IAEA Safety Standards

for protecting people and the environment

Establishing the Infrastructure for Radiation Safety

Specific Safety Guide

No. SSG-44

IAEA
International Atomic Energy Agency

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Information on the IAEA's safety standards programme is available on the IAEA Internet site

http://www-ns.iaea.org/standards/

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at: Vienna International Centre, PO Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to Official.Mail@iaea.org.

RELATED PUBLICATIONS

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

Other safety related IAEA publications are issued as **Emergency Preparedness and Response** publications, **Radiological Assessment Reports**, the International Nuclear Safety Group's **INSAG Reports**, **Technical Reports** and **TECDOCs**. The IAEA also issues reports on radiological accidents, training manuals and practical manuals, and other special safety related publications.

Security related publications are issued in the **IAEA Nuclear Security Series**.

The **IAEA Nuclear Energy Series** comprises informational publications to encourage and assist research on, and the development and practical application of, nuclear energy for peaceful purposes. It includes reports and guides on the status of and advances in technology, and on experience, good practices and practical examples in the areas of nuclear power, the nuclear fuel cycle, radioactive waste management and decommissioning.

ESTABLISHING THE INFRASTRUCTURE FOR RADIATION SAFETY

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

IAEA SAFETY STANDARDS SERIES No. SSG-44

ESTABLISHING THE INFRASTRUCTURE FOR RADIATION SAFETY

SPECIFIC SAFETY GUIDE

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FOREWORD

by Yukiya Amano
Director General

The IAEA's Statute authorizes the Agency to "establish or adopt… standards of safety for protection of health and minimization of danger to life and property" — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures[1] have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered ‘overarching’ requirements, are expressed as ‘shall’ statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

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[1] See also publications issued in the IAEA Nuclear Security Series.

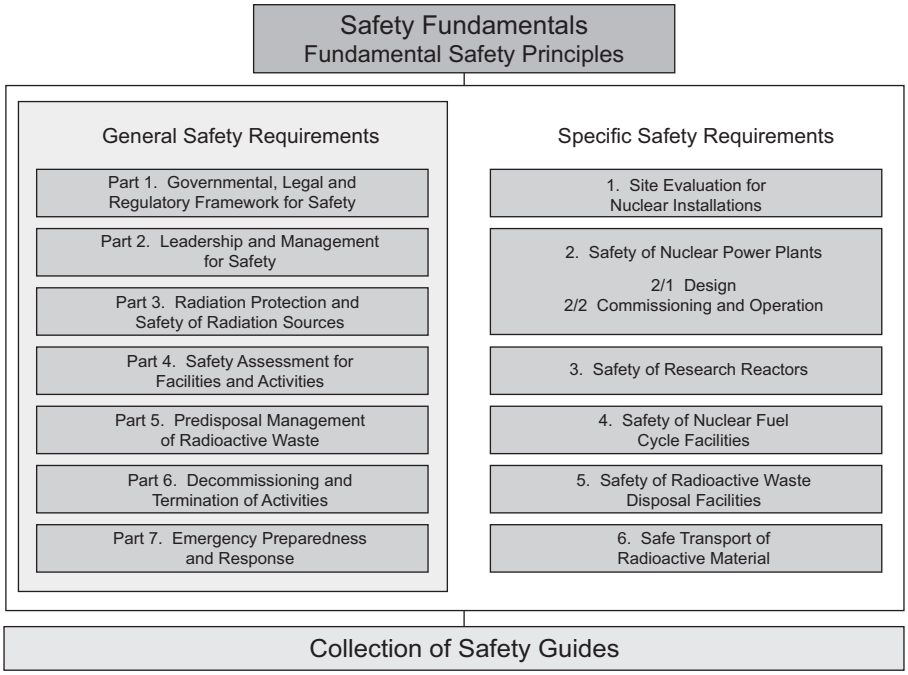

FIG. 1. The long term structure of the IAEA Safety Standards Series.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and five safety standards committees, for emergency preparedness and response (EPReSC) (as of 2016), nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of

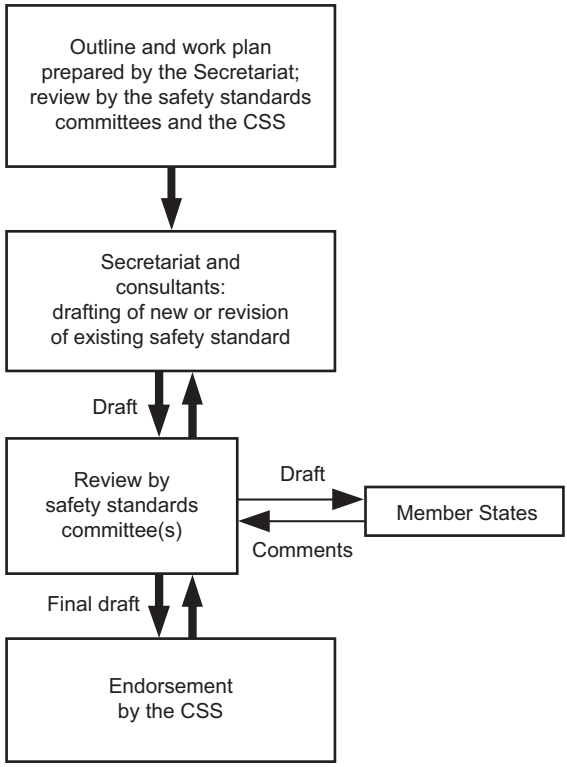

FIG. 2. The process for developing a new safety standard or revising an existing standard.

the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see http://www-ns.iaea.org/standards/safety-glossary.htm). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. The IAEA safety standards establish requirements and provide guidance for establishing and implementing a national safety infrastructure in a State to ensure protection of people and the environment from harmful effects of ionizing radiation.

1.2. IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1] provides a coherent set of ten safety principles that constitute the basis for establishing safety requirements to achieve the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation. The safety principles form a set that is applicable in its entirety. Although in practice different principles may vary in importance depending on particular circumstances, the appropriate application of all relevant principles is required.

1.3. Principle 2 of SF-1 [1] on the role of government states that "[a]n effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained." The development of the national radiation safety infrastructure takes place within this framework. IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2] lists the responsibilities and functions of the government for safety[1]. Other IAEA safety standards establish detailed requirements relating to those responsibilities and functions and address, in particular, the protection of workers, patients, the public and the environment in all exposure situations and in a variety of facilities and activities.

1.4. Following the structure of government responsibilities and functions as specified in GSR Part 1 (Rev. 1) [2], the national safety[2] infrastructure can be

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[1] States have different legislative structures, and therefore the term 'government' as used in the IAEA safety standards is to be understood in a broad sense, and is accordingly interchangeable here with the term 'State'.

[2] For the purposes of this Safety Guide, 'safety' means the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to radiation risks. The term safety here refers to radiation safety, including safety of radioactive waste management and safety of transport of radioactive material, but it does not include aspects relating to the safety of nuclear installations.

structured in a set of areas, providing collectively for the protection of workers, patients, the public and the environment in all exposure situations. Those areas are the following:

— The national policy and strategy for safety;
— The legal framework for safety;
— The regulatory framework for safety;
— Coordination of different authorities with responsibilities for safety;
— Emergency preparedness and response;
— The system for protective actions to reduce existing or unregulated radiation risks;
— Management of radioactive waste and decommissioning of facilities;
— Transport of radioactive material;
— Competence for safety;
— Provision of technical services;
— Participation in the global safety regime.

1.5. In addition to the areas listed in paragraph 1.4 above, the government is required to ensure that adequate infrastructural arrangements are established for interfaces of safety with security [2]. Other provisions are provided in the Code of Conduct on the Safety and Security of Radioactive Sources [3]. The IAEA Nuclear Security Series provides recommendations and guidance relating to the prevention and detection of, and response to, criminal or intentional unauthorized acts involving or directed at nuclear material, other radioactive material, associated facilities or associated activities. Nuclear Security Series No. 20 [4] sets out the objective and essential elements of a State's nuclear security regime, and Nuclear Security Series No. 14 [5] provides recommendations to States and competent authorities on how to develop or enhance, to implement and to maintain a nuclear security regime for radioactive material, associated facilities and associated activities. Nuclear Security Series No. 11 [6] contains more specific guidance to assist States in the development of regulatory requirements for the security of radioactive sources. Nuclear Security Series No. 9 [7] contains specific guidance on security in the transport of radioactive material.

1.6. In the establishment of the national radiation safety infrastructure, there may be interfaces between safety and nuclear security with regard to the functions of the regulatory body, particularly in cases where the regulatory body has responsibility for both radiation safety and nuclear security under the regulatory infrastructure. For example, the regulatory body may choose to carry out joint inspections of a facility for radiation safety and nuclear security. Safety measures

and security measures should be designed and implemented in a coordinated manner so that security measures do not compromise safety and safety measures do not compromise security.

The interface of safety with nuclear security may also involve coordination between the regulatory body and other organizations with relevant responsibilities, such as the State's intelligence organizations, customs and border authorities, law enforcement authorities, and ministries of the interior, defence, transport and foreign affairs.

1.7. Evaluation of the national radiation safety infrastructure in IAEA Member States over many years has revealed that many States do not have an adequate radiation safety infrastructure in place. It is often a challenge for States to find an effective and efficient means within their national circumstances to establish or strengthen a radiation safety infrastructure to a level that meets the IAEA safety standards. This Safety Guide provides advice to States to overcome this challenge.

1.8. This Safety Guide recognizes that States have various levels of experience with the use of ionizing radiation and are at different stages in the development of their national radiation safety infrastructure. Therefore this Safety Guide is to be used with flexibility by States that are in a different initial status of safety infrastructure.

1.9. This Safety Guide recommends that States make an assessment of the national situation as a first action to identify applicable subsequent actions. The IAEA promotes national self-assessments and provides for the application of its safety standards through safety review services. The actions needed to establish the national radiation safety infrastructure depend on the national circumstances, including the legal system in the State, the governmental structure, and the availability of human, technical and financial resources. Such factors will also affect the pace at which the infrastructure can be developed.

1.10. This Safety Guide is intended for use by any persons or organizations participating in the preparation, implementation and improvement of the national radiation safety infrastructure, including the following:

— Governmental officials;
— Legislative bodies;

— Organizations that have been given an explicit governmental mandate to assess or to coordinate the development of the national radiation safety infrastructure;
— The regulatory body;
— Education and training institutions and providers of technical services;
— Organizations for radioactive waste management;
— Organizations involved in preparedness for and response to a nuclear or radiological emergency;
— Competent authorities for the transport of radioactive material.

1.11. International organizations may use this Safety Guide to help determine the status or the progress of a State in developing and establishing its national radiation safety infrastructure, so that further assistance and guidance can be provided in a meaningful and timely manner.

1.12. Safety related terms used in this Safety Guide are to be understood as defined in the IAEA Safety Glossary [8].

1.13. This Safety Guide uses the generic term 'designated body' to refer to the organizations and/or individuals assigned the responsibility by the government for taking an action. However, since States have different legal structures, assigning such responsibility is not always possible, and in these cases, the general term 'government' has been used.

OBJECTIVE

1.14. The objective of this Safety Guide is to provide guidance on the establishment of a national radiation safety infrastructure that meets the IAEA safety standards. It provides recommendations, in the form of actions, on how to meet the relevant safety requirements in an effective and integrated manner while taking specific national circumstances into full consideration. This Safety Guide does not diminish the application of, or provide a synopsis of or a substitute for, the IAEA Safety Fundamentals and Safety Requirements publications and the associated Safety Guides.

1.15. This Safety Guide sets out a holistic approach to the establishment of the national radiation safety infrastructure. This Safety Guide provides advice on designing an integrated roadmap that fits the national circumstances for the application of IAEA safety standards for States with essentially no elements of

the radiation safety infrastructure in place and also for States that already have some elements in place.

SCOPE

1.16. This Safety Guide provides recommendations in relation to the relevant IAEA safety requirements for an effective national radiation safety infrastructure that ensures an appropriate level of safety commensurate with the radiation risks associated with the facilities and activities in the State. This Safety Guide also includes guidance for the application of the provisions of relevant international instruments.

1.17. This Safety Guide does not cover the IAEA safety requirements relating to nuclear safety infrastructure.[3]

1.18. This Safety Guide refers to the need for a nuclear security infrastructure and the interface with the radiation safety infrastructure, but does not provide guidance on nuclear security aspects. Detailed guidance on nuclear security can be found in the IAEA Nuclear Security Series.

STRUCTURE

1.19. This Safety Guide provides a comprehensive set of recommendations, presented as actions, on meeting safety requirements. The actions are sequentially numbered; however, this does not mean that their completion needs to be sequential.

1.20. Section 2 elaborates on the concepts of designated bodies and actions and provides guidance on the possible interdependences between actions and the sequence these actions should be taken in.

1.21. Section 3 addresses the preparatory actions to be conducted by the government towards establishing a fully functional national radiation safety infrastructure. The first set of actions is related to the assessment of the current

[3] For States considering and preparing to embark on a nuclear power programme, guidance on the establishment of a framework for safety in accordance with the IAEA safety standards is provided in IAEA Safety Standards Series No. SSG-16, Establishing the Safety Infrastructure for a Nuclear Power Programme [9].

situation in the State and to the allocation of responsibilities. For States that do not have a specific legal framework for safety, this section provides advice on actions that can be taken within the existing legal framework to provide a degree of control of radiation sources until the legal framework for safety is established.

1.22. Section 4 provides detailed advice on actions to be taken in the different areas of the national radiation safety infrastructure as listed in para. 1.4. For each of these areas, this section discusses the involvement of the different organizations, and provides examples on the assignment of responsibilities and the structure of the respective designated body.

1.23. Section 5 recommends actions to be carried out by each organization having a role in establishing or strengthening the national radiation safety infrastructure to measure, assess and continuously improve its performance in order to ensure that goals are achieved and any necessary corrective actions are implemented. A similar recommendation is also made to the government to assess the effectiveness of the national radiation safety infrastructure as a whole.

2. CONCEPTS

THE CONCEPT OF DESIGNATED BODIES

2.1. This Safety Guide uses the generic term ‘designated body’ to refer to the organizations and/or individuals assigned responsibility by the government for taking the actions relating to a particular area of the national radiation safety infrastructure. Guidance and examples are provided in Section 4 on the possible structure of the designated body in each area of the radiation safety infrastructure.

2.2. The government should assign the responsibilities for establishing or developing each of the areas of the national radiation safety infrastructure listed in para. 1.4 to a designated body and should ensure that the designated body has the authority and resources necessary to perform its assigned activities.

2.3. Depending on the structure of the government, several governmental agencies and other interested parties may be involved in developing the national radiation safety infrastructure, each in the area of its competence. The designated body in any area is not necessarily a single organization, but could be, for example, an existing organization, a newly established organization, a group

of organizations, a team of experts, or a committee spanning several relevant government organizations and interested parties.

2.4. The structure of a designated body may differ depending on the specific area of the national radiation safety infrastructure to be developed, for example:

— For establishing regulatory infrastructure, an organization or an organizational unit within the government structure may be appointed or established;
— For national coordination, a high level committee could be an effective option;
— For building competence in safety, public and private educational and training institutions and professional bodies or associations could be involved.

For certain areas of the national radiation safety infrastructure, the regulatory body, once established, could be part of the designated body. Further guidance and considerations on the structure of designated bodies is provided in Section 4.

2.5. The structure of a designated body may evolve during the development of the particular area of the national radiation safety infrastructure. In particular, the promulgation of the legal framework for safety, the establishment of the regulatory body, and the actions relating to regular monitoring, assessment and continuous improvement could be drivers for such evolvement.

2.6. Effective coordination should be maintained among the different organizations and individuals within a designated body.

2.7. Depending on the particular area of the national radiation safety infrastructure, the assignment of responsibility to a designated body may be needed for only a limited period of time. For example, the need for a designated body for preparing the legal framework for safety will end once the legal framework for safety is established.

THE CONCEPT OF ACTIONS

2.8. The guidance provided in this Safety Guide on the development of each area of the national radiation safety infrastructure is formulated in the form of a set of actions.

2.9. An action in this Safety Guide should be understood as a collection of activities contributing to a common goal. An action may be taken in steps that are completed in different timeframes.

2.10. Not all actions will be applicable to all States.[4] This Safety Guide provides advice on the assessment of the national situation and the identification of the actions that need to be prioritized and taken by the State in each area of the national radiation safety infrastructure in order to comply with the IAEA safety standards. The prioritization of the applicable actions depends on many factors, including the following:

— The importance of the action to safety and its direct or indirect impact on other actions or other sectors that may be dependent on the national radiation safety infrastructure;
— The possible consequences if the action is delayed or not implemented;
— The complexity of the action and the resources available;
— The State's priorities and development plans.

2.11. Some actions have logical interdependences, i.e. certain activities within one action could be logically dependent on the completion of activities within another action. Actions with logical interdependences could be within the same area of the national radiation safety infrastructure or in different areas.

2.12. In some cases, logical interdependence will result in relative chronological ordering of the actions. This is the case, for example, for actions relating to setting out regulatory requirements, which can only be implemented after the actions relating to the establishment of the legal framework for safety have been completed.

2.13. In cases where the logical interdependence does not lead to chronological ordering of the actions as a whole, the different activities of the actions can be taken partly in parallel. As an example, the actions relating to the establishment of authorization and inspection processes can be taken in parallel. Similarly, the actions relating to the regulatory infrastructure can be taken in parallel with the actions relating to building competence for safety or to emergency preparedness and response.

[4] Nevertheless, actions relating to measurement, assessment and continuous improvement are likely to be applicable to all States.

2.14. Actions taken by different designated bodies, where logical interdependences exist, should be coordinated.

2.15. The general scheme adopted in this Safety Guide for establishing national radiation safety infrastructure is shown in Fig. 1. The assignment of responsibilities and the identification of applicable actions are based on the assessment of the national situation in each area of the national radiation safety infrastructure. Regular monitoring, measurement and assessment are essential for continuous improvement and for ensuring the effectiveness of the infrastructure and may reveal a need for adjustments in the allocation of responsibilities or in the determination and prioritization of the necessary actions.

2.16. Figure 2 shows possible starting points, end points and interdependences in the development of a national radiation safety infrastructure. The establishment of the radiation safety legislation is shown as a milestone during the development of a national radiation safety infrastructure as a whole. In terms of Fig. 2:

(a) In each area, the respective designated body identifies, prioritizes and implements the applicable actions. The start and the pace of actions implemented in any area depend on the national circumstances and priorities. Overall coordination is essential.
(b) The promulgation of the radiation safety legislation and the establishment of the regulatory body mark milestones in the development of the infrastructure and impact, through regulatory requirements, the development of the other areas of the infrastructure.
(c) The initial regulatory activities are applicable only to States where the legal framework for safety is not already established and the regulatory body does not yet exist. While the legal framework for safety is being prepared, the government explores and implements initial regulatory activities within the existing legal framework.

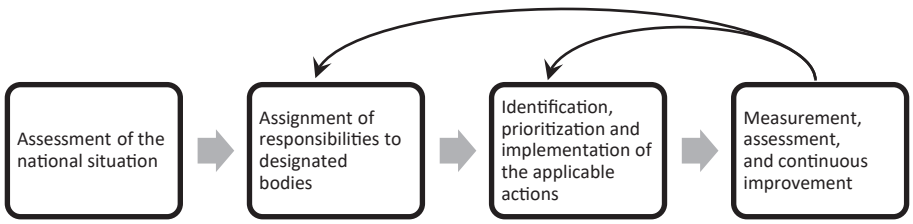

FIG. 1. Illustration of the general scheme adopted in this Safety Guide for establishing the national radiation safety infrastructure.

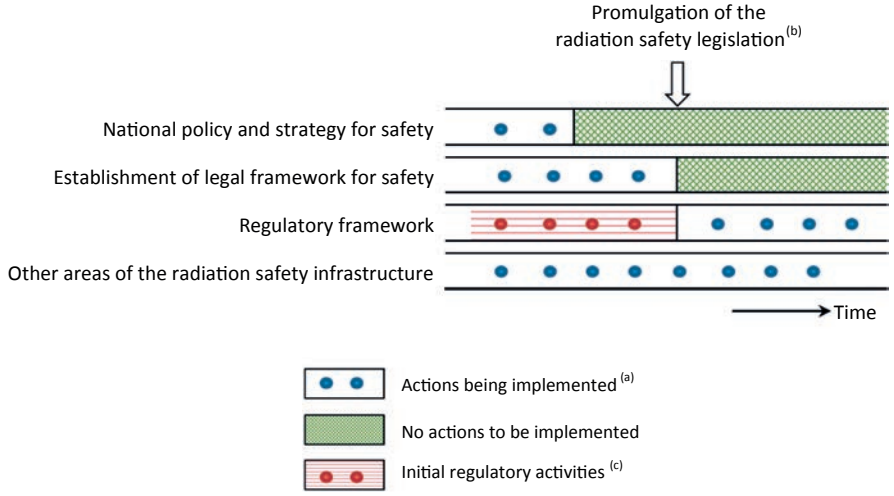

FIG. 2. Schematic visualization of the development of areas of the radiation safety infrastructure (see para. 1.4)

3. PREPARATORY ACTIONS BY THE GOVERNMENT

3.1. States are required to establish and sustain an effective legal, governmental and regulatory framework for safety [2]. Such a framework encompasses the areas listed in para. 1.4.

3.2. The government should initiate actions aimed at establishing an adequate national radiation safety infrastructure commensurate with the potential risk and nature of the hazards associated with the application of ionizing radiation in the State.

PRELIMINARY ASSESSMENT

3.3. The government establishes national policy for radiation safety by means of different instruments, statutes and laws. For example, the government establishes laws and adopts policies pertaining to safety and specifying the responsibilities and functions of different governmental entities in respect of radiation safety. The IAEA safety requirements that relate to the responsibilities and functions of the government, as established in GSR Part 1 (Rev. 1) [2], are to be understood in the

context of these functions, although some flexibility may be necessary depending on national circumstances.

3.4. The government should assess the national situation in order to be able to make informed decisions on the actions to be taken to establish the national radiation safety infrastructure.

3.5. The actions in this section are recommended as steps towards the full implementation of the IAEA Fundamental Safety Principles and the relevant Safety Requirements, in particular:

— Principle 2 of SF-1 [1];
— Requirement 2 of GSR Part 1 (Rev. 1) [2].

Action 1. The government should appoint or establish a steering group[5] to review and assess the national circumstances, the existing legal and administrative instruments, and the government's obligations relating to radiation safety.

3.6. The main goal of such a steering group is to develop a general overview of the situation in the State regarding radiation safety and advise the government on the necessary actions to establish or develop the national radiation safety infrastructure. The information gathered by the steering group will facilitate informed decision making by the government and the formulation of the next steps.

3.7. Different States may have different approaches to appointing and structuring such a steering group. For example, it could be an existing organization, a newly established organization or a committee established from representatives of the main interested parties in the State, such as the ministries of health, internal affairs, industry, the environment, education and justice, and the customs authorities and professional bodies. States already having a regulatory body in place may assign the role of the steering group to the regulatory body.

[5] The generic term 'steering group' is used in this Safety Guide to refer to an entity appointed by the government to collect and analyse relevant information and to provide advice on the establishment of the radiation safety infrastructure. Different names may be used in different States for the steering group. Examples of other names or terms used are 'committee' or 'task force'.

3.8. The government should ensure that the steering group is provided with the necessary authority and resources to fulfil its mandate and to be able to obtain information from the relevant interested parties.

3.9. The work of the steering group should cover all areas of the national radiation safety infrastructure in a holistic manner in order to develop a comprehensive overview and provide advice to the government.

3.10. The functions of the steering group should include the following, as applicable:

— Making a survey of the radiation sources and facilities in the State. The possible means for making surveys include collecting information from existing registers, contacting possible users and professional bodies, distributing questionnaires, broadcasting media announcements and making fact finding visits to sites where radiation sources are likely to be used or stored.
— Collating information on the relevant national legal and administrative instruments, such as laws on public health, customs, labour and the environment and identifying the provisions that are applicable to radiation safety.
— Collating information on the mandate of organizations that may have a role regarding safety.
— Collating information on the international obligations of the State set forth through its participation in conventions and other international instruments relating to radiation safety.
— Assessing the availability of competent persons and technical services in the State. For example, the steering group should estimate the number of qualified individuals in each practice and the availability of dosimetry services, maintenance services, training options in safety matters and other services.
— Identifying radiation risks associated with possible events in facilities or activities outside the State.
— Identifying existing exposure situations that could possibly lead to unacceptable radiation risks.
— Analysing the collected information, making an assessment of the national situation against international standards, and identifying gaps and needs for improvement.
— Assessing, to the extent possible, the interfaces between safety and nuclear security in the State.

— Informing the government of the current situation and providing advice and recommendations on the actions to be taken in the different areas of radiation safety infrastructure, including the need for decisions on a national policy and strategy for safety.
— Making proposals to the government on priorities for establishing the national radiation safety infrastructure, taking into consideration the radiation risks associated with the facilities and activities in the State in accordance with a graded approach[6].

Action 2. The steering group should assess the status of the national radiation safety infrastructure in the State, and should provide the results to the government and advise it on establishing or strengthening the infrastructure.

3.11. Close cooperation among the organizations and individuals involved in the steering group is essential for it to achieve its goals. The steering group should also establish and maintain close consultation with relevant ministries and interested parties, as necessary.

3.12. In performing its activities, the steering group should consider making use of the assistance and services offered by the IAEA and other international organizations, as well as regional and bilateral assistance. The government should enable the steering group to make use of such assistance.

3.13. In the early stages of establishing a radiation safety infrastructure, and until the government has assigned the responsibility to a different government body in accordance with Action 3, the steering group may be the only body in the State with knowledge of radiation risks. Therefore, the steering group may find itself in a position where it has to promptly propose or take actions to respond to unforeseen events, such as finding an orphan source.

3.14. The steering group should include in its advice suggested actions that are applicable to the State in each area of the national radiation safety infrastructure, as well as a suggested prioritization of these actions.

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[6] A graded approach is "…a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control" [8].

3.15. The steering group may report the results of the assessment and provide advice to the government for all areas of the radiation safety infrastructure at one time. Alternatively, it may provide the results and advice for the different areas in different timeframes, thereby providing the government with the option of making decisions for certain areas independently of other areas.

3.16. The government should consider making the results of the steering group's assessment or advice available to the public and to interested parties.

3.17. The government should consider the future role of the steering group upon fulfilling its mandate. The government may decide to dissolve the steering group or to provide it with a new mandate, such as one or more of the following:

— Assigning the steering group a role in establishing or developing some areas of the national radiation safety infrastructure. For example, the steering group may be requested to draft a national policy for safety.
— Assigning the steering group an overall coordinating role for the development of the national radiation safety infrastructure as a whole.
— Maintaining the advisory role of the steering group. In this case, the steering group may be put in charge of monitoring and assessing the overall development of the national radiation safety infrastructure and providing advice to the government on its adequacy and steps to ensure continuous improvement.

ASSIGNMENT OF RESPONSIBILITIES

3.18. This action is recommended as a step towards the full implementation of the IAEA Fundamental Safety Principles and the relevant Safety Requirements, in particular:

— Principle 2 of SF-1 [1];
— Requirements 1 and 2 of GSR Part 1 (Rev. 1) [2].

Action 3. The government should make use of the advice provided by the steering group when allocating the responsibilities for establishing the national safety infrastructure.

3.19. The government is required to clearly allocate responsibilities for safety within its governmental and legal framework [2].

3.20. The advice received from the steering group will enable the government to make informed decisions with regard to establishing the radiation safety infrastructure. In particular, the government should review the allocation of responsibilities for safety and, where gaps are identified, should clearly allocate responsibilities to a designated body.

3.21. Usually, the assignment of responsibilities in different areas of the radiation safety infrastructure is not done as a single action. The government may decide on different timeframes for the assignment of responsibilities in the different areas of the national radiation safety infrastructure. The government may introduce changes to its structure or to the roles of different agencies, which may lead to changes in the assignment of responsibilities relating to safety. However, the government should ensure continuity in the allocation of responsibilities: at any point in time, a well-defined and structured designated body should exist. The government should ensure effective coordination among the different designated bodies in order to ensure consistent development of the national radiation safety infrastructure in all areas as a whole. Related actions and guidance are provided in paras 4.120–4.132.

INITIAL REGULATORY ACTIVITIES WITHIN THE EXISTING LEGAL FRAMEWORK

3.22. The actions in this section apply only to States in which the legal framework for safety is not yet established and the regulatory body does not yet exist.

3.23. In general, the establishment of the legal framework for safety will take time. In the meantime, the government should, as far as practicable, take actions to protect people and the environment from harmful effects of ionizing radiation. Some of the actions relating to establishing the national radiation safety infrastructure could be taken by the government within the existing legal and governmental framework, while other actions, such as the regulatory activities, can only be taken at a later stage when the legal framework for safety has been established.

3.24. Even though a dedicated legal framework for safety might not yet be established in the State, some authorities may have the power, within the existing legal framework, to conduct certain activities in the area of regulatory control of radiation sources. Such activities are hereafter referred to as ‘initial regulatory activities’.

3.25. The government should ensure that the performance of the initial regulatory activities will not lead to unnecessary delays in developing the legal framework or to fragmentation of regulatory control among different bodies. The roles of the authorities involved in carrying out such activities may be subject to change once the legal framework for safety is established.

3.26. The actions in this section are recommended as steps towards the full implementation of the IAEA Fundamental Safety Principles and the relevant Safety Requirements, in particular:

— Principle 2 of SF-1 [1];
— Requirement 2 of GSR Part 1 (Rev. 1) [2].

Action 4. The government should explore and implement possible activities for controlling radiation sources within the existing legal framework.

3.27. The government should determine which activities for controlling radiation sources are possible within the existing legal framework. The preliminary work done by the steering group will help the government to identify such initial regulatory activities.

3.28. The government should ensure that the initial regulatory activities are conducted without unnecessary delay and are conducted in parallel with the process of establishing the legal framework for safety.

3.29. In general, several governmental agencies will be involved in conducting the initial regulatory activities, each within the area of its competence as defined in the existing legal framework. For example, the customs authorities may have responsibility for performing some initial regulatory activities for controlling the import and export of radiation sources. Similarly, the ministry of health may have responsibility for performing some initial regulatory activities relating to the use of ionizing radiation in the medical field.

3.30. The government may mandate the steering group to play a role with respect to the coordination or the conduct of parts of the initial regulatory activities within the existing legal framework.

3.31. Advice may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized.

3.32. Once the legal framework for safety is in place and the regulatory body has been established, the government should cease those initial regulatory activities and should ensure that the associated responsibilities are transferred to the regulatory body[7]. The government should ensure that all relevant information and records relating to the initial regulatory activities are made available to the regulatory body.

3.33. The following actions in this section provide examples of initial regulatory activities that are likely to be possible within the existing legal framework in any State. Those initial regulatory activities include, but are not limited to, the following:

— Establishment of an inventory of radiation sources;
— Establishment of controls of the import and export of radiation sources;
— Setting out requirements for safety within the existing legal framework;
— Promoting awareness for safety.

Action 5. The relevant authorities should make arrangements, within their area of competence, for the collection of the necessary information on the radiation sources and their users in the State and should keep this information up-to-date.

3.34. In performing Action 4, the government will have identified authorities that have the power within the existing legal framework to collect information on radiation sources and their users in the State. The steering group could also be tasked to continue collecting and updating such information if so decided by the government.

3.35. The relevant authorities should build upon the initial survey of radiation sources prepared by the steering group and should identify possible means for obtaining relevant information about the inventory of radiation sources in their area of competence. An important means is to make arrangements with other authorities and organizations for regular provision of such information. In particular, arrangements should be made with the customs authorities to regularly provide information on the import and export of radiation sources.

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[7] The regulatory body is "[a]n authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating the nuclear, radiation, radioactive waste and transport safety" [8].

3.36. Other sources of information on the radiation sources and their users in the State should be considered, such as notifications by the suppliers and users of radiation sources. Such notifications could be provided on a voluntary basis, when requested, or in response to instructions by the government within the existing legal framework. Notifications may be facilitated by the distribution of questionnaires or media announcements. Another possibility is to perform site visits to facilities where radiation sources are likely to be used, such as medical facilities, industrial complexes, construction sites, oil industry facilities, research centres and universities.

3.37. The collected information on radiation sources and their users should be properly managed, kept up-to-date and ultimately transferred to the regulatory body, once it has been established within the legal framework for safety.

Action 6. The authorities in charge of controlling the import and export of goods in the State should implement measures to register the import and export of radiation sources and should make this information available to other relevant authorities.

3.38. Typically, the customs authorities are in charge of controlling the import and export of all goods in the State, including radiation sources. In some States, this role is assigned to other agencies within the government.[8]

3.39. The authorities in charge of controlling import and export in the State usually have records of the import and export of all goods and may be in a position to extract or establish specific records on the import and export of radiation sources.

3.40. Such import and export data should be made available to the relevant authorities referred to in Action 5 and to other authorities when necessary. Formal arrangements, such as official correspondence or a memorandum of understanding, should be made to facilitate such exchange of information.

[8] As an example, in some States the responsibility for import and export controls is assigned to an inspection agency. The role of the customs authorities, in this case, is limited to the financial issues associated with the import and export of goods after they have been cleared or approved by the inspection agency.

Action 7. The government, through the relevant authorities in their respective areas of competence, should establish requirements for radiation safety within the existing legal framework.

3.41. Certain authorities may have a mandate within the existing legal framework to establish and enforce requirements relating to radiation safety in their areas of competence. Such mandates are likely to be limited in scope. Typical examples are the following:

— Health authorities are likely to have a mandate to establish radiation safety requirements in the medical field and to inspect medical facilities;
— Labour authorities are likely to have a mandate to establish radiation safety requirements relating to occupational exposure;
— Environment authorities may have a mandate to establish requirements relating to discharges and other areas of environmental protection;
— Transport authorities are likely to have a mandate to establish requirements for the safe transport of radioactive material;
— Agencies that have the power to inspect facilities and activities for reasons other than radiation safety may be able to include radiation safety within the scope of their inspections.

3.42. In performing Actions 1, 2 and 3, the government will have identified the authorities that have the mandate to establish safety requirements within their mandates as specified by the existing legal framework. The government should request these authorities to establish and enforce such safety requirements.

3.43. The relevant authorities should develop the necessary competence for the establishment and enforcement of radiation safety requirements and should ensure that the requirements are in compliance with the IAEA safety standards and international arrangements or regulations as applicable. For instance, in the case of transport of radioactive material, international arrangements and regulations for the different modes of transport have been established by international organizations such as the International Civil Aviation Organization or the International Maritime Organization.

3.44. The government should make arrangements to ensure consistency among the established safety requirements. The government should also ensure that the enforcement of safety requirements is coordinated, as recommended in paras 4.120–4.132.

3.45. The safety requirements established in accordance with para. 3.42 are based on the powers of existing authorities. The legal framework for safety, once established, may lead to changes in the responsibilities of those authorities, depending on the structure of the newly established regulatory body. If this is the case, consideration should be given to ensuring the smooth transfer of responsibilities for enforcing such safety requirements to the regulatory body. For example, such safety requirements could be integrated into the radiation safety regulations that will be established or adopted by the regulatory body.

Action 8. The relevant authorities, in their respective areas of competence, should maintain cooperative relationships with the users of ionizing radiation and should promote awareness of measures to enhance safety.

3.46. The relevant authorities should promote awareness of safety within the existing legal framework. Activities to raise awareness may include seminars, conferences and training courses and may use the media and the Internet.

3.47. Arrangements (formal or informal) should be established with the users (or potential users) of ionizing radiation, and other interested parties, for promoting the exchange of information and experience, providing advice, promoting safety culture, encouraging the implementation of safety measures, and strengthening staff training and qualifications.

4. DEVELOPING THE AREAS OF THE RADIATION SAFETY INFRASTRUCTURE

NATIONAL POLICY AND STRATEGY FOR SAFETY

4.1. The actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirement 1 of GSR Part 1 (Rev. 1) [2].

4.2. In performing Action 3, the government will have designated a body to be responsible for drafting a national policy and strategy for safety. The structure and composition of this designated body will depend strongly on the governmental structure. For example, the designated body could be a high level governmental committee involving relevant organizations. The steering group may also be

involved in the preparation of the national policy and strategy for safety, if so decided by the government.

Action 9. The designated body should draft a national policy and strategy for safety and should submit it to the government for approval.

4.3. Paragraph 2.3 of GSR Part 1 (Rev. 1) [2] states that:

> "National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy."

GSR Part 1 (Rev. 1) [2] also requires that the national policy and strategy for safety take account of the following:

- The fundamental safety objective and the fundamental safety principles established in SF-1 [1];
- Binding international legal instruments, such as conventions and other relevant international instruments;
- The specification of the scope of the governmental, legal and regulatory framework for safety;
- The need and provision for human and financial resources;
- The provision and framework for research and development;
- Adequate mechanisms for taking account of social and economic developments;
- The promotion of leadership and management for safety, including safety culture.

Action 10. The government should review and approve the draft national policy and strategy for safety and should prepare plans for its implementation in accordance with a graded approach.

4.4. It is required that the national policy and strategy for safety be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government [2].

4.5. The government's plans for the implementation of the national policy and strategy for safety should include a clear assignment of roles and responsibilities

as well as the timeframes and the allocation of the necessary resources for the next steps. The assignment of roles and responsibilities should be in line with Action 3.

LEGAL FRAMEWORK FOR SAFETY

4.6. In performing Action 3, the government will have designated a body to be responsible for preparing the legal framework for safety, which is a fundamental step towards the implementation of a national policy for safety. The structure and composition of this designated body will depend strongly on the structure of the government. For example, the designated body could be a governmental committee encompassing legal, political and technical experts in radiation safety. The steering group may also be involved in the preparation of the draft legislation, if so decided by the government.

4.7. The following actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirements 2–6 of GSR Part 1 (Rev. 1) [2];
— Requirement 2 of IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [10];
— Requirement 1 of IAEA Safety Standards Series No. GSR Part 5, Predisposal Management of Radioactive Waste [11].

Action 11. For establishing the legal framework for safety, the designated body should draft legislation that meets the IAEA safety standards and should submit it to the government for approval.

4.8. Many States have found it convenient to adopt a single comprehensive legislative instrument covering all the legal aspects of the radiation safety infrastructure [12]. It is recognized, however, that States might have different approaches, depending on the legal system in the State. In some States the legal framework for safety could be a set of legal documents, each covering specific areas. In this case, the government should ensure the comprehensiveness and consistency of the legal provisions throughout the entire set of legal documents.

4.9. The designated body should build upon the preliminary work done by the steering group and should ensure that the existing legislation is carefully reviewed in order to identify possible areas of overlap or conflict. It should ensure that

existing conflicts or overlaps are resolved in the new draft legislation and that responsibilities for safety are clearly assigned.

4.10. The legal framework for safety[9] should cover, inter alia, the following:

— The safety principles for protecting people — individually and collectively — society and the environment against present and future radiation risks;
— Provisions for assigning the prime responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively;
— The types of facilities and activities that are included within the scope of the legal framework for safety;
— The establishment of an independent regulatory body;
— Provisions for the authorization of facilities and activities;
— Provisions for the inspection of facilities and activities;
— Provisions for enforcement and for the specification of offences and the corresponding penalties;
— The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;
— Provisions for appeals against decisions of the regulatory body;
— Provisions for communication and consultation of the regulatory body with interested parties and the public.

4.11. In preparing draft legislation, the designated body should consult relevant interested parties, such as professional associations, representatives of the users of ionizing radiation and the public. The designated body may also seek assistance from the IAEA or from States with a similar economic and political profile.

4.12. The IAEA safety standards require the establishment of a regulatory body that is effectively independent and recognize that an independent regulatory body will not be entirely separate from other governmental bodies [2]. Therefore, the designated body should ensure that the draft legislation provides for functional separation of the regulatory body from governmental departments or agencies and other organizations that are charged with the promotion of radiation applications or are responsible for facilities or activities.

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[9] The IAEA Handbook on Nuclear Law [12] provides detailed advice on the scope and development of the legal framework for safety.

4.13. In preparing the draft legislation, the designated body should consider the following:

— The IAEA safety standards;
— International obligations established through binding international instruments, such as conventions;
— Input from interested parties.

Action 12. The government should review and approve the radiation safety legislation and should take practical steps to ensure that the regulatory body becomes operational by, inter alia, appointing senior managers of the regulatory body and providing resources to carry out regulatory processes.

4.14. The draft radiation safety legislation should be submitted to the legislative bodies in the State for approval. As such approval can be a protracted process, the government should continue building its radiation safety infrastructure and should continue to identify possible actions within the existing legal framework.

4.15. After the promulgation of the radiation safety legislation for the establishment of the regulatory safety infrastructure, the government should take the necessary steps as soon as possible to ensure that the regulatory body becomes operational by, for example, appointing senior managers of the regulatory body and providing sufficient human and financial resources to start regulatory activities. In addition, the government is required to ensure that the regulatory body is able to make regulatory decisions and perform its functions without undue pressure or constraint [2].

REGULATORY FRAMEWORK

4.16. The establishment of the legal framework for safety marks a significant milestone in the roadmap for the development of a national radiation safety infrastructure that meets international safety standards. Once the legal framework for safety is in place, regulatory responsibilities will be clearly assigned to the newly established regulatory body. The prime responsibility for safety will be clearly assigned to the person or organization responsible for a facility or activity. It will also be possible for the newly established regulatory body to set out requirements for the regulation of facilities and activities and for the development of other areas of the national radiation safety infrastructure, such as those relating to the competence of workers, dosimetry, calibration, radioactive waste

management, transport of radioactive material, and emergency preparedness and response.

4.17. Considerable time may be needed for the regulatory body to establish and fully implement a regulatory programme. It is essential that the regulatory body apply a graded approach to gradually building the regulatory system and to prioritizing its activities so that the regulatory body's resources are allocated in a manner that is commensurate with the radiation risks associated with the facilities and activities.

Core regulatory functions

4.18. The following actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements and Safety Guides, in particular:

— Requirements 23–34 of GSR Part 1 (Rev. 1) [2];
— All requirements of GSR Part 3 [10];
— Section 3 of IAEA Safety Standards Series No. GS-G-1.5, Regulatory Control of Radiation Sources [13];
— Provisions relating to the import and export of radioactive sources in the Code of Conduct on the Safety and Security of Radioactive Sources [3] and in its associated Guidance on the Import and Export of Radioactive Sources [14].

Action 13. The regulatory body should establish requirements and processes for notification.

4.19. The notification process is the mechanism by which initial information is provided to the regulatory body about the possession of a source or the intention to operate a facility or to conduct an activity. The regulatory body should establish requirements for notification, and should implement mechanisms to facilitate the submission of information through the notification process.

4.20. The requirements for notification should specify the information to be provided to the regulatory body and the prescribed timeframe. The regulatory body should make arrangements for communicating the notification requirements to users and potential users of ionizing radiation.

4.21. The notification process is often linked to the authorization process. For facilities and activities with a low radiation risk, the regulatory body may decide

that notification is the only requirement before operation of the facility or conduct of the activity may be commenced.

4.22. The regulatory body should record the information submitted in an appropriate registry system.

Action 14. The regulatory body should gradually bring all pre-existing facilities and activities under regulatory control, in accordance with a graded approach.

4.23. Pre-existing facilities and activities, i.e. facilities and activities that existed at the time of entry into force of the legal framework for safety, should be given a transitional period to comply with the provisions of the law. In some States, the transitional period is prescribed in the legislation, while in others it is decided by the regulatory body.

4.24. The regulatory body should gradually bring those pre-existing facilities and activities under regulatory control, taking into consideration that not all essential elements of the regulatory infrastructure would have been established in the transitional period, and that the regulatory body might not have completed activities relating to its organization and competence building.

4.25. The initial inventory of sources maintained before the establishment of the regulatory body, and the information collected through the notification process established in Action 13, will provide a basis for the regulatory body to assess the radiation risk, apply a graded approach, and develop a timeframe for bringing all pre-existing facilities and activities under regulatory control. For example, the regulatory body may initially focus on facilities and activities with high radiation risk, and specify requirements and criteria. The regulatory body may also request those facilities and activities to submit information demonstrating compliance with these requirements and criteria within a specified period of time.

4.26. In the transitional period, the regulatory body may start making inspections of the pre-existing facilities and activities, in accordance with a graded approach.

Action 15. The regulatory body should establish or adopt regulations and guides that take into consideration a graded approach.

4.27. The regulations should include regulatory requirements for protection of people and the environment against radiation risks arising from all facilities and activities in the State.

4.28. The regulations should include requirements for protection of workers, the public and patients, requirements relating to radiation safety in all stages in the lifetime of a facility or duration of an activity, and requirements for emergency preparedness and response.

4.29. The regulations are typically a combination of performance oriented requirements and prescriptive requirements.[10] The regulatory body should consider the legal system of the State, the availability of technical expertise in radiation safety and other national circumstances when deciding on the structure and style of the regulations.

4.30. As a pragmatic approach, the regulatory body should establish or adopt a basic set of performance oriented regulations. GSR Part 3 [10] sets out the basic safety standards to be included in such a foundation. Supplementary prescriptive regulations may be developed and established over time to strengthen the regulatory requirements. The need for and extent of prescriptive regulations will depend on the national approach to regulation. In some States, for example, detailed guidance might be preferred over prescriptive regulations.

4.31. Regulations are often published not in a single document but in a number of regulatory documents that are developed and established in different timeframes. The regulatory body should prioritize its efforts and should schedule the development of the various regulatory documents, taking into account national circumstances and the radiation risks associated with the facilities and activities covered within the scope of each regulatory document.

4.32. The regulatory body should develop guides, of a non-mandatory nature, on how to comply with the regulations, in order to enhance radiation safety and improve effectiveness and efficiency in the implementation of the regulations. Irrespective of the degree to which the regulatory body has developed prescriptive regulations, the regulatory body is required to give consideration to supplementing its regulations with guidance documents, where appropriate [2]. Guides directed at those practices that have the greatest potential to cause exposure are a useful supplement to the performance oriented regulations. There may be a need to provide for some flexibility in the application of such regulations.

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[10] The terms ‘performance oriented’ and ‘prescriptive’ refer to different approaches in regulation. Performance oriented regulations are more general and simply specify the overall radiation safety requirement and basic operational parameters. Prescriptive regulations are more specific and state how to achieve radiation safety.

4.33. The process of developing regulations and guides should involve consultation with interested parties, such as professional bodies, with account taken of international standards, such as the IAEA safety standards, and the feedback of relevant experience.

4.34. The regulatory body is required to notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and to make the regulations and guides available [2].

4.35. It is required that the regulations and guides be reviewed and revised as necessary to keep them up-to-date [2]. The regulatory body should establish a process for the review of the regulations and guides, which should take into account feedback from regulatory and operational experience, technological advances, research and development and changes in the relevant international safety standards and technical and industrial standards.

Action 16. The regulatory body should establish and implement a system that provides for authorization, approval by means of a notification, granting exemptions, and removal from regulatory control, in accordance with a graded approach.

4.36. Requirement 23 of GSR Part 1 (Rev. 1) [2] states that:

> "Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."

4.37. The regulatory body should adopt a graded approach to authorization, taking into account the radiation risk associated with the facility or activity. International guidance, such as the categorization of sealed radioactive sources set out in IAEA Safety Standards Series No. RS-G-1.9, Categorization of Radioactive Sources [15], should be taken into account.

4.38. For low radiation risk, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control, or to approve it by means of a notification process only. For higher radiation risk, it may be appropriate for the regulatory body to consider authorization by other means, such as registration or licensing. For complex facilities or activities, a multistage authorization may be appropriate in which different types of

authorization are issued at the different stages in the lifetime of the facility or duration of an activity.

4.39. The regulatory body should establish a system and processes for authorization, approval by means of notification, granting of an exemption, and removal from regulatory control. When establishing such a system, the regulatory body should take into account the available financial and human resources and the available technical expertise, and should ensure that the allocation of resources is commensurate with the radiation risks.

4.40. The regulatory body is required to issue guidance to the applicant on the format and content of the documents that the applicant has to submit to demonstrate safety [2]. The extent of the required safety assessment should be commensurate with the associated radiation risk.

4.41. The regulatory body should also issue internal guidance, including procedures, for regulatory body staff on the review and assessment of the applications for authorization. It is required that the depth and scope of the review and assessment be commensurate with the associated radiation risk, in accordance with a graded approach [2].

4.42. The regulatory body is required to record formally the basis for its decision on the authorization of a facility or an activity, or on its amendment, renewal, suspension or revocation, and to inform the applicant, in a timely manner, of its decision, and provide the applicant with a justification for the decision [2].

Action 17. The regulatory body should develop and implement a system for inspection that takes into consideration a graded approach.

4.43. The regulatory body is required to develop and implement a programme of inspections of facilities and activities to confirm compliance with the regulatory requirements and with any conditions specified in the authorization [2].

4.44. Regulatory inspection cannot diminish the prime responsibility for safety of the authorized party, and cannot substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party [2].

4.45. The regulatory body should establish a system for its regulatory inspections. The system should include procedures that define the interfaces with other

regulatory functions and processes such as the authorization and enforcement processes.

4.46. The inspection system should cover the powers, qualifications and training of inspectors and should include guidance for supervision of inspections by the regulatory body's management.

4.47. The inspection system should include the principles and the considerations to be taken into account when developing the inspection programme, such as the types of regulatory inspections, the frequency of regular inspections and the areas to be inspected, in accordance with a graded approach.

4.48. The inspection system should include guidance to the inspectors on an objective, systematic and consistent approach to conducting inspections, which allows sufficient flexibility for inspectors to take the initiative in identifying and addressing new concerns as they arise. This guidance should also include the following:

— The legal basis for inspection and the inspectors' authority;
— The use of regulatory requirements, regulations, guides and industrial standards;
— The implementation of the inspection programme, including guidance on the identification of persons to be interviewed, documents to be reviewed, measurements to be made, equipment and checklists to be used, and technical information to be considered;
— Reporting requirements and practices for inspectors;
— Standards of conduct for inspectors;
— The enforcement policy, procedures and practices.

Action 18. The regulatory body should establish and implement an enforcement policy and processes in accordance with a graded approach.

4.49. The regulatory body is required to 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, and also to require corrective actions to be taken by authorized parties in the event that risks are identified, including risks unforeseen in the authorization process, whether or not they are due to non-compliances with regulatory requirements or authorization conditions [2].

4.50. Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, civil penalties, prosecution, revocation of the authorization, and enforcing the cessation of activities or the shutting down of a facility.

4.51. The enforcement policy and the enforcement processes should specify the enforcement actions to be taken as a response to non-compliance with regulatory requirements or with any conditions specified in the authorization. Those actions should be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.

4.52. The enforcement policy and the enforcement processes should specify the timeframe and criteria for corrective actions at each significant step in the enforcement process.

4.53. The enforcement policy and the enforcement processes may include prosecution as an enforcement option, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance [2]. The related documentation, evidence gathering and legal investigation that may be warranted to support the prosecution process should follow legal procedures.

Action 19. The regulatory body should establish a process for appealing against a regulatory decision.

4.54. The regulatory body is required to establish provisions for appeal against decisions of the regulatory body [2].

4.55. Decision making by the regulatory body should follow a formal process that is based on specified policies, principles and associated criteria. The basis for decisions by the regulatory body should be formally recorded so that the regulatory body is able to justify its decisions if they are challenged.

Action 20. The regulatory body, in cooperation with the relevant authorities, should establish controls for the import and export of Categories 1 and 2 sealed radioactive sources in accordance with the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources [3] and its associated Guidance on the Import and Export of Radioactive Sources [14].

4.56. In performing Actions 15 and 16, the regulatory body will have established regulatory requirements and a system for authorizing practices involving radiation sources, including their import and export.

4.57. For the import of sealed radioactive sources of Categories 1 and 2, the regulatory body, in cooperation with the relevant governmental authorities, should ensure that:

— The import is authorized only if the recipient is authorized to receive and possess the source under the recipient State's national law;
— The State has the appropriate technical and administrative capability, resources and regulatory structure to ensure that the source will be managed in a manner consistent with the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources [3].

4.58. For the export of sealed radioactive sources of Categories 1 and 2, the regulatory body, in cooperation with the relevant governmental authorities, should ensure that:

— Export is authorized only if the receiving State has authorized the recipient to receive and possess the source and has the appropriate technical and administrative capability, resources and regulatory structure needed to ensure that the source will be managed in a safe and secure manner.
— The shipment of the sources to be exported takes place only after a prior notification to the receiving State and, as appropriate, the consent of the receiving State.

Organizational structure and competence of the regulatory body

4.59. Requirement 16 of GSR Part 1 (Rev. 1) [2] states that:

> "The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner

commensurate with the radiation risks associated with facilities and activities."

4.60. The following actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirements 16, 18 and 20 of GSR Part 1 (Rev. 1) [2].

Action 21. The regulatory body should analyse its functions, should determine the related tasks and should identify the necessary resources and competences.

4.61. Once the functions of the regulatory body have been specified by legislation or by the government, the regulatory body should determine the resources and competences necessary to perform these functions. An efficient way is to perform a task analysis of these functions and to determine the required, task based resources and competences. Such an analysis supports also the development of the regulatory body's organization.

4.62. As not all necessary resources and competences may be immediately available, the regulatory body should prioritize its needs based on radiation risk and the perceived organizational risk to the regulatory body[11] and the overall importance to safety.

Action 22. The regulatory body should structure its organization taking into account the task analysis of its functions so as to optimize the allocation of its resources and to discharge its responsibilities and perform its functions effectively.

4.63. In some States, the organizational structure of the regulatory body is fully determined by the management of the regulatory body. In other States, the

[11] Organizational risk to the regulatory body arises from its inability to discharge its regulatory functions effectively. Some examples of organizational risk are failure to deal with an incident (e.g. loss of a high activity source) in a timely manner; inadequate number of inspectors to undertake compliance monitoring activities leading to degradation in radiation safety; inability to undertake authorization activities in a competent or timely manner resulting in delay or lack of provision of business or health service delivery; lack of technical radiological services to perform radiological analysis or monitoring of authorized parties; or failure to meet budget/funding commitments.

organizational structure is prescribed by the law that establishes the regulatory body, or by the government, down to a certain organizational level.

4.64. The detailed organizational structure and the size of the regulatory body will be determined by a number of factors, including the following:

— The functions of the various organizations that comprise the regulatory body;
— The workload, determined by the location, number, type (including scale and complexity) and associated radiation risks of the facilities and activities in the State;
— The regulatory approach adopted (i.e. prescriptive, performance oriented, or a combination of both approaches);
— Constraints on resources and the availability of staff for the regulatory body;
— A decision to use external advisory bodies or technical support organizations;
— A decision to locate staff centrally or to have regional offices.

4.65. As mentioned in para. 4.64, the regulatory body's organizational structure will be affected by whether the regulatory body's staff are located in a single central headquarters or whether some are located in different regions in the State. In considering whether to locate staff in regional offices, there are a number of factors that should be considered, including the following:

— The type, number and geographical spread of facilities and activities in the State;
— The ease and cost of travel to sites;
— The need to be close to other governmental organizations or to authorized parties;
— The number of regulatory staff and the amount of time they need to spend at the site to carry out their duties.

4.66. When developing the structure of the regulatory body, consideration should also be given to whether to organize according to regulatory processes or according to types of facilities or activities. Irrespective of the organizational structure selected, attention should be paid to the distribution of specialists within organizational units, as each has its benefits and drawbacks. There is also a continuing need for constructive interaction between the various organizational units.

4.67. The regulatory body should periodically review its organization, taking into account the following:

— Operating experience;
— Changes in the regulated facilities and activities, such as the introduction of new technologies;
— Changes in the regulatory environment or in regulatory processes;
— Staffing and funding matters;
— The outcome of internal and external audits, evaluations and peer reviews;
— Feedback and lessons learned from experience.

Action 23. The regulatory body should analyse its staffing and competence needs and develop and implement a human resources plan that states the number of staff needed and their necessary competence to perform all of the regulatory functions.

4.68. The regulatory body is required to 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 [2].

4.69. In performing Action 21, the regulatory body will have performed a task analysis of functions and determined the required task based resources and competences. By comparing this information with the existing staffing and competence levels, the regulatory body will be able to make informed decisions on the optimal means for filling the identified staffing and competence gaps.[12] This contributes also to the development of the regulatory body's human resources plan.

4.70. The regulatory body should also use the competences derived from the task analysis to develop job descriptions and selection criteria that should include the following:

— Educational qualifications;
— Work related knowledge;
— Technical, administrative and management skills and experience;
— Behavioural attitudes.

[12] For instance, the regulatory body may opt to recruit new staff members, to increase the level of competence of existing staff members, or to seek technical or professional support from external advisory bodies.

4.71. The regulatory body should use the job descriptions, selection criteria and the identified task based resource requirements to determine the staffing needs across the organization. These needs should be compared with the current staffing numbers, and their distribution and composition, and should determine how existing staff may be assigned to meet the organizational needs. Furthermore, the regulatory body should also identify gaps in human resources that will need to be addressed through recruitment. Such information should be captured in the human resources plan.

4.72. The number and the specialized skills of the staff of the regulatory body will also depend on decisions about the tasks that are to be carried out by the regulatory body itself and those which could be referred to external experts, advisory committees or technical support organizations.

4.73. The regulatory body should ensure that staff assignments are regularly reviewed to ensure that potential conflicts of interest are identified and managed, and that staff members maintain independence and objectivity in their dealings with the regulated parties. This is of particular importance when recruiting staff from organizations involved in regulated facilities or activities.

4.74. The regulatory body should implement strategies to retain qualified staff, for example by supporting professional development and ensuring adequate and competitive remuneration.

4.75. The regulatory body should ensure that its organization is sufficiently robust and flexible to deal with staff changes through succession planning, which should be taken into account in the human resources plan. In succession planning, consideration should be given to the need for knowledge management to facilitate transition.

Action 24. The regulatory body should prioritize the identified competence gaps of its staff and should take the necessary measures to address these gaps.

4.76. It is required that a process be established to develop and maintain the necessary competence of staff of the regulatory body, as an element of knowledge management [2]. This process should take into account the analysis of the individual and organizational competence needs and include the development of a specific training programme.

4.77. In performing Actions 21 and 23, the regulatory body will have determined the competence gaps of its staff. The regulatory body should prioritize the

identified gaps, taking into account their importance to the regulatory functions, and should take the necessary measures to address these gaps. Such measures may include, inter alia, training, learning through academic institutions and other learning centres, and research and development work.

4.78. The regulatory body should adopt a systematic approach to training that includes a needs analysis and the design, implementation, assessment, evaluation and improvement of the training programme. The regulatory body should ensure that feedback from operating experience is used to inform and improve the training programme.

4.79. The regulatory body's training programme may include self-study, formal training courses, workshops and seminars, and on the job training in the State or abroad. Where appropriate, the training may be provided by the regulatory body itself, by academic or professional organizations, by regulatory bodies of other States or by the IAEA.

4.80. Each member of the regulatory body's staff should be provided with an individual learning plan that links the requirements of their job with the individual's knowledge, skills and experience. In addition, the individual learning plan should take into account the organization's needs and the individual's career aspirations. The individual learning plan should specify the following:

— The nature of the training needed;
— The timing and sequence of the training;
— Where the training is to be obtained;
— The necessary equipment and facilities;
— The competences to be achieved.

4.81. The individual learning plans for new staff should ensure that they receive an adequate overview of all aspects relating to the discharge of regulatory functions. This should include an introduction to the relevant laws, legal powers, policies, procedures and internal guidance of the regulatory body. In addition, in order to help in their development and to gain experience, consideration should be given to the seconding of new staff to another regulatory body. New staff should be assigned only limited tasks and should work under supervision until they have completed an initial period of their training and an evaluation of their performance has been made.

4.82. Individual learning plans should be reviewed and updated regularly to identify the training necessary 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, in processes or in other matters.

4.83. Training demands substantial human and financial resources. The regulatory body should therefore carefully specify and justify its training programme, and include the training costs in its budget. There is often pressure to reduce or delay training because of other, short term needs for funds or personnel. Although such circumstances cannot be avoided entirely, the management of the regulatory body should ensure that these other needs do not unduly disrupt the training programme.

Action 25. The regulatory body should establish mechanisms for obtaining technical or other expert professional advice as needed in support of its regulatory functions.

4.84. If the regulatory body is not entirely self-sufficient in all the identified tasks, it should seek advice or assistance, as appropriate, from advisory bodies.

4.85. Technical and other expert professional advice may be provided by experts external to the regulatory body, professional organizations, universities or dedicated technical support organizations. If technical support is not available domestically, then the regulatory body may seek advice, or assistance may be sought from other States or from international organizations.

4.86. The regulatory body should establish mechanisms to identify potential sources for obtaining technical and other expert professional advice, and to ensure that no conflict of interest exists when obtaining such advice. The regulatory body should also consider giving formal status to processes by which expert opinion or advice is provided.

4.87. When obtaining technical or other professional advice, the regulatory body should establish mechanisms and maintain the competence necessary to be an 'intelligent customer'[13] and to assess the advice provided and to make informed decisions. Detailed guidance is given in IAEA Safety Standards Series No. GSG-4, Use of External Experts by the Regulatory Body [16].

[13] The 'intelligent customer' concept relates mainly to a capability required of organizations when using external expert support. An intelligent customer capability is the capability of the regulatory body to have a clear understanding and knowledge of the advice or service being supplied (see GSG-4 [16]).

Action 26. The regulatory body should develop a knowledge management strategy and should implement measures to proactively address and reduce its vulnerability to knowledge loss.

4.88. Knowledge accumulated within the regulatory body over many years may be easily lost if measures are not taken to transfer the knowledge from experienced staff who depart the organization, for example through retirement or resignation, to the new generation of staff. Continuity in knowledge, know-how and expertise is fundamental to undertaking regulatory functions in a sustainable and effective manner. The regulatory body should take the risk of knowledge loss into account when developing its human resources plan as mentioned in para. 4.75.

4.89. The regulatory body should apply knowledge capture or transfer methods and techniques such as the following:

— Fostering a culture of knowledge sharing. For example, staff should be encouraged to build on what is already known within the organization to create new knowledge rather than to reinvent a solution.
— Establishing communities of practice, learning networks or thematic groups that share similar interests and in which individuals can learn from each other.
— Upgrading information management such as building web sites and databases.

4.90. The regulatory body should implement measures to learn from regulatory experience so that lessons learned are institutionalized and preserved through changes to operating procedures, equipment and training programmes. This will facilitate the work to be carried out by new or replacement staff members (see para. 4.75).

4.91. The regulatory body should establish work control methods to facilitate the embedding of knowledge management into key processes or activities rather than as add-on tasks. One possibility is to incorporate controls into critical tasks so that the intended outcome is ensured and situations likely to lead to errors are eliminated (e.g. calculations of radiation shielding design and radiation surveys of facilities and sources). Other measures include ensuring that the composition of teams assigned to specific tasks will enable knowledge transfer, i.e. the distribution of experienced and more capable individuals across teams and specific projects.

4.92. Knowledge management and human resources management should be integrated and effectively implemented as part of the management system of the regulatory body.

Communication and consultation

4.93. The regulatory body is required to promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities and about regulatory processes and decisions [2]. The regulatory body is also required to establish, either directly or through authorized parties, provisions for effective mechanisms of communication [2]. The legal and regulatory framework for safety should enable the regulatory body to establish such provisions.

4.94. The following actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirements 15 and 36 of GSR Part 1 (Rev. 1) [2];
— Paragraphs 2.33 and 2.36 of GSR Part 3 [10].

Action 27. The regulatory body should develop and implement a strategy for effective communication and consultation with interested parties and the public.

4.95. Communication and consultation with interested parties should be part of the functions of the regulatory body.

4.96. The regulatory body should develop a communication strategy for communicating and consulting with interested parties and the public. An effective communication strategy will guide the regulatory body's interactions with interested parties and the public during the course of various regulatory actions and will contribute to earning trust and protecting the regulatory body's credibility.

4.97. Clear responsibilities should be established within the regulatory body for communication and consultation activities. Such responsibilities may be located within one or more organizational units, but they should be clearly defined to ensure effective implementation of the communication strategy.

4.98. The regulatory body should develop a communication plan to implement the communication strategy. The communication plan should include: the overall

objectives; the list of interested parties; appropriate timing for the engagement of these parties; the concerns, expectations and perspectives of these parties; and channels and tools for communication and consultation.

4.99. Communication and consultation with interested parties and the public should be part of a formal process within the regulatory body's management system.

4.100. Confidential information should be properly protected. Restriction of information should be limited to sensitive information and proprietary information.

4.101. The authorized party has an obligation to inform the public about the possible radiation risks associated with the operation of a facility or the conduct of an activity. It is required that this obligation be specified in the regulations promulgated by the regulatory body, in the authorization or by other legal means [2].

Action 28. The regulatory body should take steps to implement the requirements on collecting feedback from operating experience and regulatory experience, on the analysis of lessons learned and on the dissemination of such lessons learned.

4.102. The regulatory body is required to make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities [2].

4.103. The collection, analysis and dissemination of operating experience and regulatory experience has led to significant corrective actions in relation to equipment, human performance and the management system.

4.104. The regulatory body should encourage interested parties to participate effectively in the consultation activities it organizes, such as dialogues or meetings, in order to develop common understanding of radiation safety issues.

4.105. The regulatory body is required to establish and maintain a means for receiving information relating to operating experience from other States, regulatory bodies of other States, international organizations and authorized parties [2]. Participation in international regulatory and professional networks

or forums and networks for learning from operating experience or regulatory experience is a valuable means for the acquisition of information and for its analysis.

4.106. The regulatory body should use operating experience and regulatory experience, whether gained domestically or received from other States,[14] to assess the need to make changes in regulatory requirements and practices and the need to impose corrective actions, or to require safety enhancing modifications to be carried out by authorized parties or suppliers of sources, in order to prevent the recurrence of safety significant events.

4.107. The regulatory body is required to establish and maintain a means for making lessons learned from operating experience and regulatory experience available to others [2]. Such feedback should include measures that have been taken in response to information received via national and international knowledge and reporting networks (see Action 62). Feedback should also cover descriptions of good practices that have been adopted to reduce radiation risks.

Safety related records

4.108. The following actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Paragraphs 4.39, 4.48 and 4.51 of GSR Part 1 (Rev. 1) [2];
— Requirement 35 of GSR Part 1 (Rev. 1) [2];
— Paragraph 2.35 of GSR Part 3 [10].

Action 29. The regulatory body should establish and maintain records relating to the discharge of its functions.

4.109. The regulatory body should formally record the basis for its decisions, and maintain records relating to the safety of the facilities and activities that it regulates. Typically, the records of the regulatory body include:

— The basis for the regulatory body's decisions on the authorization of a facility or an activity, or on its amendment, renewal, suspension or revocation;

[14] Actions 60–63 provide examples of possible means to receive experience from other States.

— Results and decisions derived from reviews and assessments;
— Results of inspections;
— Records on enforcement actions taken;
— Records on the inventory of facilities and activities;
— Records on the inventory of radiation sources;
— Records on occupationally exposed workers;
— Records of the activities of the regulatory body relating to preparedness and response to nuclear or radiological emergencies.

4.110. The regulatory body should adopt appropriate tools for the maintenance and effective use of such records.

4.111. The regulatory body should use such records as feedback to inform the regulatory processes.

4.112. The regulatory body should take the necessary measures to ensure the confidentiality and protection of its records and should regularly review and assess their integrity.

Action 30. The regulatory body should establish and maintain a register of sealed radioactive sources and radiation generators.

4.113. The regulatory body will inherit the initial inventory of sources, facilities and activities from the steering group or the authorities referred to in Action 5. The regulatory body should maintain this inventory and ensure that it is kept up-to-date.

4.114. The regulatory body should specify which sealed radioactive sources and radiation generators are to be included in the register of sources, with due consideration given to the associated radiation risks. With regard to sealed radioactive sources, the register should include Categories 1 and 2 sources as a minimum.

4.115. Notifications and applications for authorization are the primary sources for information on the inventory of sources. Other sources of information are inspection reports, incident reports and information provided by other authorities, such as customs authorities, and suppliers of sources.

4.116. The regulatory body should include in the register of radiation sources all legacy sources in the State that predated the establishment of the regulatory body

and, in particular, the radiation sources that are no longer used for the purposes for which they were initially brought into the State.

Action 31. The regulatory body should ensure that registers and inventories relating to doses from occupational exposure, events, radioactive waste, and shutdown and decommissioning (or closure) of facilities are in place, and should use such records to support the discharge of its regulatory functions.

4.117. The regulatory body is required to make provisions for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities, including records of occupational exposure, events, radioactive waste, and shutdown and decommissioning (or closure) of facilities [2].

4.118. The regulatory body may or may not be the sole entity responsible for the maintenance of the registers and inventories mentioned in Action 31, but the regulatory body is required to be involved in their proper retention and use [2].

4.119. The regulatory body is required to establish and enforce requirements for recording occupational exposure [10]. Employers and authorized parties are required to maintain records of occupational exposure and to exchange data on occupational exposure when needed [10]. Some States have adopted different approaches to ensuring the exchange of data on occupational exposure among employers and relevant authorities or organizations, but a national dose register has considerable advantages in comparison to such approaches, in particular with regard to itinerant workers and foreign workers. Therefore, the regulatory body should promote the establishment of such a national dose register by, for instance, increasing government awareness of its benefits, but should also take into account the potential complexity of such a task and the necessary resources involved.

NATIONAL COORDINATION

4.120. A number of organizations, ranging from local councils to professional bodies, may have roles and responsibilities relating to safety. The work done by the steering group on the survey of facilities and activities involving radiation sources and the review of existing legislative requirements will enable the government to identify these organizations and their existing responsibilities.

4.121. In performing Actions 1, 2 and 3, the government will have identified national agencies and other organizations having roles with regard to radiation safety.

4.122. In performing Action 3, the government will have assigned to a designated body the responsibility for coordinating the development of the national infrastructure for safety. The structure of this designated body will differ depending on national circumstances. For example, the designated body could be a high level committee of relevant government officials and relevant interested parties, or a task force comprising senior management of the relevant organizations. Different designated bodies could be established at different times to coordinate specific areas or activities of the national radiation safety infrastructure. The steering group may also be given responsibility for coordinating the development of the national infrastructure for safety, if so decided by the government.

4.123. The actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirement 7 of GSR Part 1 (Rev. 1) [2];
— Paragraph 2.15(e) of GSR Part 3 [10].

Action 32. The designated body should make arrangements to ensure effective coordination among all organizations involved in the development of the national radiation safety infrastructure.

4.124. The organizations involved in the development of the national radiation safety infrastructure should identify interfaces in their respective areas of competence and should make arrangements for effective coordination and cooperation.

4.125. Appropriate coordination mechanisms should be established to manage the interface of safety and security. In particular, coordination arrangements should be made with the agencies involved in establishing requirements for security, such as the regulatory body, the State's intelligence organizations, customs and border authorities, law enforcement authorities, and ministries of the interior, defence, transport, and foreign affairs.

4.126. The arrangements for coordination should comprehensively cover the identified interfaces, including consistency of requirements, procedures for implementation, communication and flow of information.

4.127. The arrangements for coordination may include regular meetings of representatives of relevant designated bodies and/or interested parties, which could take place bilaterally or could involve several designated bodies. Such arrangements could also take the form of a formal agreement, for example, a memorandum of understanding among relevant designated bodies.

4.128. The designated body should monitor and assess the effectiveness of the established coordination arrangements and, when necessary, should undertake actions to improve coordination.

Action 33. The regulatory body should ensure that arrangements are put in place for effective coordination, liaison and communication with relevant organizations, interested parties and regulated parties.

4.129. The regulatory body, once established by the legal framework for safety, will be involved in national coordination and this will lead to changes in the designated body's structure.

4.130. The regulatory body should liaise with the organizations and professional bodies that are relevant to the discharge of regulatory functions and should make arrangements for coordination with such organizations, taking into account the arrangements that existed before the establishment of the regulatory body.

4.131. The regulatory body should ensure that there is a mechanism for organizations with responsibilities relating to safety to be consulted on relevant issues as they arise. An example of a formal mechanism for such organizations to provide advice and comments is the establishment of an advisory committee, to which organizations would nominate representatives and which would meet periodically following an agenda set by the regulatory body.

4.132. The regulatory body should seek feedback from regulated parties regarding their views on the effectiveness of the coordination arrangements. Mechanisms should be developed to collect and analyse such feedback, for example upon completion of an on-site inspection and/or through the regulatory body's web site.

EMERGENCY PREPAREDNESS AND RESPONSE

4.133. Authorized parties, the regulatory body and the relevant government agencies are required to establish, in advance, arrangements for preparedness

and response for a nuclear or radiation emergency at the scene, at local, regional and national levels and, where so agreed between States, at the international level [1, 10, 17].

4.134. In performing Action 2, the steering group will have developed a preliminary assessment of the radiation risks associated with the facilities and activities inside and outside the State, and provided initial advice to the government on the level of preparedness needed to respond to radiological and nuclear emergencies based on this preliminary assessment. The steering group will have also identified the organizations in the State that may have a role in preparedness and response to radiological or nuclear emergencies.

4.135. In performing Action 3, the government will have assigned responsibilities for the establishment of an integrated and coordinated emergency management system to a designated body. In the context of emergency preparedness and response, the designated body will typically encompass the organizations involved in the national coordinating mechanism, the organizations involved in performing the hazard assessment, the regulatory body, and the authorities involved in making arrangements for the transition from an emergency exposure situation to an existing exposure situation [17].

4.136. The designated body should have the ability to coordinate the response preparations for all national organizations having roles in preparedness and response for a nuclear or radiological emergency, conventional emergencies or security related events (see IAEA Safety Standards Series No. GS-G-2.1, Arrangements for Preparedness for a Nuclear or Radiological Emergency [18], para. 3.9).

4.137. The following actions are recommended as steps towards the full implementation of the IAEA Fundamental Safety Principles and the relevant Safety Requirements, in particular:

— Principle 9 of SF-1 [1];
— Requirement 8 of GSR Part 1 (Rev. 1) [2];
— Requirements 43–46 of GSR Part 3 [10];
— Requirements 1, 2, 4, 5, 18 and 20–26 of the IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [17].

Action 34. The designated body should perform a hazard assessment to provide a basis for a graded approach to emergency preparedness and response.

4.138. The government is required to ensure that an integrated and coordinated emergency management system is established and maintained (see GSR Part 3 [10] and GSR Part 7 [17]). It is required that the emergency management system provide for an assessment of the hazards associated with the facilities, activities or sources within or beyond the borders of the State [10].

4.139. It is required that the nature and extent of the arrangements for emergency preparedness and response be commensurate with the assessed hazards [17]. The designated body should build upon the preliminary assessment done by the steering group and should conduct a national hazard assessment to identify facilities and activities, on-site areas, off-site areas and locations that may warrant protective actions or other response actions.

4.140. The result of the hazard assessment provides a basis for developing, justifying and optimizing protection strategies and identifies the emergency preparedness categories that are applicable to the State [17].

Action 35. The designated body should ensure that the roles and responsibilities of the response organizations with regard to preparedness and response to a nuclear or radiological emergency are clearly assigned.

4.141. The response to a nuclear or radiological emergency may involve many organizations at the national, regional and local levels and, where appropriate, at the international level. The responsibilities in preparedness and response for a nuclear or radiological emergency of many such organizations may be the same as those for conventional emergencies, such as earthquakes, tsunamis, fires, floods or storms. Therefore, the government, through the designated body, should consider the responsibilities of such organizations and should make use of the existing arrangements and mechanisms in order to ensure an all hazards approach in emergency preparedness and response.

4.142. The designated body should review the legal infrastructure and national policies to ensure that there is agreement on roles and responsibilities for emergency preparedness and response.

4.143. In the case that gaps or conflicts are identified with regard to roles and responsibilities in emergency preparedness and response, arrangements should

be made by the government to fill the gaps and resolve the conflicts. If necessary, the legal infrastructure and the roles and responsibilities should be revised. Government policy statements or agreements between response organizations can be used in the interim to resolve or reduce any such conflicts.

4.144. The designated body should coordinate the response preparations of the response organizations and the resolution of differences and incompatible arrangements between such organizations.

4.145. The roles of the regulatory body with regard to emergency preparedness and response are to ensure that arrangements for coordinated and integrated emergency preparedness and response for facilities and activities under the regulatory control are dealt with through the regulatory processes, to advise the government and competent authorities, and to provide expert services (e.g. services for radiation monitoring and risk assessment for actual and expected future radiation risks) [2, 17].

Action 36. The designated body should establish an interim response capability.

4.146. The designated body:

— Should develop a planning basis for the collection and documentation of information that must be considered before emergency response plans can be developed (e.g. postulated emergencies, expected consequences, local conditions);
— Should develop a concept of operations that briefly describes the ideal response to a postulated emergency;
— Should identify and assign the tasks that are critical for an effective response.

4.147. Since the full development of the integrated emergency management system and the national emergency response capability can be a long process, an interim emergency response capability should be developed and tested to ensure that acceptable response can take place if a nuclear or radiological emergency occurs before the full emergency arrangements are developed. In the very early stages, the steering group may be the only organization with knowledge of radiation safety and may thus be confronted with a situation requiring quick response to radiological hazards, as mentioned in para. 3.13.

4.148. The interim capability for emergency response might not be optimal. In the interest of quickly developing an interim emergency response capability, it may be necessary to manage with the available means and resources, and with only minimal additional arrangements (e.g. training).

Action 37. The designated body and each response organization should develop, implement and maintain an emergency response plan and demonstrate response capabilities.

4.149. The designated body should develop a national emergency response plan that integrates all relevant plans for responding to a nuclear or radiological emergency in a coordinated manner and consistently with the all hazards approach. This plan should be approved by the government.

4.150. Each response organization is required to prepare plans for coordinating and performing their assigned functions, and should make arrangements to implement such plans [17].

4.151. Once an emergency response capability has been developed, it is required that drills and exercises be conducted to demonstrate this capability [17]. The drills will provide training and the exercises will test and verify the adequacy of the entire system, including the plans, procedures, facilities, equipment and training. After the exercises have been conducted, deficiencies should be identified, prioritized and corrected. Opportunities for improvement should also be identified, prioritized and implemented.

4.152. Each response organization is required to establish a quality management programme as part of its management system to ensure a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities necessary to perform the functions of the organization. It is required that arrangements be made to maintain, review and update emergency plans, procedures and other arrangements and to incorporate lessons learned from research, operating experience (such as the response to emergencies) and emergency drills and exercises [17].

4.153. The designated body should establish arrangements for coordination between emergency response plans of the relevant response organizations.

Action 38. The regulatory body should include in the regulatory processes provisions for emergency preparedness and response for facilities and activities that are under regulatory control.

4.154. The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based [2]. It is required that these principles, requirements and associated criteria include principles, requirements and associated criteria for emergency preparedness and response of the operating organization [17].

4.155. The regulatory body is required to review and assess the emergency arrangements of authorized parties, verify compliance with the regulatory requirements, and ensure that such emergency arrangements provide reasonable assurance of an effective response in the event of a nuclear or radiological emergency [2, 17].

Action 39. The designated body should make arrangements for the transition from an emergency exposure situation to an existing exposure situation.

4.156. The government is required to ensure that arrangements are in place for the transition from an emergency exposure situation to an existing exposure situation as part of the overall emergency preparedness [10]. It is required that such arrangements ensure that the transition is made in a coordinated and orderly manner, by making any necessary transfer of responsibilities between organizations and with the involvement of relevant authorities and interested parties [17].

ESTABLISHING A SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

4.157. Radiation risks may arise in situations other than in facilities and activities that are under regulatory control.

4.158. Examples of existing exposure situations and unregulated risks include the following:

— Exposure due to contamination of areas by residual radioactive material arising from past activities, such as mining activities, that were never

under regulatory control or that were subject to an earlier, less rigorous, regulatory control;
— Exposure to natural sources including radon in dwellings or in workplaces other than those for which exposure due to other radionuclides in the uranium or thorium decay chains is controlled as a planned exposure situation;
— Exposure due to radionuclides of natural origin in commodities and existing residues in the environment;
— Unregulated risks arising as a consequence of an accident, a discontinued practice, or inadequate control over a radioactive source or a natural source.

4.159. The government is required to ensure that, when an existing exposure situation is identified, responsibilities for protection and safety are assigned [2, 10].

4.160. Where unacceptable radiation risks arise, the government is required to designate the organizations to be responsible for making the necessary arrangements for the protection of workers, the public and the environment. It is also required that the organization taking the protective action has access to the resources necessary to fulfil its function [2].

4.161. In performing Action 2, the steering group will have identified existing exposure situations that would possibly lead to unacceptable radiation risks. This does not, however, exclude the possibility that further existing or unregulated radiation risks might be identified in the future.

4.162. In performing Action 3, the government will have assigned to a designated body the responsibility for evaluating each identified existing exposure situation or unregulated risk, and for establishing and implementing the related protection strategies.

4.163. The structure of the designated body could comprise working groups or other relevant authorities with the necessary technical capabilities in each of the identified existing exposure situations or unregulated risks. The regulatory body, once established, could be the designated body or could be involved as part of the designated body. The designated body should be able to have access to expertise from other national organizations, such as universities or research institutions, or international organizations, if needed.

4.164. After performing Actions 11 and 12, the government will have included, in the legal framework for safety, provisions on the management of existing exposure situations and unregulated risks.

4.165. The regulatory body is required to provide any necessary inputs for protective actions, including advice on exercising regulatory control over protective actions, and to establish the regulatory requirements and criteria for protective actions in cooperation with the other authorities involved and in consultation with interested parties, as appropriate [2]. In particular, the regulatory body is required to establish requirements for the protection of workers in existing exposure situations [10].

4.166. The actions in this section should be taken whenever an existing or unregulated radiation risk is identified.

4.167. The actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements and Safety Guides, in particular:

— Requirement 9 of GSR Part 1 (Rev. 1) [2];
— Requirements 47–52 of GSR Part 3 [10];
— Provisions of IAEA Safety Standards Series No. SSG-19, National Strategy for Regaining Control over Orphan Sources and Improving Control over Vulnerable Sources [19], as a whole;
— Provision 8(c) of the Code of Conduct on the Safety and Security of Radioactive Sources [3].

Action 40. The designated body should evaluate all existing exposure situations that have been identified.

4.168. The government is required to ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection [10]. The designated body should make this determination and should develop a protection strategy.

Action 41. The designated body should establish and implement a protection strategy when an existing exposure situation is evaluated as leading to undue radiation risks.

4.169. In establishing the protection strategy, the designated body should define appropriate reference levels. Typically, reference levels are defined for the following:

— Remediation of areas with residual radioactive material;
— Public exposure due to radon indoors;
— Exposure due to radionuclides in commodities.

4.170. It is required that the reference levels be periodically reviewed to ensure that they remain appropriate in the light of the prevailing circumstances [10].

4.171. It is required that remedial actions and protective actions be justified and that protection and safety is optimized [10].

4.172. For remediation of areas with residual radioactive material, the designated body should identify those persons or organizations having a responsibility for the implementation of the protection strategy, such as persons or organizations responsible for:

— The contamination of areas;
— Financing the implementation of the protection strategy;
— Planning, implementing and verifying the results of remedial actions.

4.173. The designated body should ensure that a radioactive waste management strategy is put in place to deal with any radioactive waste arising from remedial actions (see Action 46).

4.174. The designated body should include in the protection strategy provisions for post-remediation controls, taking into consideration the regulatory requirements and the future use of the remediated area. Those controls should be subject to periodic review.

Action 42. The designated body should assess the national situation relating to orphan sources.

4.175. The primary function of the assessment is to collect data on the current situation relating to orphan sources and vulnerable sources so that it can be

assessed and proposals for improvement can be made. Data collection is often compromised by lack of knowledge about past and current uses of radioactive sources, and care should be taken not to significantly underestimate the situation. The following steps should be carried out in the assessment:

— Deciding on the scope of the assessment;
— Gathering specific information on all aspects of the past and current degree of regulatory control of radioactive sources, including disused sources;
— Identifying problems and potential issues (gap analysis).

4.176. The scope of the assessment should be established in order to identify where the subsequent data gathering will be focused. In most cases, the focus should be at least on those sources capable of causing severe deterministic effects if not under control (i.e. dangerous sources, see GSR Part 7 [17]). Such sources are in Categories 1, 2 and 3.

4.177. The assessment will be iterative as a State's situation changes, and some degree of assessment will be continuous.

4.178. Some decision making will be necessary as part of the assessment, particularly in relation to deciding on the scope of the assessment, dealing with identified hazards that require urgent action and modifying the assessment in the light of experience.

4.179. As part of the assessment, data should be gathered on sources, both those known to be present in the State and those that are potentially present in the State. The risk from orphan sources or vulnerable sources cannot be characterized unless information is available on what sources are likely to exist within the State. Characterization of the risk associated with orphan sources should involve an evaluation of both the potential for orphan sources to exist and the potential consequences that such sources may cause. The assessment process should also address whether vulnerable sources, such as disused sources, although currently under control, might become orphaned in the future, and whether orphan sources might be introduced into the State from another State.

Action 43. The designated body should develop a national strategy for regaining control of orphan sources.

4.180. The following steps should be carried out to develop a national strategy for regaining control over orphan sources and improving control over vulnerable sources:

— Listing the problems or potential issues identified in the assessment phase;
— Developing actions that will solve each problem, or, if it is a complex situation, identifying the first steps towards a solution of the problem;
— Prioritizing actions and presenting them in a format that is suitable for review by decision makers;
— Identifying the various agencies involved and reaching an agreement on the assignment of responsibilities for the actions.

4.181. The actions identified should be prioritized and an action plan should be developed. This action plan should be written with decision makers in mind as the primary audience, as a high level of commitment and additional national resources will probably be necessary to implement the action plan. Further resources from donor States or international agencies may also be necessary.

Action 44. The designated body should implement the national strategy for regaining control of orphan sources.

4.182. Once the action plan for the national strategy has been developed, the decision to implement it should be made by the requisite authority.

4.183. The agencies responsible for ensuring that control over radioactive sources is maintained and improved should be granted the necessary authority and resources to implement the plan, otherwise the plan will not be effective.

4.184. If there are long term actions or very costly actions that need further discussion and evaluation prior to their adoption, these should be treated separately.

RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING

4.185. Waste that contains, or is contaminated with, radionuclides arises from a number of activities involving the use of radioactive material. Such activities include the use of radionuclides in medicine, industry, agriculture, research and education; the remediation of sites affected by radioactive residues from operations of various types or from accidents; and the processing of raw material containing radionuclides of natural origin. The nature of the radioactive waste is likely to be such that radiation safety considerations must be taken into account for its safe management (see GSR Part 5 [11]).

4.186. The government is required to make provisions for the safe decommissioning of facilities, and for the safe management and disposal of radioactive waste arising from facilities and activities [2].

4.187. In completing Action 2, the steering group will have developed a broad assessment of the radioactive waste in the State. It will have collected information on the generation of radioactive waste and waste streams in the State, and will have also assessed the existing legislation for dealing with hazardous material, and identified legislative gaps for dealing with radioactive waste that need to be considered when preparing the legal framework for safety as mentioned in para. 4.10.

4.188. In completing Action 12, the government will have established a national legal framework for safety, within which radioactive waste management and decommissioning can be planned and carried out safely.

4.189. Specifically for the management of radioactive waste and decommissioning, it is required that the governmental, legal and regulatory framework for safety:

— Provides for the securing of financial and other resources [11, 20, 21];
— Provides for the protection beyond national borders, as appropriate and necessary for neighbouring States that may be affected [11];
— Includes confirmation at a national level of the need for disposal facilities of different types [20].

4.190. After completing Action 3, the government will have assigned to a designated body the responsibility of developing the national infrastructure for the decommissioning of facilities and activities and radioactive waste management.

4.191. The structure of the designated body for radioactive waste management and decommissioning will differ depending on the national circumstances; the types, locations and amount of radioactive waste in the State; the rate of radioactive waste generation; and the availability of technical and financial resources. Given that the designated body may be involved in establishing national policies and strategies for radioactive waste management, it could be a high level committee supported by technical expertise in the relevant disciplines enabling it to analyse and balance possible options for radioactive waste management in the State. In States where radioactive waste is limited to very short lived waste generated in medical applications and waste arising from disused sealed sources, the designated body may be an organization that has the capability of managing the

waste generated. The steering group, and the regulatory body once established, may be involved if so decided by the government.

4.192. After completing Action 8, the designated body will have initiated arrangements to increase awareness about the existence of radioactive waste in the State among users of radiation sources and generators of radioactive waste.

4.193. The following actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirement 10 of GSR Part 1 (Rev. 1) [2];
— Requirements 1–3 of GSR Part 5 [11];
— Requirements 1 and 2 of IAEA Safety Standards Series No. SSR-5, Disposal of Radioactive Waste [20];
— Requirements 4 and 5 of IAEA Safety Standards Series No. GSR Part 6, Decommissioning of Facilities [21].

Action 45. The designated body should refine the preliminary assessment prepared by the steering group on the radioactive waste generated or likely to be generated in the State.

4.194. The designated body should build upon the preliminary assessment done by the steering group, and should use the inventory of radiation sources and facilities and activities established in Actions 2 and 5 to determine the potential generators of radioactive waste in the State and should subsequently carry out an assessment of the radioactive waste generated, or likely to be generated, including radioactive waste resulting from potential decommissioning activities. The assessment should address, inter alia, the location, practices, types and quantity of radioactive waste and rates of their generation.

4.195. The outputs of this exercise are the inventory of radioactive waste in the State and the anticipated generation of radioactive waste. These outputs will provide a basis for the drafting of a national policy for the management of radioactive waste proposed in Action 46.

4.196. The inventory of radioactive waste should be maintained and made available to relevant interested parties. The regulatory body, once established, should make provision for maintaining the register as mentioned in Action 31, in coordination with the designated body.

Action 46. The designated body should propose to the government a national policy on the radioactive waste management and decommissioning of facilities.

4.197. The designated body should develop a comprehensive national policy on radioactive waste management and decommissioning of facilities, commensurate with the nature and the amount of radioactive waste generated in the State. The designated body should take into account the information gained and the assessment done in Action 45 and should apply a graded approach for the preparation of this national policy, which should then be submitted to the government for approval.

4.198. It is required that the national policy for radioactive waste management and decommissioning of facilities:

— Be appropriate for the nature and the amount of the radioactive waste in the State [11];
— Indicate the regulatory control required [11];
— Consider relevant societal factors [11];
— Be compatible with international instruments, conventions and codes that have been ratified by the State such as the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [22].

4.199. It is required that the national policy on radioactive waste management set out the preferred options for radioactive waste management, including waste resulting from decommissioning activities [11]. It is also required that this policy reflect national priorities and available resources and be based on knowledge of the waste to be managed now and in the future. It is also required that the policy assign responsibilities for various aspects of radioactive waste management, including regulatory oversight [11].

Action 47. The government should review and approve and implement the national policy on radioactive waste management and decommissioning of facilities.

4.200. The approved national policy for radioactive waste management and decommissioning of facilities is not meant to be implemented in isolation but rather as an integral part of the overall national policy for safety, including the decommissioning of facilities and management of the resulting radioactive waste.

4.201. The governmental and regulatory requirements and approaches should ensure that all activities from the generation of radioactive waste up to its disposal, including its processing, storage and transport, are seen as parts of a larger entity, and that the management elements of each step are selected so as to be compatible with those of the other steps [2, 11].

4.202. In terms of implementing the national policy for radioactive waste management, the government should consider the following:

— Setting clearly defined legal, technical and financial responsibilities for organizations involved in radioactive waste management and decommissioning activities, including provisions for any institutional arrangements that are envisaged after closure of radioactive waste disposal facilities;
— Ensuring the continuity of responsibility for safety through regulatory control (e.g. by means of a licensing system) over the different steps in waste management, including the transfer of waste;
— Defining and putting in place an overall process for the development, operation and closure or decommissioning of facilities (including the legal requirements at each step), the decision making process and the process for the involvement of interested parties;
— Ensuring that the necessary scientific and technical expertise remains available to the operator and is available for the support of independent regulatory functions and other review functions at the national level.

4.203. It is required that various factors, including the nature and the amount of radioactive waste; occupational exposure and public exposure; environmental impacts; and human health, safety, and social and economic factors be considered when deciding between options in the predisposal management of radioactive waste [11].

4.204. In the predisposal management of radioactive waste, decisions often have to be made at a time when no disposal facility is available and the waste acceptance criteria for disposal are unknown. A similar situation could arise if radioactive waste were to be stored over long periods of time. In both cases, it is required that consideration be given to the need for radioactive waste treatment or conditioning. It is required that the anticipated needs for any future steps in radioactive waste management be taken into account as far as possible in making decisions on the processing of the waste [11].

4.205. Decisions on the development, operation and closure of a radioactive waste disposal facility are constrained by external factors, which include: national policy and preferences, the capacity and capability of existing storage and disposal facilities to accommodate waste, and the availability of suitable sites and geological formations to host planned new disposal facilities. It is required that an adequate level of confidence in the safety of the disposal facility be developed before decisions are made [20].

4.206. It is required that appropriate financial provision be made for the following [2]:

— Decommissioning of facilities;
— Management of radioactive waste, including its storage and disposal;
— Management of disused radioactive sources and radiation generators.

Action 48. The regulatory body should develop and implement the necessary processes and procedures to carry out its functions and responsibilities relating to the regulatory control of waste management and decommissioning of facilities.

4.207. The regulatory body is required to establish the requirements for the development of radioactive waste management facilities and activities, and to set out procedures for meeting the requirements for the various stages of the authorization process [11]. The regulatory body is further required to carry out such activities as necessary to ensure that the requirements and any conditions attached to the authorization process are met [20].

4.208. The regulatory body is required to review and assess the safety case and environmental impact assessment prepared by the operator of the facility or activity, both prior to authorization and periodically during operation [11]. It is required that enforcement actions be taken as necessary by the regulatory body in the event of deviations from, or non-compliance with, requirements and conditions [11].

4.209. The regulatory body is responsible for the regulation of all phases of decommissioning, from initial planning to termination of the practice or final release of the facility from regulatory control, or closure with continuation of institutional control [21].

TRANSPORT OF RADIOACTIVE MATERIAL

4.210. Activities involving radioactive sources (e.g. in industrial or medical applications of radiation) that require the establishment of regulations with respect to the transport of radioactive material are likely to be carried out in most States.

4.211. The safe transport of radioactive material is principally assured through a graded approach including elements of design, testing and review of the transport package. The graded approach to the application of the transport requirements is established on the basis of the type and quantity of radioactive material to be shipped.

4.212. The transport of certain radioactive material requires prior approval of the package design and, depending on the material to be shipped, approval of the shipment by a competent authority.

4.213. The requirements for the transport of radioactive material are internationally harmonized. A comprehensive corpus of regulations is established in IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition [23]. Additionally, different modes of transport (by road, rail, sea, air) have their own international or regional regulations as issued by the respective transport organizations. The national legal and regulatory framework for safety should incorporate these international and regional regulations.

4.214. In performing Action 2, the steering group will have made a preliminary analysis of the extent of transport of radioactive material, the competent authorities[15] within the governmental structure, and the existing legal and regulatory provisions.

4.215. In performing Action 3, the government will have assigned to a designated body the responsibility for developing the national infrastructure for the transport of radioactive material. The designated body will typically include all competent authorities and the regulatory body, when established.

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[15] In the context of transport of radioactive material, the term ‘competent authority’ refers to any body or authority designated or otherwise recognized as such for any purpose in connection with SSR-6 (Rev. 1) [23].

4.216. The actions in this section are recommended to be completed as steps towards the full implementation of the relevant IAEA Safety Requirements and Safety Guides, in particular:

— Requirement 7 of GSR Part 1 (Rev. 1) [2];
— Paragraph 2.25 of GSR Part 3 [10];
— All requirements of SSR-6 (Rev. 1) [23];
— All provisions of IAEA Safety Standards Series No. TS-G-1.5, Compliance Assurance for the Safe Transport of Radioactive Material [24].

Action 49. The designated body should assess the transport of radioactive material and identify gaps within the national requirements and arrangements for the transport of radioactive material.

4.217. The designated body should build upon the preliminary assessment done by the steering group and should perform a more detailed assessment of the existing, or likely to exist, activities relating to the transport of radioactive material, including the transport of radioactive waste generated within the State to a storage facility or a disposal site.

4.218. The existing legal and regulatory framework for the control of transport of hazardous material in general, and of Class 7 material (radioactive material) in particular, and the need for introducing changes, should be part of this assessment.

4.219. The assessment should also cover existing arrangements for the transport of radioactive material, including the possible routes and modes of transport in the State: by road, rail, sea, air, or inland waterway, as applicable.

Action 50. The designated body should plan and implement the necessary changes to the national requirements and arrangements for the transport of radioactive material.

4.220. In performing Action 15, the regulatory body will have established regulations for radiation safety including regulations for the safe transport of radioactive material.

4.221. The key functions of the designated body in relation to the transport of radioactive material are set out in TS-G-1.5 [24]. Each of these functions should be examined by the designated body and the required resources and skills should be assessed.

4.222. The key functions that are likely to exist in any State where transport of radioactive material is taking place, and for which the designated body should develop the necessary competences, are the following:

— Monitoring of transport operations.
— Enforcement actions and investigation of incidents.
— Interdepartmental liaison and/or cooperation.
— Issuing of approvals. Even in the case that no packages are designed or manufactured within the State, the State may need to issue approvals, for example, when multilateral approvals are requested according to the transport regulations. Issuing of approvals may be a new process for the designated body.
— Regulatory review and maintenance of an effective legal framework.
— Training and distribution of information.
— Emergency planning and exercises. An appropriate level of emergency response planning, taking into account that the environment through which radioactive material is being transported is subject to change, should be made in accordance with the national infrastructure and arrangements for an emergency mentioned in paras 4.133–4.156.
— Audits of management systems of all organizations involved in activities relating to the transport of radioactive material.

4.223. Key functions relating to the design, manufacturing and testing of packages do not necessarily exist in all States. Those functions are:

— Design assessment;
— Witnessing of testing;
— Witnessing of manufacture;
— Examination of maintenance and servicing arrangements.

The designated body should examine whether these functions apply to the State, and develop the required competences, as necessary.

Action 51. The competent authority and any organizations in charge of the transport of radioactive material should participate in international activities and networks to provide mutual support.

4.224. There are several international groups or associations of competent authorities for the transport of radioactive material, such as the European Association for Competent Authorities. Joining such a group or association is an opportunity for mutual support.

4.225. In general, several private and public stakeholders dealing with different competence areas are involved in education and training, such as educational institutes, national vocational training accreditation authorities, professional bodies, and regional or international organizations. The regulatory body may be a stakeholder contributing to the design, development and implementation of the education and training programme.

4.226. In performing Actions 1, 2 and 3, the steering group will have identified the existing options of providing education and training for safety in the State. The government will have established a designated body to promote and coordinate education and training.

4.227. The structure of the designated body depends on many factors, including the general education and training infrastructure in the State. For example, it could be a high level committee that may be mandated to propose policies in education and training for safety. The designated body may also involve ministries, organizations or professional bodies responsible for, or with a role in, education and training in the State. The designated body may also involve the regulatory body.

4.228. The actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Paragraph 2.5 (15) and Requirement 11 of GSR Part 1 (Rev. 1) [2];
— Paragraphs 2.21 and 2.22 of GSR Part 3 [10].

Action 52. In the early stages of establishing the radiation safety infrastructure, the designated body should encourage educational institutions and any organization with the relevant expertise to start providing training in safety.

4.229. In the early stages of establishing the national radiation safety infrastructure, competence building is unlikely to go through a systematic approach. Focus will probably be given to providing knowledge to the widest group of people possible. In this early stage, qualification requirements may be limited and might not address all the necessary areas of expertise.

4.230. Despite these circumstances, organizations such as universities, training providers and professional bodies with the appropriate expertise may be

encouraged to offer education and training courses, either on a commercial basis, or supported by the government. In doing so, such organizations may benefit from the syllabi of similar courses organized by the IAEA, other international organizations, or education and training institutions in other States.

4.231. The designated body, through a process of constructive engagement, should encourage relevant stakeholders to offer training options for safety and should seek support from the government or other sponsors, including international organizations.

4.232. For the preparation of the syllabi of the education and training courses for safety, the relevant organizations should consider the applicable IAEA safety standards.

4.233. The government, through the designated body, should ensure that the education and training activities are coordinated, should start as soon as possible developing a systematic approach, and should consider establishing a national strategy for education and training. The following actions provide guidance on the development of this national strategy.

Action 53. The regulatory body and other authorities should establish requirements for competence in safety for all persons engaged in activities relevant to protection and safety, including radiation protection officers and qualified experts.

4.234. As mentioned in para. 4.229, prior to having the legal framework for safety in place, limited requirements relating to competence in safety may exist for certain work activities in the State. The designated body should advise the government on areas where competence requirements can be established within the existing legal framework. For example:

— Health authorities may have the mandate to request minimum qualifications in safety for workers in the medical field.
— Professional bodies may set up criteria for competence in safety from an operational perspective for certain work activities. This is common, for example, for industrial radiography.

4.235. The designated body should request the authorities and professional bodies referred to in para. 4.234 to establish requirements or criteria on the minimum level of competence in safety in their respective areas.

4.236. Once the legal framework for safety is in place, specific qualification requirements should be established either by the regulatory body or by other governmental agencies or professional bodies, as appropriate. Authorized parties should be required to ensure the provision of adequate training to their staff to comply with the established qualification requirements.

4.237. The regulatory body and other authorities or professional bodies in charge of setting up requirements or criteria for the minimum level of competence in safety should consider international guidance, such as that from the IAEA, and experiences of other States.

4.238. When establishing requirements, the regulatory body and other authorities or professional bodies should identify work activities where formal recognition of competence in safety is warranted.

4.239. The government, through the regulatory body or other competent organization, should identify the need for formal accreditation of the education and training provided. As an example, and depending on the government structure, this accreditation may be under the authority of a national accreditation body, the regulatory body, higher education authorities or other professional bodies or associations.

Action 54. The designated body, in cooperation with relevant organizations, should identify and prioritize education and training needs in the State.

4.240. Based on the inventory of facilities and activities, and the established minimum levels for competence in safety, the designated body in cooperation with relevant organizations should assess the number of persons to be trained in safety in each work activity. Consideration should be given not only to the existing situation but also to projected needs taking into account anticipated demands in the near future.

4.241. The designated body, in cooperation with relevant organizations, should establish priorities and follow a graded approach in the design, development and implementation of an education and training programme to ensure that education and training is provided on a priority basis to key groups including, inter alia, regulators, radiation protection officers, qualified experts, and persons involved in high radiation risk work activities.

Action 55. The designated body, in cooperation with relevant organizations, should design a national education and training programme on the basis of the identified needs and priorities.

4.242. A national education training programme should be designed on the basis of an analysis of training needs and priorities.

4.243. After identifying the education and training needs and priorities, the designated body, in cooperation with relevant organizations, should assess the existing education and training capabilities, both in terms of the resources available and the appropriateness of those resources.

4.244. By matching the outcome of the assessments in paras 4.240 and 4.243, the designated body and the relevant organizations will identify the education and training that can be provided domestically. For the residual needs, consideration should be given either to obtaining the necessary education and training from abroad or to gradually building the capacity in the State for providing this education and training.

4.245. External resources for education and training may be available through bilateral or multilateral agreements or from international organizations.

4.246. Completion of Action 55 will structure the profile of the national education and training programme by identifying what needs to be done, where and when. This provides the input for formulating the details of the training programme.

Action 56. The designated body, in cooperation with relevant organizations, should make provisions to ensure the development and implementation of the national education and training programme.

4.247. In the development and implementation phase of a national education and training programme, all training activities should be developed and implemented by education and training centres or providers.

4.248. The development phase includes the production of appropriate training material including, inter alia, syllabi, timetables, lecture plans, lecture notes, practical workshop instructions and assignments, scenarios for exercises and drills, and training assessment tools such as examinations.

4.249. Resources and arrangements for implementing the education and training programme will need to be in place, including facilities for theoretical and

practical training, workshops, tutorials, seminars or practical training exercises, and/or on the job training of appropriate duration.

4.250. The designated body, in cooperation with the training providers, should ensure the timely implementation of the education and training programme. While certain training activities may need to be offered regularly, either to address a large number of individuals or to ensure that refresher training is available to the target group of concern, other training activities may be needed just a few times (e.g. if the target group is small or if the topic is very specific).

Action 57. The designated body, in cooperation with relevant organizations, should periodically evaluate the implementation of the national education and training programme.

4.251. Performance indicators should be identified and used to evaluate the effectiveness of the national education and training programme. The evaluation should cover the impact of the programme, the overall process and its content. The following examples of indicators should be applied as appropriate:

— Number of training courses, types and levels;
— Number of people undergoing initial and refresher training;
— Percentage of successful completions of training by trainees;
— Feedback from employers on the basis of a formal and documented appraisal of the performance of trainees after training;
— Feedback from trainees about the quality and effectiveness of training;
— Comparison of data on individual and collective doses before and after training;
— Comparison of accident reports before and after training;
— New levels of competence reached by trainees.

4.252. The results of the evaluation should be used as feedback to improve the national education and training programme.

4.253. Where the evaluation indicates any areas of improvement, the causes should be determined and steps taken to rectify matters in future programmes.

ESTABLISHING TECHNICAL SERVICES

4.254. The government is required to make provision for technical services in relation to safety [2]. Examples of such technical services are:

— Personal dosimetry services for occupational radiation protection;
— Services for the calibration of sources giving rise to medical exposure;
— Calibration services for equipment used for radiation monitoring and measurement;
— Specialized services for safety assessment;
— Analytical services for the analysis of radioactivity in environmental samples;
— Maintenance services for radiation equipment and facilities.

4.255. In performing Actions 1 and 2, the steering group will have identified the required technical services that may have significance for radiation safety based on the national survey of practices and radiation sources. The steering group will have also developed a broad analysis of which services are needed and which are available within the State.

4.256. In performing Action 3, the government will have assigned responsibilities relating to the provision of these technical services to a designated body.

4.257. The structure of the designated body in charge of making arrangements for the provision of technical services depends on the governmental structure, the variety of technical services needed and the existing technical resources in the State.

4.258. The designated body for technical services may involve several private or public organizations for different technical services. For example, a technically competent organization may establish and provide external dosimetry services. Another organization may establish and provide internal dosimetry or calibration services. Maintenance services are often provided by suppliers on a commercial basis. Additionally, universities and professional bodies may be able to provide specific services relating to safety such as analytical services or expert services for safety assessment.

4.259. The following actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements and Safety Guides, in particular:

— Requirement 13 of GSR Part 1 (Rev. 1) [2];
— Paragraphs 3.99 and 3.73(c) of GSR Part 3 [10];
— Paragraphs 2.5 and 2.8 of IAEA Safety Standards Series No. GS-G-3.2, The Management System for Technical Services in Radiation Safety [25].

Action 58. The designated body should ensure that arrangements are in place for the provision of technical services necessary for safety.

4.260. In the early stages of establishing a national radiation safety infrastructure, the government would have only a broad assessment of the needs for technical services based on the initial survey of facilities and activities in the State, as well as based on the IAEA safety standards and the approaches in other States. A detailed assessment of the scope and capacity of technical services depends strongly on the regulatory approach that will be adopted in the State and on requirements that will be set forth later in regulations, as an outcome of Action 15.

4.261. Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government should make provision for the availability of such services.

4.262. If it is not feasible to establish technical services inside the State owing to national circumstances (e.g. due to lack of resources or due to national priorities) the provision of technical services from other countries should be sought (e.g. through bilateral or regional cooperation).

4.263. Once the legal framework is in place, and radiation safety regulations are established, the regulatory body will be able to develop accurate information on the need for technical services in the State. The government should ensure that national needs are covered so that regulatory requirements can be fulfilled.

4.264. The regulatory body is a source of expertise and in many States it is the organization with the most competence in radiation safety in the State. If the regulatory body provides expert advice or technical services, then care should be taken to ensure that any conflict with its main regulatory functions is avoided.

4.265. The government should consider how, in a time of crisis (including economic crisis), continuity of service provision will be maintained, and should ensure availability of services beyond commercial considerations.

Action 59. The regulatory body should establish requirements for authorization or approval of providers of technical services that may have significance for safety.

4.266. The regulatory body is required to authorize technical services that may have significance for safety, as appropriate [2].

4.267. The regulatory body should establish requirements and a mechanism to authorize or approve technical services that may have significance for safety, in particular service providers for individual monitoring and calibration services.

4.268. The providers of such technical services should be required to demonstrate competence through mechanisms such as professional and trade accreditations or registrations. If necessary, regional or international organizations should be used.

4.269. Service providers should have a management system in place that demonstrates their ability to consistently meet the customer's requirements, and the applicable regulatory requirements, and to achieve customer satisfaction through effective application of the system, including processes for continuous improvement and for the prevention of non-conformances. In many States, this demonstration is achieved through third party audit or accreditation to internationally accepted management standards, for example, ISO/IEC 17025 [26].

4.270. Providers of technical services should be encouraged to participate in inter-comparison programmes, such as those offered by the IAEA, or in peer reviews as applicable.

PARTICIPATION IN THE GLOBAL SAFETY REGIME

4.271. International cooperation and assistance in relation to radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material, has contributed to the development of a global safety regime. The organizations and persons involved in the utilization of radiation sources are interdependent in that the performance of one may have implications for all. Recognition of this mutual dependence has led to a number of regional and international arrangements that are intended to enhance safety in all States.

4.272. Effective participation in international activities and networks promotes the exchange of knowledge on lessons learned and best practices among States. It is also an opportunity to share and benefit from the experience of other States. Establishing effective international cooperation is an essential element in ensuring an appropriate level of protection from harmful effects of ionizing radiation globally and nationally.

4.273. The government is required to fulfil its respective international obligations, participate in the relevant international arrangements, including

international peer reviews, and promote international cooperation and assistance to enhance safety globally [2].

4.274. In performing Action 2, the steering group will have reviewed the international obligations of the State set forth through its participation in conventions and other international instruments, and will have advised the government on measures to strengthen its participation in the global safety regime.

4.275. In performing Action 3, the government will have assigned the responsibility for the participation in the global safety regime to a designated body. Typically, the designated body will be the ministry of foreign affairs. The regulatory body, the ministry of justice, and the legislative bodies in the State all have significant roles in the State's involvement in the global safety regime and will be part of, or contributors to, the designated body.

4.276. The actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirements 1, 14 and 15 of GSR Part 1 (Rev. 1) [2];
— Paragraphs 2.28 and 4.6 of GSR Part 3 [10].

Action 60. The designated body should prepare for participation in the global safety regime.

4.277. The designated body should build upon the review done by the steering group, should consider a means for participation in the global safety regime, and should evaluate the associated benefits, obligations, necessary resources and allocation of responsibilities within the State.

4.278. The designated body should prepare for involvement in the global safety regime considering the following elements:

— The international conventions that establish robust common principles and obligations for ensuring protection and safety, and that provide for an effective and coordinated response to emergencies;
— Codes of conduct that promote the adoption of good practices in the relevant operations;
— Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, safety guides and practices;

— International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States;
— Knowledge networks and expert networks;
— Regional agreements relating to safety;
— Multilateral and bilateral cooperation with relevant national and international organizations on safety matters to enhance safety by means of harmonized approaches, as well as to increase the quality and effectiveness of safety reviews and inspections, by means of knowledge sharing and feedback of experience.

4.279. On the basis of this preparation, the government, the designated body and relevant organizations will be able to make decisions regarding their participation in the global safety regime.

Action 61. The designated body should cooperate with authorities in other States and international organizations regarding radiation safety and should establish measures for information exchange and seeking assistance.

4.280. The designated body should establish contact with organizations in other States and international organizations to seek advice on safety related matters. This action should be coordinated with Action 28.

4.281. Bilateral and multilateral arrangements should be prepared and formally agreed to foster cooperation with neighbouring States, other States and international organizations with regard to radiation safety. Areas of possible cooperation include coordinated procedures, information exchange with regard to transport of radioactive material, import or export of radiation sources, possible transboundary exposures, response to events such as unauthorized radiation sources detected at borders, and mutual assistance.

Action 62. The regulatory body and the relevant organizations should actively participate in radiation safety networks and international peer reviews and should use other international safety standards and other instruments.

4.282. Activities and participation in the global safety regime should be progressively implemented by those parties who were identified and were assigned the responsibility to carry them out.

4.283. Participation in radiation safety networks is an important means for receiving information from, and disseminating information to, other States

and international organizations, and for sharing lessons learned. A number of international, regional or professional networks exist, such as the Global Nuclear Safety and Security Network, the Asian Nuclear Safety Network, the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies, the Forum of Nuclear Regulatory Bodies in Africa, the Arab Network of Nuclear Regulators, and the Heads of the European Radiological Protection Competent Authorities.

4.284. Participation in peer reviews provides for an independent assessment of the relevant areas of the national radiation safety infrastructure, and opportunity for exchanging knowledge and experience. The IAEA offers review services in different areas of radiation safety including regulatory infrastructure, occupational exposure, emergency preparedness and response, transport of radioactive material, and education and training (see para. 5.15).

4.285. Commitment to complying with the IAEA safety standards, and to participation in international safety reviews and safety services based on the IAEA safety standards, should be reaffirmed. Consideration should also be given to other international safety standards and to codes of conduct.

Action 63. The government should become a party to the relevant international conventions.

4.286. The international conventions and codes of conduct establish common principles and obligations for ensuring protection and safety in the use of radiation sources, radioactive material and nuclear energy, and provide for an effective and coordinated response to emergencies.

4.287. The list of related conventions and codes of conduct includes:

— The Convention on Early Notification of a Nuclear Accident [27];
— The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency [28];
— The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [22];
— The Convention on the Physical Protection of Nuclear Material and its Amendment [29];
— The Code of Conduct on the Safety and Security of Radioactive Sources [3] and its supplementary Guidance on the Import and Export of Radioactive Sources [14].

5. MEASUREMENT, ASSESSMENT AND CONTINUOUS IMPROVEMENT OF THE RADIATION SAFETY INFRASTRUCTURE

5.1. The actions in this section are recommended as steps towards the full implementation of the relevant IAEA Safety Requirements, in particular:

— Requirement 19 of GSR Part 1 (Rev. 1) [2];
— Requirement 2, 3, 7, 8, 13 and 14 of IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [30].

Action 64. Every organization constituting part of a designated body should monitor, measure and assess the progress made in implementing the actions of establishing the radiation safety infrastructure in its area of competence.

5.2. The concept of progress monitoring, measurement and assessment is key to ensuring that the implementation of the actions undertaken to establish or strengthen the national radiation safety infrastructure is aligned with the goals of the organization, and is key to identifying, as early as possible, any deviations or needs for adjustments.

5.3. The concept of monitoring, measurement and assessment is also important after the goals of the organization have been achieved. Monitoring, measurement and assessment are the main mechanisms for ensuring that goals are continuously met and for identifying opportunities for improvement.

5.4. Monitoring, measurement and assessment should be part of the establishment of a learning culture in the organization. Individuals at all levels should review their work critically on a routine basis to identify areas needing improvement and the means of achieving these improvements.

5.5. Monitoring, measurement and assessment should be done by each organization that is part of a designated body in the relevant area of the national radiation safety infrastructure. The scope and depth of the measurement and assessment depend on the competence of the organization as well as the stage of infrastructure development.

5.6. Monitoring, measurement and assessment should be done on a regular basis, and as necessary, to continuously ensure alignment with the organization's objectives at the targeted level of performance.

5.7. For the purposes of this Safety Guide, the main goal is to establish a radiation safety infrastructure that is compatible with international safety standards. Monitoring, measurement and assessment should reflect compliance with IAEA safety standards in each area of the national radiation safety infrastructure, and help to identify non-conformances and areas of improvement.

Self-assessment

5.8. Managers and individuals at all levels in the organization are required to carry out self-assessment periodically [30].

5.9. Self-assessment can be conducted at different levels, depending on the maturity and immediate needs of the organization. A simple questionnaire addressing the essential performance indicators could be used at the early stages of establishing the radiation safety infrastructure. Such a questionnaire provides a broad picture of the main areas of concern. At later stages, more detailed questionnaires and sophisticated tools could be used to provide a more in-depth assessment of the organizational performance.

5.10. Feedback from interested parties and the public also provides input that can be used by the organization in a self-assessment process.

5.11. The IAEA has developed a self-assessment methodology and a supporting computer software package to assist organizations and, in particular, the regulatory body in meeting the full range of IAEA Safety Requirements [31].

Independent assessment

5.12. Independent assessment, by peer review, is an examination or review of performance conducted by others in the same area of competence. Peer review can add substantial benefits to the organization, such as driving continuous improvement. Peer review can be conducted as an external audit by other organizations or as an internal audit by other units within the same organization.

5.13. The government is required to allow for participation in relevant international arrangements, including international peer review [10].

5.14. Every organization constituting part of a designated body, in particular the regulatory body, should proactively look for opportunities to cooperate in the carrying out of peer review with other similar organizations in other States.

Such peer reviews can be facilitated through established regional or international cooperative programmes, or though cooperation between organizations.

5.15. States are encouraged to benefit from the range of peer review services offered by the IAEA in the various areas of radiation safety infrastructure, including:

— Integrated Regulatory Review Services;
— IAEA Advisory Missions relating to the national regulatory infrastructure for the control of radiation sources;
— Occupational Radiation Protection Appraisal Service;
— Emergency Preparedness Review;
— International Physical Protection Advisory Service;
— Transport Safety Appraisal Service;
— Education and Training Appraisal.

Action 65. Based on the results of monitoring, measurement and assessment, every organization constituting part of a designated body should identify opportunities, and undertake measures, to improve the effectiveness of the actions it has been conducting to establish radiation safety infrastructure.

5.16. Continuous improvement is a means by which an organization can drive changes in its methods and procedures to improve radiation safety. It is very rare, if ever, that an organization can justifiably describe itself as no longer needing to improve. Consequently, continuous improvement should be seen as an ongoing and iterative endeavour that can be expected to incrementally deliver performance gains.

5.17. An organization should establish methods and procedures to collect, analyse and effectively use feedback received from all sources, including the outcomes of self-assessment and independent assessments and feedback from interested parties. This is a vital component, without which continuous improvement cannot effectively take place.

5.18. On the basis of performance monitoring, measurement and assessment, non-conformances that may impact the organization's performance should be identified. Corrective actions for eliminating non-conformances and preventive actions to avoid recurrence should be determined and implemented in a timely manner.

5.19. The status and effectiveness of the corrective and preventive actions should also be monitored and assessed.

Action 66. Every organization constituting part of a designated body should establish and implement an integrated management system.

5.20. Every organization constituting part of a designated body should establish and implement an integrated management system that is aligned with the goals of the organization and contributes to their achievement. It is required that the management system integrate all elements of management, including safety, health, environmental, security, quality, societal and economic elements, so that safety is not compromised [30].

5.21. The management system should include, inter alia, the organization's activities relating to the monitoring, measurement, assessment and continuous improvement of its performance, and should confirm the organization's ability to achieve the intended results and to identify opportunities for improvement.

5.22. Ideally, an organization's management system will have fully implemented a management system approach as described in GSR Part 2 [30].

5.23. The application of the management system requirements should be subject to a graded approach that takes into account significance to safety and possible consequences in case of failure. Grading the application of the management system requirements enables valuable resources and attention to be targeted at areas of greater significance. This can result in minimizing total costs while improving safety.

5.24. The management system should be based on documented processes, and the owners, inputs, outputs, drivers and constraints of these processes should be specified. This approach facilitates the implementation of the results of monitoring, measurement and assessment and consequently supports continuous improvement.

Action 67. The government should plan and implement measures to regularly assess the radiation safety infrastructure in the State in a holistic and integrated manner, and should implement measures for continuous improvement.

5.25. This Safety Guide includes actions on assessing the national situation regarding radiation safety in a holistic manner. In Action 1, the government

is recommended to establish a steering group to make this assessment and to provide advice on improvement.

5.26. In this Safety Guide, the government is recommended to assign responsibilities and to implement actions to establish or strengthen the radiation safety infrastructure in the State. The organizations involved are recommended, in Actions 64–66, to implement measures for monitoring, measurement, assessment and continuous improvement of their own performance.

5.27. In general, the collective review of the performance assessments undertaken separately by each organization constituting part of a designated body may provide reasonable confidence in the effectiveness of the radiation safety infrastructure as a whole. Nevertheless, it is advised that the government make arrangements for a holistic and integrated assessment of the national radiation safety infrastructure in a manner similar to Action 1.

5.28. To make this assessment, the government may follow a similar approach to Action 1 and designate a body to play an equivalent role to the steering group. The government may request that the regulatory body undertake or lead such an assessment, considering the central role the regulatory body has in ensuring radiation safety in the State. The regulatory body usually has detailed knowledge on radiation safety in each area of the national infrastructure, has access to relevant information and has formal arrangements for coordination with other organizations.

5.29. This integrated assessment may be done regularly at intervals that take into consideration the national circumstances, the pace of developments in the different areas of radiation safety infrastructure and the availability of resources.

5.30. The integrated assessment may reveal areas of shortcomings and opportunities for improvement. The government should review the actions taken, and undertake measures for improvement, which may include adjustment to the legal framework, responsibility assignment or resources allocation.

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