to prepare staff for job changes and promotions.

6.73. The regulatory training programme should consist of a combination of self-study, formal university level instruction and occupational or technical training courses, workshops and seminars (organized by the regulatory body and provided by 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.

6.74. 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.

6.75. The organization of training will depend on the size and resources of the regulatory body. A small and newly established regulatory body will need external expert support, whereas a large and experienced regulatory body may be self-sufficient. International exchange of information should be a part of continuing training in order to obtain new ideas for further development.

6.76. As part of the processes, 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 facilities which have the necessary equipment to teach specific techniques.

6.77. Efforts commensurate with the size of the regulatory body should be made to develop a systematic approach to the training (SAT) of personnel in order to ensure consistency in the conduct of regulatory activities, including the application of quality assurance principles to training. The SAT is a suitable technique that provides a logical progression from the identification of the competences required to perform a job to the design, development and implementation of training to achieve these competences, and subsequent evaluation of this training. Safety Reports Series 79 provides an excellent overview of competence management for regulatory bodies including training methods and options (classroom based training, distance learning, on the job training) and, in addition, a detailed description of SAT.

6.78. Training requires 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 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.

6.79. Training alone cannot ensure the required competence. Necessary work experience, mentoring, continuing professional development and refresher training should be included in competence development plans for individuals. Regulatory staff should be encouraged to make a habit of continuing professional development throughout their careers, 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. Many countries' engineering and scientific institutions require continuous professional development to maintain their members' credentials.

### **Participation in knowledge networks**

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

6.81. The regulatory body would 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**

6.82. 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.



## APPENDIX I EXTERNAL EXPERT SUPPORT

### PURPOSE AND RESPONSIBILITY FOR USING CONTRACTORS

A1.1. The regulatory body needs to have the required competences to perform its functions. It may, however, be practicable for the regulatory body to use the services of external experts or a Technical Support Organisation (TSO).

A1.2. The need for external expert support may be caused by:

- Unexpected applications/demands combined with lack of internal resources (number of specialists, lack of specific competences);
- Need for external expert support to build up specific internal competences;
- Single project with need of special competences;
- Scope outside the regulatory body's competence area;
- Need for second opinion;
- Permanent outsourcing of certain activities (complex, specialized, infrequent activities).

### PROVIDERS OF EXTERNAL EXPERT SUPPORT

A1.3. Examples of external expert support providers include:

- Advisory bodies: many governments and regulatory bodies appoint external experts in the form of an advisory committee. In some cases, the advisory body will provide technical advice to the regulatory body, while in other cases, the advisory body provides policy advice.
- Dedicated TSOs; some States have established arrangements for particular independent organizations to dedicate part of their resources to assisting the regulatory body. They are separate from the regulatory body and have the mission to maintain a proven capability and to provide support as necessary;
- Government laboratories or research centres can conduct experimental investigation, analysis or verification;
- Legal organizations can review the language of 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 dose monitoring or water quality 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 and economic 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

A1.4. 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 organisation, 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

A1.5. 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 required to perform the work, the deliverables required from the external experts and the expected standards.

A1.6. Where the regulatory body uses a technical support organization or consulting company, the regulatory body should establish the requirements for the integrated management system to be used. In some cases, the TSO or company integrated management system may be adequate, while in other cases, the regulatory body should use the contract to establish the requirements for the integrated management system to be used. In the case of individual experts, the expert should conform to the regulatory body’s integrated management system.

## SELECTION OF A PROVIDER OF EXTERNAL EXPERT SUPPORT

A1.7. Choices of provider are best made by comparing tenders from several competitive bids. National laws may prescribe competition rules for letting such contracts.

A1.8. The regulatory body should ensure that external experts are chosen based on their expertise and experience in the required field. The regulatory body should specify requirements for the selection of external experts and ensure that the successful bidder meets these requirements.

A1.9. 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 a bias in the advice given; the potential for any such conflict of interest should be minimized and when recognized, it should be dealt with.

A1.10. When selecting external experts providers, the regulatory body should take the following recommendations into account:

- The external expert's processes and systems should meet the standard of and be compatible with those of the regulatory body;
- External experts support providers should be able to demonstrate technical competence to the regulatory body's standards;
- There should be no conflicts of interest. In case of a potential or perceived conflict of interest, the situation should be discussed with all involved parties and managed;
- External experts support providers should be able to conduct their work within the time frame specified by the regulatory body. The time allowed for the work to be performed should be commensurate with the scope of the work and consistent with the time frame set by the regulatory body;
- External expert support providers should be able to prepare and deliver specific documentation as required to formalize its advice and the rationale;
- The documentation that supports the advice should be sufficient, accurate and relevant 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.

## CONTROL OF CONTRACTS

A1.11. 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.

A1.12. 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 need for timeliness of the expected results. Those supervising 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;
- 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.

A1.13. The regulatory body should be aware of, and approve, situations where the provider of external expert support will need to interact with authorized or interested parties. 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.

A1.14. The regulatory body should keep sufficient records so that its advice from external providers can be traced and audited, including how different professional views were addressed.

A1.15. 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 of security and confidentiality.

## REVIEW OF WORK

A1.16. 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.

## REQUIREMENTS TO AN EXTERNAL EXPERT SUPPORT ORGANIZATION

### **Independence**

A1.17. The provider of external expert support needs to be able to form and express a technical judgement that is: based on safety related criteria; takes into account state of art 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 owing to political opinion. Technical competence and the safety culture in the provider of external expert support contribute to the independence of the technical advice.

A1.18. An important element in ensuring effective independence is the development and implementation of adequate arrangements that avoid conflicts of interest. All situations should be analysed early in the process for potential or perceived conflicts of interest. Conflicts of interests should be eliminated, while potential and perceived conflicts of interest should be addressed. Activities that can be undertaken include:

- 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 a licensee or other organization. The links between such units should be carefully monitored.

A1.19. If neither can be verified, an alternative opinion from other providers should be sought and, in doubt, legal advice should be pursued. Potential and perceived conflicts of interest should be explicitly discussed and managed.

A1.20. 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 personnel 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 together with other interested parties.

A1.21. In all cases, the requirement to assess for conflicts of interest 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**

A1.22. The regulatory body should ensure that the competence of the provider of external expert support is adequate. Technical competence is the ability to evaluate and potentially apply the state of the art of the relevant science and 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 performed in the assigned area.

A1.23. 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.

A1.24. For an individual expert, the regulatory body could verify that the expert has already provided similar external expert support in a satisfactory way or be recommended by other experienced experts.

A1.25. For an academic expert, a publication list is a useful additional tool, and documented research activity should indicate skills and knowledge that are adequate for the task to be assigned. Certification may demonstrate continued competence in the expert's specialized area.

A1.26. For an organization that has an established long term relationship 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;
- The existence of an ongoing up to date research and development program in its field of competence;
- Involvement in significant research activities in its field of competence;
- Development of technical tools and equipment (including software, key scientific investments...),
- Access to operating experience information from licensees;
- 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 the licensee;
- International activities aimed at research analyses, participation in international activities related to safety, development of software products and other areas of cooperation;
- Assessment results from self-assessments, assessments by a national body, international peer reviews, etc.

### **Management system**

A1.27. Any potential provider of external expert support should adhere to basic management requirements. Safety Requirements GS-R-3 establishes the general requirements for the integrated management system.

A1.28. Where the regulatory body uses a technical support organization or consulting company, the regulatory body should establish the requirements for the integrated management system to be used. In some cases, the existing TSO or company integrated management system may be adequate, while in other cases, the regulatory body should use the contract to establish the requirements for the

integrated management system to be used. In the case of individual experts, the expert should conform to the requirements of the regulatory body's integrated management system.

### **Confidentiality**

A1.29. The organization providing external expert support may have to address two types of confidential information: nuclear security related or protected information, and proprietary information.

#### *Nuclear security related or protected information*

A1.30. In most States, the management of nuclear security related confidential information is controlled at the government level, and the verification of the trustworthiness of every organization and individual requiring access to this information is required. Such information can only be transmitted to any provider of external expert support (or its subcontractors) in accordance with relevant government requirements.

### **Proprietary information**

A1.31. An applicant or authorized party may be obligated to provide proprietary information, including information of commercial value, to the regulatory body. The regulatory body should inform the owner of the proprietary information of its intention to provide that information to a provider of external expert support. 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 precise 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 to protect this type of information.

### **Safety culture**

A1.32. The provider of external expert support should be able to provide the requisite technical support in accordance with the policy on safety culture of the regulatory body and to raise with the regulatory body any safety concerns regarding work. The regulatory body should address any safety 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 MANAGEMENT PROCESSES

### DOCUMENT CONTROL

A2.1. 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.

A2.2. Blank forms that are associated to procedures and need to be filled in during the regulatory activities e.g. inspections, are also considered documents, and they are used to capture data or information from performing a task associated to a procedure.

A2.3. Records are generated when written instructions in procedures are followed. In other words, after data, information, or results are recorded onto a form, it becomes a record, in paper or electronic form.

A2.4. A document control process should be established to provide 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.

A2.5. The responsibilities of each participating organizational unit or individual should be defined in the document control process.

A2.6. 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.

A2.7. 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.

A2.8. Document control of requirement documents e.g. processes and procedures, should ensure identification and availability of current version. Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves.

## CONTROL OF PRODUCTS

A2.9. The products of the regulatory body can be regarded as the outputs of regulatory activities. Typically, for a regulatory body, products include documents which relate to the discharge of core and supporting functions and their related processes. For example:

- Review and assessment reports;
- Inspection and audit reports;
- Regulations, policies and guides;
- Authorizations (including drafts);
- Certificates of Approval (e.g. transport, personnel etc.)
- Enforcement action (notices, directions, orders, reports, etc.);
- Integrated management system documents;
- Plans (e.g. strategic, regulatory activities, training etc.);
- Interested party communications (e.g. annual reports, financial reports, seminars, decision letters, requests for information, research & development reports, contribution to international and national co-operation, etc.);
- Public information (e.g. press releases, websites, conferences);
- Regulatory recommendations in support of decision making;
- Internal communications to staff;
- Results of analysis of operational experience and external events.

A2.10. 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 integrated management system requirements; in others the requirements for control of a product may be embedded within specific processes. For example, the inspection process may set out the way in which the inspection reports will be structured and reviewed.

## CONTROL OF RECORDS

A2.11. Regulatory bodies need to keep extensive records of their work and their interactions with authorised and interested parties. This includes all the documents incoming documents as well as documents created by the regulatory itself (see Control of Products).

A2.12. 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 need to be identified and addressed within the regulatory body's integrated management system.

A2.13. In order to allow an easy control the records, an index system should be established that allows a reliable and unique categorization of the records. In many cases the system is structured according facilities, activities and processes.

A2.14. The control of records process 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.

A2.15. 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.

A2.16. The management and retention of records should take into account the sensitivity of the recorded information, giving due regard to confidentiality, security, distribution, routing and notification, availability to interested parties, search and retrieval and destruction.

A2.17. Records should be readily retrievable to support and justify decision-making. However, the access should be limited to individuals authorized for the use of the records in accordance with requirements concerning security, privacy and confidentiality.

## PURCHASING

A2.18. Regulatory bodies will need to purchase products and services which 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

A2.19. Information relevant to safety, health, environment, security, quality and economic related goals shall be communicated to individuals in the regulatory body and, where necessary to other interested parties.

A2.20. The regulatory body should adopt a communication policy in order to promote effective sharing of information with all interested parties. It should establish the information which it needs to communicate both within the regulatory body and to external organizations. It should also identify the information which it seeks from these external organizations in order to discharge its mandate effectively.

A2.21. 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. This information needs to be communicated effectively within the regulatory body. The internal communications policy should promote sharing of relevant up-to-date information, and enable staff to work effectively and efficiently. Management of the regulatory body should systematically identify the information which 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.

A2.22. 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 information, personnel data etc.

A2.23. 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 which 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

A2.24. The regulatory body should have a process for managing organizational change, whether that change is 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. The changes should not be implemented without further review and modification (e.g. compensatory measures) if they impact negatively upon the effectiveness with which the regulatory body discharges its mandate.

## MEASURING AND TEST EQUIPMENT

A2.25. Activities for the Inspection, testing, verification and validation shall be completed before acceptance, implementation or operational use of products. The tools and equipment used for these activities shall be of the proper range, type, accuracy and precision.

A2.26. In the event that 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.

A2.27. Calibration should be performed using certified equipment traceable to a recognized standard or other documented bases 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 REGULATORY BODY'S TRAINING PROGRAMME**

### A3.1. Basic knowledge of:

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

### A3.2. Depending on the tasks to be performed, solid knowledge of:

- Physics;
- Nuclear engineering;
- Systems engineering;
- Electrical engineering;
- Mechanical engineering;
- Civil engineering;
- Radioprotection;
- Chemistry;
- Biology;
- Behavioural sciences (human and organizational factors);
- Ergonomics;

- Medicine;
- Geology;
- Law;
- Communication;
- Administration;
- Etc.

#### A3.3. Knowledge of regulatory policies and processes:

- Legislative aspects;
- 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.

#### A3.4. Professional knowledge:

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

#### A3.5. Communication and management skills:

- Oral communication;
- Effective writing;
- Interviewing;
- Negotiation;
- Leadership;
- Project management;
- Teamwork;

- Decision making;
- Dispute resolution;
- Languages;
- Computer use;
- Public information.

#### A3.6. Continuous training:

- Refresher training;
- Further personal development.

#### A3.7. Information exchange and international co-operation.



## ANNEX I STRUCTURE OF THE INTEGRATED MANAGEMENT SYSTEM

I-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

I-2. Level one should provide an overview of the policies and objectives of the regulatory body and should describe the integrated management system that addresses the requirements that apply to the regulatory body's work. The information at this level of the integrated management system should be the most senior manager'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.

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

- 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.

I-4. The senior management in the regulatory body should ensure that level 1 information is distributed to individuals for the purposes of implementation and that its contents are effectively understood and implemented.

## LEVEL 2

I-5. This level of information contains the process descriptions which provide 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 the process map of the integrated management system providing an overview of the interactions between processes.

I-6. The process descriptions typically contain:

- 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 (Process Owner);
- Details: How is the work that is the subject matter of the document 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 expeditiously;
  - 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 possibly 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 permit 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.

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

### LEVEL 3

I-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.

## ANNEX II PROCESS DESCRIPTIONS

### MANAGEMENT PROCESSES

#### II-1. Policy making

Purpose	Describe how senior management develops the policies of the regulatory body, which are necessary for discharging the regulatory mandate.
Inputs	<ol style="list-style-type: none"> <li>1. External demands for change/improvement arising from political/legislative change or reform impacting on the regulatory mandate; and,</li> <li>2. Internal information on performance and regular policy reviews identifying potential areas for improvement in policy.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Review and analysis of relevant information/requirements and lessons learned;</li> <li>2. Development of policy options based on evidence and involvement of relevant experts;</li> <li>3. Consultation with regulatory body staff and interested parties;</li> <li>4. Impact/cost-benefit assessment of proposals;</li> <li>5. Refinement of proposals into new policies; and,</li> <li>6. Development of specific proposals for approval by senior management, including implementation plans.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Policies which are: focused on outcomes; evidence based; take account of national and international expectations; aligned with other regulatory and other government policies; and,</li> <li>2. Practical implementation/communication plans and criteria for the future evaluation of impact/effectiveness.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Governance;</li> <li>2. Process Management;</li> <li>3. Performance Management; and</li> <li>4. Communication and Consultation</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Achieving policy making process development/implementation targets;</li> <li>2. Achievement of policy implementation deadlines; and,</li> <li>3. Achievement of evaluation criteria.</li> </ol>

#### II-2. Process management

Purpose	Manage all processes to ensure they are systematically and consistently developed, implemented and maintained in a controlled and integrated fashion.
Inputs	<ol style="list-style-type: none"> <li>1. List of key processes;</li> <li>2. Integrated management system (IMS) document hierarchy;</li> <li>3. Legal and regulatory requirements, guidance and procedures; Applicable government requirements or national legislation (e.g. records retention and</li> </ol>

	<p>control);</p> <ol style="list-style-type: none"> <li>4. Corrective actions/adjustments resulted from performance management activities;</li> <li>5. Existing processes that need to be streamlined and documented;</li> <li>6. Senior management directions and expectations; and,</li> <li>7. Feedback and review comments from staff and other interested parties.</li> </ol>
Process	<p>Develop an individual process</p> <ol style="list-style-type: none"> <li>1. Scope the process</li> <li>2. Prepare and map the process</li> <li>3. Identify purpose, roles and responsibilities, process description, inputs, outputs, records, key interfaces, and resource implications, (e.g. IT tools, competence and training requirements)?</li> <li>4. Establish/Identify Control Points and Performance Indicators</li> <li>5. Identify references</li> <li>6. Document the Process which may include: <ol style="list-style-type: none"> <li>a. Procedures</li> <li>b. Work Instructions</li> <li>c. Criteria and Guides (e.g. writing guide)</li> <li>d. Standard forms, templates, checklists</li> </ol> </li> <li>7. Validate (desktop) the Process</li> <li>8. Approve the Process</li> </ol> <p>Implement an individual process</p> <ol style="list-style-type: none"> <li>1. Plan the implementation</li> <li>2. Launch the process,</li> <li>3. Verify initial process performance and identify and implement corrective actions, as necessary</li> </ol> <p>Maintain an individual process</p> <ol style="list-style-type: none"> <li>1. Execute the process</li> <li>2. Review performance and assessment results</li> <li>3. Address any identified process improvement opportunities</li> <li>4. Modify Process (as needed)</li> </ol> <p>Control documents and records associated with or generated by an individual process</p> <ol style="list-style-type: none"> <li>1. Review and approve documents and records</li> <li>2. Manage and retain documents and records (interface with the information management process)</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Process documents;</li> <li>2. Documents and records generated by the process;</li> <li>3. Resource implications of each process.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Information management process;</li> <li>2. Purchasing process (e.g. requirements for IT tools);</li> <li>3. Competence management processes</li> </ol>

Performance criteria	1. Assessments of adequacy, effectiveness and efficiency of the IMS including all its processes.
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### II-3. Performance management

Purpose	To measure the effectiveness and efficiency of the regulatory body and its activities.
Inputs	<ol style="list-style-type: none"> <li>1. Progress with strategy, objectives and plans;</li> <li>2. Key performance indicators;</li> <li>3. Self-assessment reviews;</li> <li>4. Process performance information;</li> <li>5. Internal audit review reports;</li> <li>6. International peer reviews;</li> <li>7. Operational experience feedback information;</li> <li>8. Staff suggestions; and,</li> <li>9. Results of interested party surveys.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Identify reporting/accountability responsibilities at each level of the regulatory body;</li> <li>2. Identify monitoring/review and reporting frequencies at each level of the regulatory body;</li> <li>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 bottle necks in processes; consistency of application of a process, e.g. timeliness specifications are met 90% of the time; standards for measuring the consistent exercise of judgment and discretion within a process; – numbers, nature and trends of non-conformances;</li> <li>4. Analyze/synthesize information to identify key issues and significant aspects relative to the performance objectives and criteria, (present right information, in the right way at the right time and in the right place for evaluation);</li> <li>5. Compare information with performance objectives and criteria to establish the performance 'gap';</li> <li>6. Decide what to do to address performance gap, including initiating further studies/analysis, (e.g. root cause analysis) to understand the reasons for the gap and identifying appropriate, prioritized corrective actions/adjustments; and,</li> <li>7. Plan and implement corrective actions, including adjustments to strategy, programme and plans.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Results from applying performance methodologies; and,</li> <li>2. Corrective action plans.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Governance;</li> <li>2. Policy Making;</li> <li>3. Planning; and,</li> </ol>

	4. Communication and Consultation.
Performance criteria	1. Timeliness and adequacy of monitoring and reviews activities.

## II-4. Governance

Purpose	To provide the strategic direction and oversight of the regulatory body to ensure it fulfils its regulatory mandate in line with the expectations of interested parties.
Inputs	<ol style="list-style-type: none"> <li>1. National and international developments amongst interested parties; and,</li> <li>2. Internal information on performance of regulatory activities.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Led by senior management supported by advisers;</li> <li>2. Aims to link the external demands and expectations of interested parties with the internal operations of the regulatory body;</li> <li>3. Clarifies what responsibilities powers and decisions are reserved for the senior management and those which are delegated to others;</li> <li>4. Sets out the cycle of activities by which senior management plan, monitor and review: <ol style="list-style-type: none"> <li>a. the effectiveness of strategy, policy, plans and performance;</li> <li>b. the relevance of vision, mission, values, (typically every 3 to 5 years);</li> <li>c. the effectiveness policies, strategy and structure of the regulatory body, (typically annually);</li> <li>d. the implementation of programmes and plans and supervising the activities of management, (typically several times within a year e.g. monthly or quarterly).</li> </ol> </li> <li>5. Identifies the information needs relevant to each activity graded to the significance of the topic/issues in scope;</li> <li>6. For each activity (event/meeting): <ol style="list-style-type: none"> <li>a. Collect relevant information and provide to participants in advance of the meeting/event/activity.</li> <li>b. Ensure adequate: <ol style="list-style-type: none"> <li>i. consideration of information relative to its significance,</li> <li>ii. discussion and debate,</li> <li>iii. consideration of options where appropriate</li> <li>iv. clear decisions and actions which can be implemented.</li> </ol> </li> <li>c. After each meeting/event/activity provide appropriate notes, records or reports and communicate these to interested parties.</li> </ol> </li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Mission, vision and values;</li> <li>2. Strategic direction, policies, programmes, plans, priorities;</li> <li>3. Budget, structure, roles and responsibilities;</li> <li>4. Performance reports.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Policy making;</li> <li>2. Planning;</li> <li>3. Performance Management;</li> </ol>

	4. Communication and Consultation.
Performance criteria	1. Timeliness of governance activities; 2. Effectiveness and efficiency of regulatory body.

## II-5. Planning

Purpose	To establish and maintain strategic and detailed work plans to optimize planned activities, time line and resources in order to achieve the desired regulatory outcomes.
Inputs	<ol style="list-style-type: none"> <li>1. Results of regulatory performance;</li> <li>2. Interested parties expectations;</li> <li>3. Changes in regulated facilities, activities and programmes;</li> <li>4. Research and development.</li> </ol>
Process	<p>Strategic Plan:</p> <ol style="list-style-type: none"> <li>1. Analysis and documentation of all relevant regulatory challenges for the coming multi-year period;</li> <li>2. Establishing priorities using the graded approach, assessment of available resources; and,</li> <li>3. Drafting of plan with objectives, outcomes, resources and timelines</li> </ol> <p>Operational Work Plan:</p> <ol style="list-style-type: none"> <li>1. Extracting of relevant information from strategic plan; and,</li> <li>2. Drafting of detailed work plan identifying (scope, objectives, key interfaces, the various tasks involved, who is responsible for these tasks, work schedule, identifying the resources and competences needed, regulatory requirements associated with the work, work controls; and expected deliverables).</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. One strategic plan;</li> <li>2. Detailed work plans as needed;</li> <li>3. Allocation of necessary resources.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Training and Competences Management;</li> <li>2. Performance Management;</li> <li>3. Communication and Consultation; and,</li> <li>4. All core processes.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Capture of the all relevant circumstances for the regulatory body during the coming three years;</li> <li>2. Provision of relevant priorities for the regulatory body;</li> <li>3. Engagement of all managers and relevant staff;</li> <li>4. Optimization of resources; and,</li> <li>5. Planning completed within set time limits</li> </ol>



## II-6. Management of changes

Purpose	To manage change in response to external or internal initiatives and minimize the risks to performance.
Inputs	1. Proposed changes to strategy, policy, organization or process.
Process	<ol style="list-style-type: none"> <li>1. Identify changes which may impact on performance;</li> <li>2. Assess/filter to identify those changes with significant potential impact;</li> <li>3. Graded systematic assessment of change and potential impact on strategy, policy, structure, capability and competence of staff, and processes;</li> <li>4. Impact/cost-benefit assessment of change;</li> <li>5. In consultation with relevant stakeholders, development of graded milestone change plan which includes controls to exploit opportunities and minimize the risks of change – aligned with other plans;</li> <li>6. Development of monitoring scheme and success criteria for the supervision of change plan implementation and the review of its effectiveness; and,</li> <li>7. Agreement to change plan at appropriate management level.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Proportionate change implementation plan with monitoring scheme and success criteria; and,</li> <li>2. Plan for the evaluation of the assessment of the effectiveness of the change.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Governance;</li> <li>2. Policy Making;</li> <li>3. Planning; and,</li> <li>4. Communication and Consultation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Proportionate change plan prepared on time before change is commenced;</li> <li>2. Implementation of change plan to time and cost; and,</li> <li>3. Evaluation of change completed on time.</li> </ol>

## II-7. Communication and consultation

Purpose	To communicate and interact with interested parties about matters related to safety regulation and control, commensurate with applicable legislation.
Inputs	<ol style="list-style-type: none"> <li>1. Legal and regulatory requirements; documents and records produced or received by the regulatory body; and,</li> <li>2. Documents and opinions from private or public organizations or persons.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Identify relevant interested parties, their particular rights, interests and/or concerns and appropriate means of informing and interacting;</li> <li>2. Set out a communications policy of what information is to be provided to interested parties and how they will be contacted;</li> <li>3. Establish/maintain regular contact with interested parties in line with legal requirements and national or international obligations;</li> <li>4. Establish means to inform other interested parties on key regulatory decisions, possible associated radiation risks at facilities and activities, incidents in facilities and activities, and scientific and technical information;</li> </ol>

	<ol style="list-style-type: none"> <li>5. Establish web presence where interested parties can access relevant information on regulatory strategies, policies and activities; and,</li> <li>6. Record feedback from interested parties with suitable proportionate records of what action has been made in response to the feedback.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Appropriate information to meet legal requirements and the reasonable needs of interested parties in a form that is designed to assist understanding and engagement.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Governance;</li> <li>2. Policy Making; and,</li> <li>3. Planning.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Timely issue of information and involvement of appropriate interested parties; and,</li> <li>2. Interested party feedback.</li> </ol>

## CORE PROCESSES

More information and requirements related to the functions supported by these processes can be found in DS473 [9].

### II-8. Review and assessment of facilities and activities

Purpose	The purpose of this process is to review and assess information related to safety, technical and other information 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	<ol style="list-style-type: none"> <li>1. Legal and Regulatory requirements, guidance and regulatory procedures specific to review and assessment;</li> <li>2. Application and documents submitted in support of the application;</li> <li>3. Technical and other documents required to assess compliance with the regulatory requirements and the authorization;</li> <li>4. Operating experience feedback;</li> <li>5. Developments in international standards and research; and,</li> <li>6. Outputs of other regulatory processes (e.g. inspection results, previous reviews and assessment results)</li> </ol>
Process	<p>Review and assessment to support the authorization process</p> <ol style="list-style-type: none"> <li>1. Extract relevant information from all inputs;</li> <li>2. Establish a review and assessment plan (identify key issues/tasks, milestones, assigned resources – internal/external);</li> <li>3. Conduct review and assessment activities;</li> <li>4. Collect and integrate assessment results, and request additional information if needed;</li> <li>5. Document the conduct of review and assessment and results;</li> </ol>

	<ol style="list-style-type: none"> <li>6. Propose authorization conditions; and,</li> <li>7. Provide feedback into the authorization process.</li> </ol> <p>Review and assessment to support regulatory oversight</p> <ol style="list-style-type: none"> <li>1. Extract relevant information from all inputs;</li> <li>2. Establish a review and assessment plan (identify key issues/tasks, milestones, assigned resources – internal/external);</li> <li>3. Request additional technical and other documents, if needed;</li> <li>4. Conduct review and assessment activities;</li> <li>5. Document the conduct of review and assessment and results; and,</li> <li>6. Provide feedback information for other regulatory processes</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Reports and documents covering review and assessment results, proposed conditions for authorization.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Authorization;</li> <li>2. Inspection;</li> <li>3. Enforcement;</li> <li>4. Event reporting;</li> <li>5. Document control; and,</li> <li>6. Communication and consultation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Review completed with planned resources and within set time limits, successful communication with the applicant or licensee holder and the public.</li> </ol>

## II-9. Authorization and notification

Purpose	To make decisions on requests for authorizations in line with legal and regulatory requirements.
Inputs	<ol style="list-style-type: none"> <li>1. Legal and regulatory requirements, guidance and regulatory procedures specific to authorizations;</li> <li>2. Application for an authorization;</li> <li>3. Demonstration of safety in support of the application (e.g. Safety assessment);</li> <li>4. Outputs of other regulatory processes (e.g. review and assessment, inspection); and,</li> <li>5. (Operational) performance of the applicant – safety history – compliance history</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Extract relevant information from all inputs;</li> <li>2. Verify completeness of the application;</li> <li>3. Require applicant to submit a safety assessment commensurate with the risk;</li> <li>4. Require applicant to submit additional safety related information, if necessary;</li> <li>5. Conduct review and assessment;</li> </ol>

	<ol style="list-style-type: none"> <li>6. Conduct verification activities (e.g. on-site inspection), as appropriate;</li> <li>7. Make a decision on the application, specifying any necessary limits and conditions and controls on the authorized party's subsequent activities;</li> <li>8. Formally record and document the decision and basis for decision; and,</li> <li>9. Issue an authorization or refusal.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Authorization document (including limits, conditions, controls); and,</li> <li>2. Decision and basis for decision.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Review and assessment;</li> <li>2. Inspection;</li> <li>3. Document control; and,</li> <li>4. Communication and consultation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Issuing of authorization completed with planned resources and within set time limits; and,</li> <li>2. Successful communication with the applicant or authorized party and the public.</li> </ol>

## II-10. Inspection of facilities and activities

Purpose	To inspect the facilities and activities of the authorized parties to verify they are in compliance with the regulatory requirements and the conditions specified in the authorization.
Inputs	<ol style="list-style-type: none"> <li>1. Legal and regulatory requirements, guidance and regulatory procedures specific to inspection;</li> <li>2. List of licensed facilities and activities and the relative hazard/risk posed by each;</li> <li>3. Relevant authorizations and issues or concerns for follow up;</li> <li>4. Safety performance of the authorized parties, including results of regulatory inspections;</li> <li>5. Strategic directions/ plans;</li> <li>6. Reports of incidents and events; and,</li> <li>7. Outputs of other core regulatory processes.</li> </ol>
Process	<p>Develop overall programme for inspection of facilities and activities:</p> <ol style="list-style-type: none"> <li>1. Identify key aspects (see GSR Part1 [2]) to be included in the baseline inspection programme, as appropriate to the type of facility and activities;</li> <li>2. Priorities and safety significant targets for the programme;</li> <li>3. Allocate inspection resources across facilities and activities in proportion to the relative hazard/risk posed by each, taking into account safety performance, results of regulatory inspections, numbers and nature of outstanding issues; and,</li> <li>4. Make provisions for reactive inspections</li> </ol> <p>Develop specific inspection plans for individual facility/ activities:</p> <ol style="list-style-type: none"> <li>1. Prepare inspection plan for types of facility/ activity, including</li> </ol>

	<p>objectives/outcomes for the facility/ activity, number and types of inspections, method(s), resources, schedules/timetables; and,</p> <ol style="list-style-type: none"> <li>2. Prepare plans for each individual inspection, including objectives, resources, question sets, resources, conduct of inspection/data collection, identification of non-compliances, inspection report, notification of authorized party. Note: Individual inspections could be performed both announced and unannounced.</li> </ol> <p>Develop procedures for inspections, covering all facilities and activities under regulatory control.</p> <p>Develop procedure for reactive inspections:</p> <ol style="list-style-type: none"> <li>1. Assess unexpected, unplanned situation or incidents against relevant inspection selection criteria and decide if a reactive inspection is needed;</li> <li>2. For each reactive inspection, select objectives in line with significance and nature of incident/event and in context of with overall plan for organization/site and current licensee performance, assign resources, prepare question sets, verify access arrangements, analyses relevant documents, conduct of inspection/data collection, prepare inspection report and communicate to authorized party.</li> </ol> <p>Conduct inspections;</p> <p>Record findings and follow-up.</p>
Outputs	<ol style="list-style-type: none"> <li>1. Programme of inspection of facilities and activities;</li> <li>2. Inspection plan for individual facility/ activities;</li> <li>3. Internal report(s) of inspection and findings and conclusions on non-compliance and correspondence/communication to authorized party; and,</li> <li>4. Inspection records.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Authorization;</li> <li>2. Enforcement;</li> <li>3. Document control; and,</li> <li>4. Communication and consultation</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Degree of fulfilment of planned inspection programme;</li> <li>2. Number and reason for additional announced and unannounced inspections; and,</li> <li>3. Number of enforcement cases.</li> </ol>

## II-11. Enforcement of regulatory requirements

Purpose	To identify and apply the appropriate action to ensure compliance with regulatory requirements.
Inputs	<ol style="list-style-type: none"> <li>1. Applicable laws, regulations, standards and codes;</li> <li>2. Enforcement policy;</li> <li>3. Authorization (e.g. licence, certificate or permit);</li> </ol>

	<ol style="list-style-type: none"> <li>4. Inspection facts and findings (planned and reactive);</li> <li>5. Review and assessment results;</li> <li>6. Compliance history; and,</li> <li>7. Operational experience and feedback</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Assess the significance of a non-compliance by considering the following criteria: actual or potential safety consequences; number or recurrence of non-compliances; and intentional aspects of the non-compliance situation, taking into consideration the severity of the non-compliance; the risk classification of the key risk areas or criteria; and the level of risk tolerance that the regulatory body is willing to accept;</li> <li>2. Select enforcement actions – which may include one or more of: request for voluntary action, orders, amendment or revocation of authorizations, investigation and prosecution;</li> <li>3. Apply enforcement- there should be an associated procedure for each selected tool, in all cases, a clear documentation of the facts, findings and the basis of the enforcement; and,</li> <li>4. Confirm that the authorized party has effectively implemented any necessary corrective actions. If necessary consider next iteration of enforcement action.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Enforcement actions; and,</li> <li>2. Record of completion of corrective actions.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Review and assessment;</li> <li>2. Authorization;</li> <li>3. Inspection;</li> <li>4. Document control; and,</li> <li>5. Communication and consultation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Number of appeals;</li> <li>2. Number of different kinds of enforcement cases (should be few serious cases); and,</li> <li>3. Time for issuing of enforcement decision after finding the non-compliance.</li> </ol>

## II-12. Development of regulations and guides

Purpose	To develop and maintain the regulations and guidance documents that define the regulatory requirements and expectations applicable to the regulated facilities and activities.
Inputs	<ol style="list-style-type: none"> <li>1. Legal mandate of the regulatory body to issue regulations and guides;</li> <li>2. Government regulations or guides to authorities on the process to issue regulations;</li> <li>3. New developments in international safety standards and industrial standards;</li> <li>4. New developments in technology, R &amp; D and operational lessons learned;</li> <li>5. Identification of needs for new regulations or guides in a specific area; and,</li> <li>6. Identification of needs to revise existing regulations or guides.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Analysis and scoping of the specific needs for new or updated regulations or</li> </ol>

	<p>guides;</p> <ol style="list-style-type: none"> <li>2. Establishment of project to develop the regulations or guides;</li> <li>3. Review of relevant international safety standards and industrial standards;</li> <li>4. Drafting;</li> <li>5. Assessment of draft within the regulatory body, including legal review;</li> <li>6. Consultation with interested parties, including the public via website;</li> <li>7. Consultation with advisory committee (as appropriate);</li> <li>8. Revision of draft and final legal review;</li> <li>9. Decision to adopt the regulations or guides;</li> <li>10. Publication;</li> <li>11. Information on website and distribution of copies; and,</li> <li>12. Information and training of staff in the new regulations or guides.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. New or revised regulations and guides.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Review and assessment;</li> <li>2. Inspection;</li> <li>3. Enforcement;</li> <li>4. Operational experience feedback; and,</li> <li>5. International cooperation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Production completed with planned resources and within set time limits;</li> <li>2. Successful communication with interested parties; and,</li> <li>3. New or revised regulations shown to provide benefits for interested parties.</li> </ol>

### II-13. Emergency preparedness

Purpose	To effectively respond to radiological or nuclear emergency
Inputs	<ol style="list-style-type: none"> <li>1. Legal and regulatory provisions regarding emergency preparedness and response, including international obligations</li> <li>2. National radiation emergency response plan;</li> <li>3. Authorized parties' emergency plans;</li> <li>4. Internal emergency plan of the regulatory body;</li> <li>5. Developments, experiences and lessons identified in the area of emergency preparedness and response, both nationally and internationally</li> <li>6. International cooperation.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Analysis of national requirements and of arrangements to be made for emergency preparedness by the regulatory body;</li> <li>2. Development of necessary arrangements as identified in the analysis (for example: developing procedures, supplying tools and equipment, assigning facilities etc.);</li> <li>3. Identifying necessary skills and knowledge among its staff for fulfilling its functions in emergency preparedness and in emergency response;</li> <li>4. Development of annual training programme and exercise programme which takes into account the authorized party, national and international exercises;</li> <li>5. Carrying out training and exercises according to programme;</li> <li>6. Evaluation of training and exercises;</li> </ol>

	<ol style="list-style-type: none"> <li>7. Feedback of experiences to planning and involved staff; and,</li> <li>8. Review and revision of emergency arrangements as needed.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Verification that internal emergency arrangements are realistic and provide for an effective discharge of assigned functions;</li> <li>2. Improved personnel skills and arrangements of the regulatory body; and,</li> <li>3. Up-to-date emergency plan and procedures;</li> <li>4. Feedback for consideration into next year's programmes in emergency preparedness and response.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Planning;</li> <li>2. Inspection;</li> <li>3. Coordination with other national authorities and authorized parties; and,</li> <li>4. International cooperation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Demonstrated performance in relation to expectations in plans.</li> </ol>

#### II-14. Information of interested parties

Purpose	To inform interested parties about radiation risks and hazards.
Inputs	<ol style="list-style-type: none"> <li>1. Scientifically based information about radiation risks and hazards associated with facilities and activities; and,</li> <li>2. Legal and regulatory provisions regarding protection of the public.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Development of information plan;</li> <li>2. Development of information material on radiation risks and hazards understandable for ordinary people;</li> <li>3. Development of information material about requirements to protect the public from radiation risks and hazards;</li> <li>4. Planning and selection of efficient means to reach and interact with the public, such as printed information material, website, exhibitions, information meetings, visits in schools etc.; and,</li> <li>5. Updating of printed material and website.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Answering of questions from the public and media;</li> <li>2. Conduct of information meetings; and,</li> <li>3. Information of interested parties.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Communication and Consultation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Satisfaction of the public and media.</li> </ol>



## PROCESSES TO SUPPORT CORE REGULATORY FUNCTIONS

### II-15. Legal support

Purpose	To provide legal advice to regulatory body in connection with the development of regulations, regulatory judgments and decision making such as enforcement decisions.
Inputs	<ol style="list-style-type: none"> <li>1. Draft regulatory guidelines;</li> <li>2. Draft inspection reports;</li> <li>3. Draft regulatory statements; and,</li> <li>4. Draft authorization documents.</li> </ol>
Process	It may be that this is not an explicit process, however, in some processes a statement may appear to look for or to consult legal advice. For each core process, the legal advice may be different.
Outputs	<ol style="list-style-type: none"> <li>1. Legal advice;</li> <li>2. Complements to regulations and guides;</li> <li>3. Complements to authorization documents; and,</li> <li>4. Advice on enforcement activities.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Authorization;</li> <li>2. Development of Regulations and Guides; and,</li> <li>3. Enforcement.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Number of contestations to authorizations issued;</li> <li>2. Number of contestations to regulations issued;</li> <li>3. Number of contestations to enforcement actions.</li> </ol>

### II-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	<ol style="list-style-type: none"> <li>1. Identification of the external expert support (questions, scope, timeline, milestones, etc.);</li> <li>2. Develop the specifications;</li> <li>3. Identify possible support organizations;</li> <li>4. Start (sub-) process purchasing;</li> <li>5. Closely follow the project, checks at milestones;</li> <li>6. Check deliverables against specifications;</li> <li>7. Evaluate quality of deliverables;</li> <li>8. If necessary, start iterations with the support organization;</li> <li>9. If deliverables are acceptable, end (sub-) process purchasing;</li> <li>10. Document and look for improvements.</li> </ol>

Outputs	1. Deliverables specified.
Interfaces	1. Processes for core functions; 2. Processes of functions supporting core functions; and, 3. Others.
Performance criteria	1. Numbers of iterations; 2. Delays; 3. Quality of deliverables; 4. Internal resources needed compared with external resources.

## II-17. 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 nuclear safety that are not yet resolved; 2. Questions from international collaboration; and, 3. Questions that may arise from operational experience.
Process	1. Identify the research questions; 2. Conduct a literature search; 3. Contact institutions (scientific, regulatory, universities, IAEA, etc.) for additional information; 4. Specify the research to be done; 5. Specify the acceptance/success criteria; 6. Start (sub-) process purchasing; 7. Closely follow the project, checks on milestones; 8. Check deliverables against specifications; 9. Evaluate quality of deliverables; 10. If necessary, start iterations with the support organization. 11. If deliverables are acceptable, end (sub-) process purchasing; and, 12. Document and look for improvements.
Outputs	1. Research and development report; and, 2. Answers to research questions
Interfaces	1. Purchasing; 2. Review and assessment; and, 3. Others.
Performance criteria	1. Numbers of iterations; 2. Delays; 3. Quality of deliverables; 4. Internal resources needed compared with external resources.

## II-18. International cooperation

Purpose	To engage in international cooperation according to multilateral or bilateral agreements, including international conventions as well as preparations of international standards and regulatory assistance. To exchange experience and gain information on unfamiliar regulatory activities.
Inputs	<ol style="list-style-type: none"> <li>1. Questions;</li> <li>2. Experience; and,</li> <li>3. Obligations of international conventions and codes of conduct.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Identify the information to be dealt with;</li> <li>2. Identify the institutions/organizations/countries that may contribute to the subject;</li> <li>3. Contact the corresponding institution/organization/country;</li> <li>4. Define the form of contact and collaboration;</li> <li>5. Get an agreement with the institution/organization/country;</li> <li>6. Identify the responsible staff members to contact the institution/organization/country;</li> <li>7. Develop a collaboration plan;</li> <li>8. If necessary start the (sub-) process purchasing;</li> <li>9. Start the cooperation; and,</li> <li>10. Iteration: Regularly check the effectiveness of the collaboration and the need for continuing the collaboration.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Protocols;</li> <li>2. Reports; and,</li> <li>3. Meeting minutes.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Purchasing; and,</li> <li>2. Communication and consultation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Results achieved as a consequence of international cooperation.</li> </ol>

## PROCESSES TO SUPPORT THE ORGANIZATION

Note: these processes are not specific to a regulatory body.

## II-19. Human resources management

Purpose	To ensure that the regulatory body has all times sufficient competent and qualified staff to discharge its responsibilities.
Inputs	<ol style="list-style-type: none"> <li>1. SRS 79; and,</li> </ol>

	2. Regulatory body organization chart.
Process	<ol style="list-style-type: none"> <li>1. Periodically evaluate the regulatory body’s staffing needs (link to competence management); and,</li> <li>2. Apply subprocesses such as: <ol style="list-style-type: none"> <li>a. Recruitment;</li> <li>b. Induction of new staff (education and training);</li> <li>c. Staff development (including appraisals, career development, continual training, etc.); and,</li> <li>d. Leave and retirement.</li> </ol> </li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Regulatory body with sufficient competent and qualified staff; and,</li> <li>2. Succession plan for key staff.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Planning;</li> <li>2. Finance;</li> <li>3. Knowledge management (retirements, leaves);</li> <li>4. Training and competence management; and,</li> <li>5. External expert support.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Percentage of staff fully qualified for position;</li> <li>2. Number of positions vacant;</li> <li>3. Amount of time a position remains unfilled.</li> </ol>

## II-20. Training and competence management

Depending on the size and the structure of the regulatory body, the related processes may vary. Some details are discussed in Chapter 6 Staffing and competence of staff, under Competence Management and Methods for acquiring competence. The concept of systematic approach to training is detailed in SRS 79 – see there also “Systematic Approach to Training”.

## II-21. Knowledge management

Purpose	To ensure that knowledge relevant for the activities of the regulatory body is acquired, stored, preserved and distributed – in general: managed as a very valuable resource of the regulatory body.
Inputs	<ol style="list-style-type: none"> <li>1. Any information relevant for the regulatory body to discharge its responsibilities and to fulfil its functions. Special attention should be paid to tacit knowledge which forms part of the experience of individuals (leaves, retirements).</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Periodically identify the regulatory body’s information needs;</li> <li>2. Periodically review the existing knowledge base;</li> <li>3. Identify needs for update of information;</li> <li>4. Compare with existing knowledge base and identify gaps;</li> </ol>

	<ol style="list-style-type: none"> <li>5. Identify and access internal and external sources of information and capture the necessary information to fill the gaps (essential: retirements and leaves);</li> <li>6. Convert information to knowledge of use to the regulatory body; <ol style="list-style-type: none"> <li>a. Store the information adequately;</li> <li>b. To assure safe storage;</li> </ol> </li> <li>7. To assure easy retrieval; and,</li> <li>8. Inform the concerned individuals about changes and updates.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Knowledge base; and,</li> <li>2. Comprehensive collection of up-to-date information.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Planning;</li> <li>2. Human resources management (retirements, leaves);</li> <li>3. Training and competence management;</li> <li>4. Research and development;</li> <li>5. External expert support; and,</li> <li>6. International cooperation.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Positive feedback of users;</li> <li>2. Completeness of knowledge base;</li> <li>3. Ease of access to relevant information; and,</li> <li>4. Accuracy and currency of information.</li> </ol>

## II-22. Document control

Purpose	To ensure that the IMS documents used by the regulatory body remain relevant, updated, available, understandable, unambiguous, user friendly and readily accessible (preparation, review, approval, issuance, distribution, use and revision of documents).
Inputs	<ol style="list-style-type: none"> <li>1. Existing IMS (list of documents);</li> <li>2. List of functions and tasks to be performed by the regulatory body;</li> <li>3. Changes in legislation;</li> <li>4. Changes in standards;</li> <li>5. Changes in the regulatory body;</li> <li>6. Changes in external expert support organizations; and,</li> <li>7. Changes in interested parties, etc.</li> </ol>
Process	<p>Used periodically or on demand of users.</p> <ol style="list-style-type: none"> <li>1. Compare input data with existing documentation;</li> <li>2. Regularly identify important activities (processes) performed by the regulatory body which are not documented yet ( in form of process descriptions, procedures, forms, etc.);</li> <li>3. Regularly identify needs for modifications in documents (caused by e.g. changes in legislation, organization, changed modes of collaboration, etc.);</li> <li>4. Use subprocess drafting/modifying documents; <ol style="list-style-type: none"> <li>a. Collect necessary information;</li> <li>b. Draft new or modified document using templates and writers guide;</li> </ol> </li> </ol>

	<ul style="list-style-type: none"> <li>c. Review of the draft (by different people), test user friendliness (may need iterations);</li> <li>d. Approval of the draft by authorized people;</li> <li>e. Inform the staff about changes in documentation (if necessary, do training);</li> <li>f. Issue new document;</li> <li>g. Distribute new document;</li> <li>h. Archive old documents; and,</li> </ul> <p>5. Regularly identify obsolete documents, take them out of order, archive.</p>
Outputs	1. Comprehensive set of up-to-date documents.
Interfaces	1. All other processes.
Performance criteria	<ul style="list-style-type: none"> <li>1. Positive feedback of users; and,</li> <li>2. Completeness of process descriptions and forms.</li> </ul>

## II-23. Control of records

Purpose	To ensure that relevant records are collected, processed and retained for specified periods as well as the records are reliable, complete, identifiable and easily retrievable.
Inputs	<ul style="list-style-type: none"> <li>1. Structure of the document management system (archive); and,</li> <li>2. All types of records (incoming documents, outgoing documents, internal documents like reports, protocols, notes, etc.).</li> </ul>
Process	<ul style="list-style-type: none"> <li>1. Subprocess registration/archiving; <ul style="list-style-type: none"> <li>a. Register all documents (incoming, outgoing, internally produced) according the structure of the document management system;</li> <li>b. Distribute copies of the document to concerned users. Respect confidentiality and security rules;</li> <li>c. Archive original document according the structure of the document management system; and,</li> </ul> </li> <li>2. Subprocess retrieval.</li> </ul>
Outputs	<ul style="list-style-type: none"> <li>1. Well structured archive;</li> <li>2. Easy access to documents in a reliable and timely manner for concerned users.</li> </ul>
Interfaces	<p>1. All other processes.</p> <p>Note: At a regulatory body, most of the processes create documents as a product. So, most of the processes use the Control of records as subprocess.</p>
Performance criteria	<ul style="list-style-type: none"> <li>1. Comprehensiveness of archive; and,</li> <li>2. Easy and timely access to relevant information.</li> </ul>

## II-24. Finance

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.

Purpose	To plan and account for the financial resources necessary to deliver the regulatory mandate, in accordance with the national laws and standards.
Inputs	<ol style="list-style-type: none"> <li>1. Strategies and plans;</li> <li>2. Identified financial needs; and,</li> <li>3. Available resources.</li> </ol>
Process	<ol style="list-style-type: none"> <li>1. Main process creates periodically the budget and provides the necessary financial resources; and,</li> <li>2. Subprocess: financial controlling, book-keeping.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Budget;</li> <li>2. Adequate financial resources for the regulatory body to discharge its responsibilities; and,</li> <li>3. Well balanced income and expenses.</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Planning;</li> <li>2. Human resources management; and,</li> <li>3. Purchasing.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Adequate financial resources available; and,</li> <li>2. Well balanced income and expenses.</li> </ol>

## II-25. Control of products

Products of the regulatory body are documents. Control of products means in this case assuring that the documents produced by the regulatory body are comprehensive, complete, reviewed and approved – in general that all quality assurance steps to finalize the document have been performed.

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 IMS.
Inputs	Information
Process	<ol style="list-style-type: none"> <li>1. Define the necessary information to create the document (as subprocess of other processes: core functions, functions supporting core functions, etc.);</li> <li>2. Screen the available information for relevance and completeness – if necessary, collect more information;</li> <li>3. Perform the task (core functions, functions supporting core functions, etc.);</li> <li>4. Draft the document;</li> <li>5. Review of draft document by an expert;</li> <li>6. Consider comments, and revise document if necessary;</li> <li>7. Finalize the document; and,</li> </ol>

	8. Approval of document by an authorized person in the regulatory body.
Outputs	1. Quality assured comprehensive and complete documents.
Interfaces	1. All other processes.
Performance criteria	1. Number of iterations to finalize the document; 2. Satisfaction of the addresses; and, 3. Timeliness of delivery.

## II-26. Purchasing

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

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 costs 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; 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); and, 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; and, 3. Subprocess for many processes within the IMS
Performance criteria	1. Satisfactory products and services (within specifications); 2. Timely delivery of products and services; and, 3. Cost of product or service within budget.

## II-27. Measuring and test equipment



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

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	<ol style="list-style-type: none"> <li>1. Information from suppliers;</li> <li>2. Requirements for calibration of measuring and test equipment: range of the instrument, admissible tolerance, periodicity for calibration, authorization for calibration, methods for calibration, documentation, etc.</li> </ol>
Process	<p>Adequacy of measuring and test equipment</p> <ol style="list-style-type: none"> <li>1. Periodically review the adequacy of measuring and test equipment;</li> <li>2. If measuring and test equipment is outdated, look for adequate new equipment; and,</li> <li>3. If needed, start purchasing process.</li> </ol> <p>Calibration of measuring and test equipment</p> <ol style="list-style-type: none"> <li>1. Periodically review the calibration of measuring and test equipment (database);</li> <li>2. If calibration date is close, start calibration, respect the necessary criteria;</li> <li>3. After successful calibration: note the calibration date and the date for next calibration on the measuring and test equipment; and,</li> <li>4. Write calibration date and the date for next calibration into database.</li> </ol>
Outputs	<ol style="list-style-type: none"> <li>1. Adequate measuring and test equipment with up-to-date calibration</li> </ol>
Interfaces	<ol style="list-style-type: none"> <li>1. Measuring and test processes; and,</li> <li>2. Purchasing.</li> </ol>
Performance criteria	<ol style="list-style-type: none"> <li>1. Measuring and test equipment adequate and calibrated.</li> </ol>

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