

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



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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.

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ESTABLISHING THE
INFRASTRUCTURE FOR
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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

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2018

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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 measures¹ 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.

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

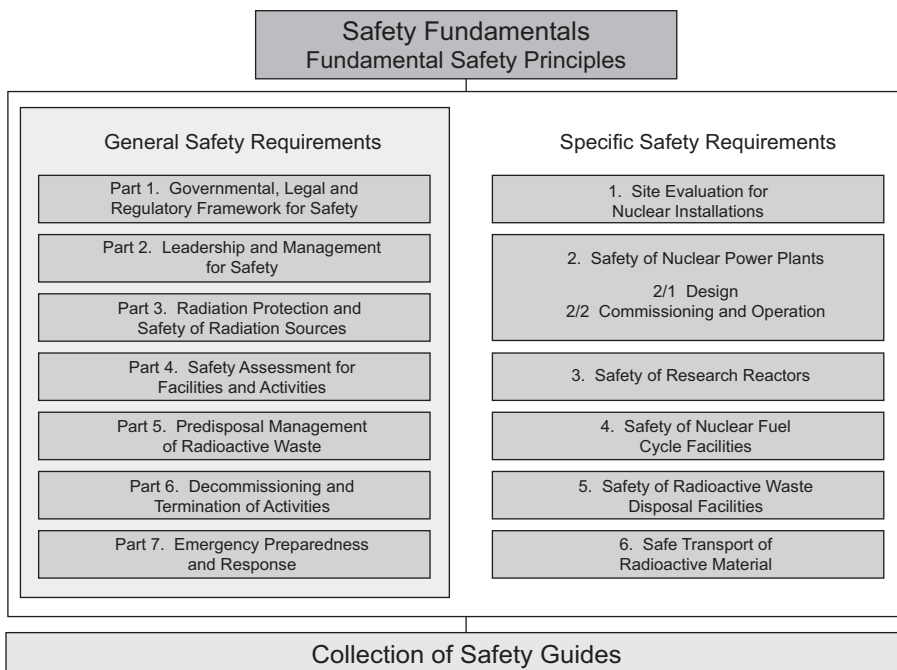


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

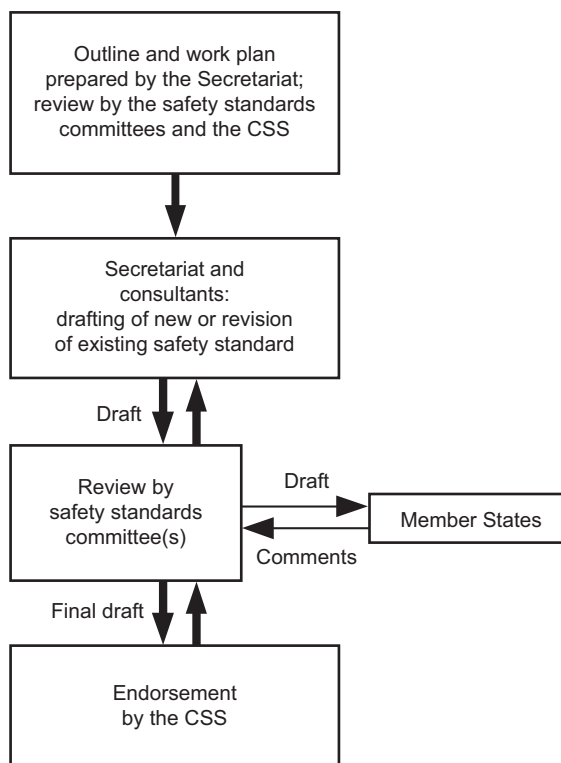


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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.

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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 safety¹. 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 safety² infrastructure can be

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.

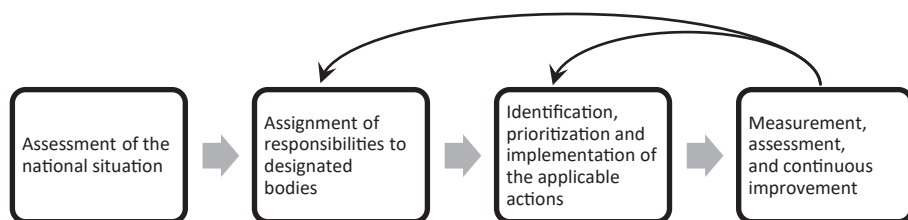


FIG. 1. Illustration of the general scheme adopted in this Safety Guide for establishing the national radiation safety infrastructure.

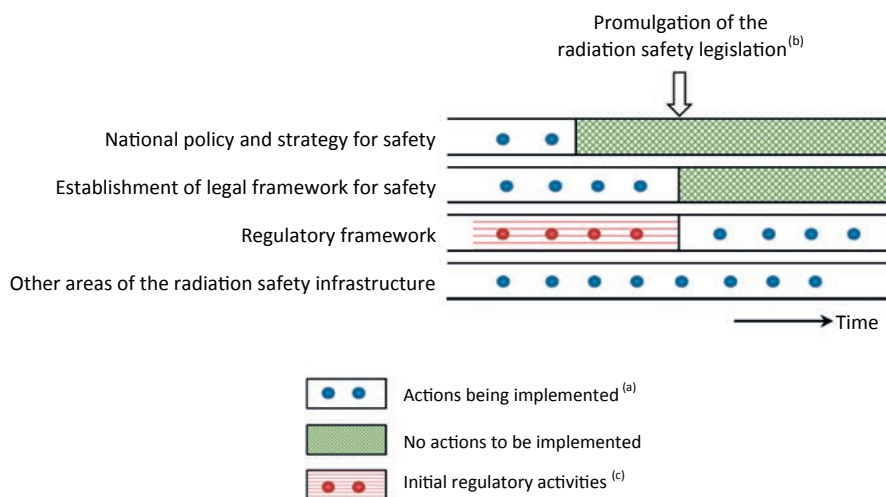


FIG. 2. Schematic visualization of the development of areas of the radiation safety infrastructure (see para. 1.4)

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 group⁵ 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 approach⁶.

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.

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.