

IAEA Safety Standards

for protecting people and the environment

Establishing the Safety Infrastructure for a Nuclear Power Programme

Specific Safety Guide
No. SSG-16



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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 at the IAEA Internet site

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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 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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Other safety related IAEA publications are issued as **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.

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This publication has been superseded by SSG-16 (Rev. 1).

ESTABLISHING THE SAFETY INFRASTRUCTURE FOR A NUCLEAR POWER PROGRAMME



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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".

This publication has been superseded by SSG-16 (Rev. 1).

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ESTABLISHING THE SAFETY INFRASTRUCTURE FOR A NUCLEAR POWER PROGRAMME

SPECIFIC SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
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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.

NOTE BY THE SECRETARIAT

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. The process of developing, reviewing and establishing the IAEA standards involves the IAEA Secretariat and all Member States, many of which are represented on the four IAEA safety standards committees and the IAEA Commission on Safety Standards.

The IAEA standards, as a key element of the global safety regime, are kept under regular review by the Secretariat, the safety standards committees and the Commission on Safety Standards. The Secretariat gathers information on experience in the application of the IAEA standards and information gained from the follow-up of events for the purpose of ensuring that the standards continue to meet users' needs. The present publication reflects feedback and experience accumulated until 2010 and it has been subject to the rigorous review process for standards.

Lessons that may be learned from studying the accident at the Fukushima Daiichi nuclear power plant in Japan following the disastrous earthquake and tsunami of 11 March 2011 will be reflected in this IAEA safety standard as revised and issued in the future.

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.

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

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

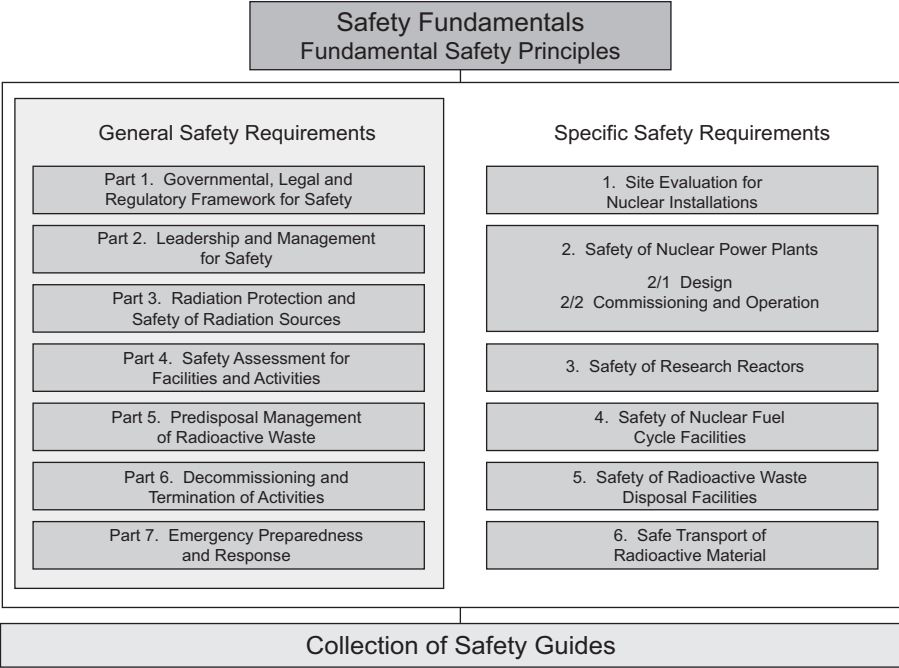


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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 four safety standards committees, for 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 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

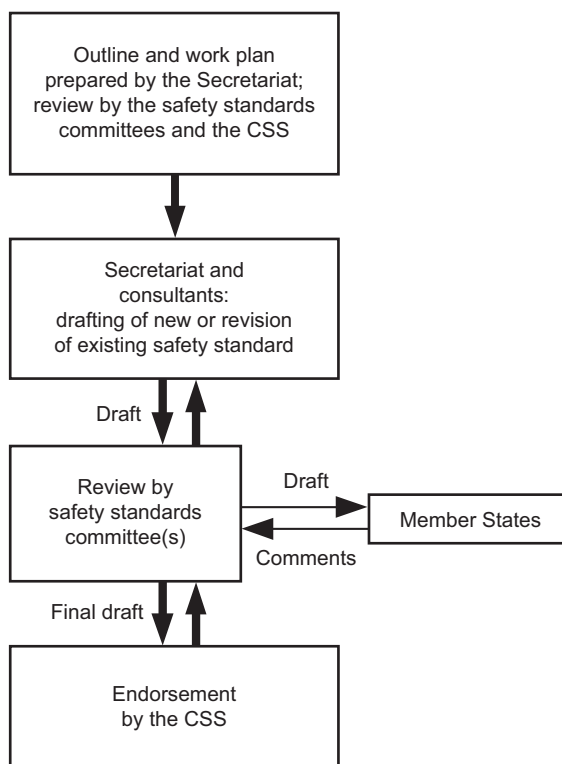


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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 General Conference encouraged the Secretariat to develop approaches to supporting the development of infrastructure for nuclear power in States either considering the introduction of nuclear power or expanding an existing nuclear power programme. A number of States have requested guidance on how to apply the IAEA Safety Standards in the development of a nuclear power programme.

1.2. The IAEA Safety Fundamentals publication on 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 be more or less important in relation to particular circumstances, the appropriate application of all relevant principles is required. When a State is considering embarking on a nuclear power programme, Principle 1, Responsibility for safety; Principle 2, Role of government; Principle 3, Leadership and management for safety; and Principle 4, Justification of facilities and activities, are crucial to preparing properly for the future safe operation of nuclear power plants.

1.3. A considerable period of time is necessary to acquire the necessary competences and a strong safety culture before operating a nuclear power plant. While prime responsibility for safety must rest with the operating organization, the State has the responsibility, upon committing itself to a nuclear power programme that demands significant investment, to create a robust framework for safety. This responsibility is incumbent on those who live and work within the State and it cannot be outsourced. Establishing a sustainable safety infrastructure is a long process, and it has been internationally acknowledged that a period of 15 years under optimum conditions would generally be needed between the consideration of nuclear power as part of the national energy strategy and the commencement of operation of the first nuclear power plant.

1.4. In 2007, the IAEA published a brochure entitled Considerations to Launch a Nuclear Power Programme [2] and a report entitled Milestones in the Development of a National Infrastructure for Nuclear Power [3]. In 2008, a report was published by the International Nuclear Safety Group on Nuclear Safety

Infrastructure for a National Nuclear Power Programme Supported by the IAEA Fundamental Safety Principles (INSAG-22) [4]. This INSAG report defines ‘nuclear safety infrastructure’ as “the set of institutional, organizational and technical elements and conditions established in a State to provide a sound foundation for ensuring a sustainable high level of nuclear safety”.

1.5. In 2010, the IAEA Board of Governors approved for publication an IAEA Safety Requirements publication on the Governmental, Legal and Regulatory Framework for Safety [5], which establishes requirements in respect of the infrastructure for safety. Reference [5] covers the essential aspects of the governmental and legal framework for establishing a regulatory body and for taking other actions necessary to ensure the effective regulatory control of facilities and activities — existing and new — utilized for peaceful purposes, from the use of a limited number of radiation sources to a nuclear power programme. This framework for safety is essentially the governmental part of the ‘nuclear safety infrastructure’.

1.6. In INSAG-22 [4], consistent with Refs [2, 3], the lifetime of a nuclear power plant is divided into five phases from a nuclear safety standpoint and indicative average durations are provided for each of these phases. The present Safety Guide uses the same approach in considering Phases 1, 2 and 3:

- Phase 1 is ‘Safety infrastructure before deciding to launch a nuclear power programme’ (average duration: 1–3 years);
- Phase 2 is ‘Safety infrastructure preparatory work for construction of a nuclear power plant after a policy decision has been taken’ (average duration: 3–7 years);
- Phase 3 is ‘Safety infrastructure during implementation of the first nuclear power plant’ (average duration: 7–10 years);
- Phase 4 is ‘Safety infrastructure during the operation phase of a nuclear power plant’ (average duration: 40–60 years);
- Phase 5 is ‘Safety infrastructure during the decommissioning and waste management phases of a nuclear power plant’ (average duration: 20 to more than 100 years), as shown in Fig.1.

1.7. This Safety Guide provides recommendations, presented in the form of sequential actions, on meeting safety requirements progressively during Phases 1, 2 and 3 of the development of the safety infrastructure (see Fig. 2).

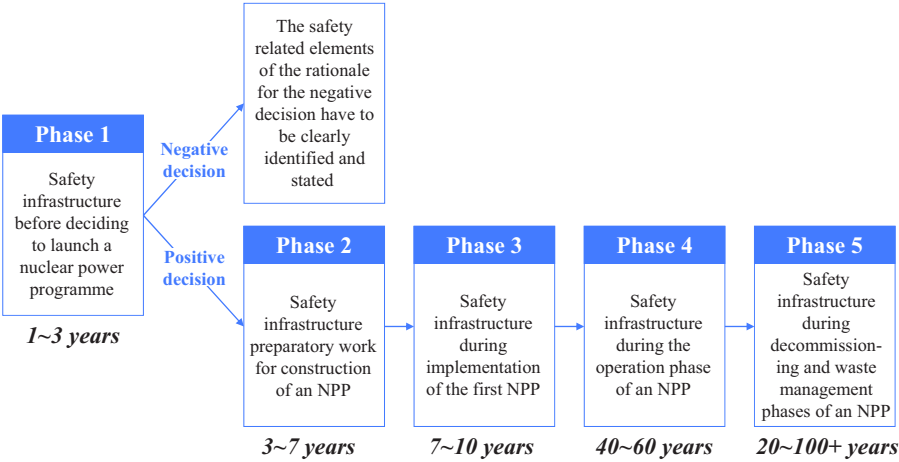


FIG. 1. Main phases of safety infrastructure development over the lifetime of a nuclear power plant (based on INSAG-22 [4]). NPP: nuclear power plant.

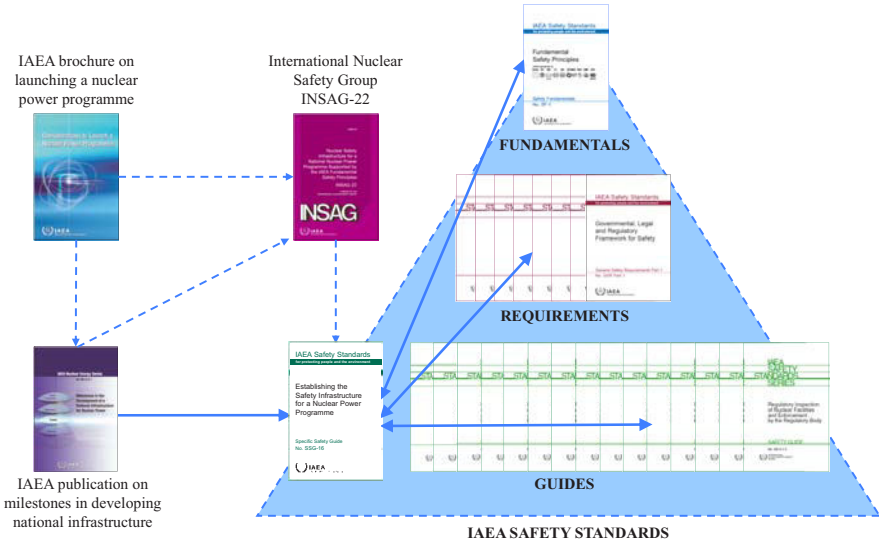


FIG. 2. This Safety Guide provides guidance on the progressive implementation of the IAEA safety standards.

1.8. The use of the IAEA Safety Requirements publications alone is not considered sufficient to understand the need for or to develop a safety infrastructure. It is expected that the organizations or persons using this Safety Guide will understand and use the recommendations provided in the Safety Guides supporting the Safety Requirements publications in the respective subject areas. The IAEA promotes national ‘self-assessments’ and provides for the application of its safety standards through safety review services such as the Integrated Regulatory Review Service or the Operational Safety Review Team service upon request by the State, to guide and/or to peer review a national self-assessment.

1.9. States have different legal 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 with the term ‘State’.

1.10. The actions set out in this Safety Guide are not reformulations of safety requirements; they provide recommendations, expressed as ‘should’ statements, on when to implement the relevant requirements. The 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.

1.11. This Safety Guide is applicable for States with various levels of experience with nuclear activities. While some States seeking to establish a nuclear power programme may have few or no nuclear activities already established, others may have extensive experience from the operation of research reactors and other applications of ionizing radiation. For the purpose of this Safety Guide, it is assumed that the State has little or no experience with a nuclear power programme. In the scenario presented in this Safety Guide, the State has no regulatory body and no operating organization at the beginning of the process (Phase 1); this Safety Guide is therefore to be used with flexibility by States that are in a different initial situation. The IAEA welcomes feedback from States for a future revision of this Safety Guide.

1.12. This Safety Guide is intended for use by any persons or organizations participating in the preparation and implementation of a nuclear power programme. Such persons or organizations are referred to collectively in the text as ‘all relevant organizations’. This includes:

- Governmental officials;
- Legislative bodies;

- Organizations that are given an explicit governmental mandate to assess the feasibility of or to coordinate the development of a nuclear power programme¹;
- Regulatory bodies;
- Operating organizations;
- External expert support entities, including technical and scientific support organizations²;
- Industrial organizations, including designers and constructors;
- Organizations for radioactive waste management and spent fuel management;
- Organizations involved in preparedness for and response to a nuclear or radiological emergency;
- Organizations involved in the transport of nuclear material;
- Competent authorities for matters relating to nuclear security;
- Education and training organizations;
- Research centres.

1.13. International organizations may use this Safety Guide to help determine the progress accomplished by a State in developing and establishing the infrastructure necessary for executing a nuclear power plant project, so that assistance can be provided in a meaningful and timely manner.

1.14. Any other relevant organizations, as well as the news media and the public, may also use this Safety Guide for assurance that the State has established the safety infrastructure necessary for commencing the construction of a nuclear power plant. They may also use it for assurance that the State has commenced preparations for the commissioning, operation, maintenance and eventual decommissioning of the plant, as well as for properly managing the radioactive waste generated during plant operation and decommissioning.

1.15. In identifying actions to be conducted, this Safety Guide tries to specify as far as practicable the entity responsible for taking the action. However, since States have different legal structures, it is not possible to specify in general which

¹ Such organizations are called ‘governmental project management organizations’ or ‘nuclear energy programme implementing organizations’ in other publications of the IAEA and the International Nuclear Safety Group. For the purpose of this Safety Guide, such organizations are referred to by the general term ‘the government’.

² The term ‘external support organization’ is used throughout this text to include external experts and external expert support entities, including technical and scientific support organizations.

entity within the State (the government as a whole, executive body, the legal system, regulatory body, etc.) is responsible for a given action. In such cases, the general term ‘State’ or ‘government’ is used.

OBJECTIVE

1.16. The objective of this Safety Guide is to provide guidance on the establishment of a framework for safety in accordance with the IAEA safety standards for States deciding on and preparing to embark on a nuclear power programme. In this regard, it proposes 200 safety related actions to be taken in the first three phases of the development of the nuclear power programme, to achieve the foundation for a high level of safety throughout the entire lifetime of the nuclear power plant, including safety in the associated management of radioactive waste and spent fuel, and safety in decommissioning.

1.17. This Safety Guide is intended to contribute to the building of leadership and management for safety and of a safety culture. It is intended for use as guidance for self-assessment by all organizations involved in the development of a safety infrastructure.

1.18. The government, through the legal system, establishes national policy for safety by means of different instruments, statutes and laws. The regulatory body, as designated by the government, is charged with the implementation of policies through a regulatory programme or a strategy set forth in its regulations or standards. The government, through the legal system, determines the specific functions of the regulatory body and the allocation of responsibilities. For example, the government establishes laws and adopts policies pertaining to safety, whereas the regulatory body develops plans and promulgates regulations in execution of such laws or policies. In addition, the government establishes laws and adopts policies specifying the responsibilities and functions of different governmental entities in respect of safety and emergency preparedness and response, whereas the regulatory body establishes a system to provide for effective coordination. The recommendations made in this Safety Guide are to be understood in the context of these respective functions, although some flexibility may be necessary in following them, depending on the particular national circumstances.

SCOPE

1.19. The scope of this Safety Guide covers all the relevant IAEA safety requirements to be incorporated into an effective safety infrastructure for the first three phases of a nuclear power programme. The recommendations are presented for ease of use in the form of 200 actions.

1.20. This Safety Guide addresses the necessary safety infrastructure before a decision to launch a nuclear power programme is taken (Phase 1), the safety infrastructure for preparatory work for the construction of a nuclear power plant (Phase 2), and the safety infrastructure during construction and commissioning of the first nuclear power plant (Phase 3) (see Fig. 3).

1.21. Figure 3 provides an indicative time frame with some steps important to safety in establishing a safety infrastructure for a nuclear power programme. Figure 4 utilizes this time-frame to provide insights on the progressive involvement of the regulatory body and the operating organization in nuclear power related activities, as well as the progressive allocation of responsibilities from the government to these organizations. This also reflects the development of sufficient human resources with the competence to perform the necessary activities. In addition, Fig. 4 identifies, for each relevant IAEA Safety Requirements publication, at which stages, respectively:

- There should be awareness of the requirements;
- Implementation of the requirements should be started;
- Requirements should be fully implemented.

1.22. Research reactors and fuel cycle facilities are not explicitly covered in this Safety Guide, which concentrates on the nuclear power programme.

1.23. The Fundamental Safety Principles [1] state that: “Safety measures and security measures have in common the aim of protecting human life and health and the environment.” This Safety Guide does not address nuclear security considerations and the actions that need to be taken to incorporate security elements progressively into an effective nuclear security regime for a nuclear power programme. Considerations of nuclear security matters are covered in IAEA Nuclear Security Series publications. Specific recommendations on security for nuclear power plants are provided in IAEA Nuclear Security Series No. 13, Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5) [6]. Implementing Guides are also issued in the IAEA Nuclear Security Series. The scope of this

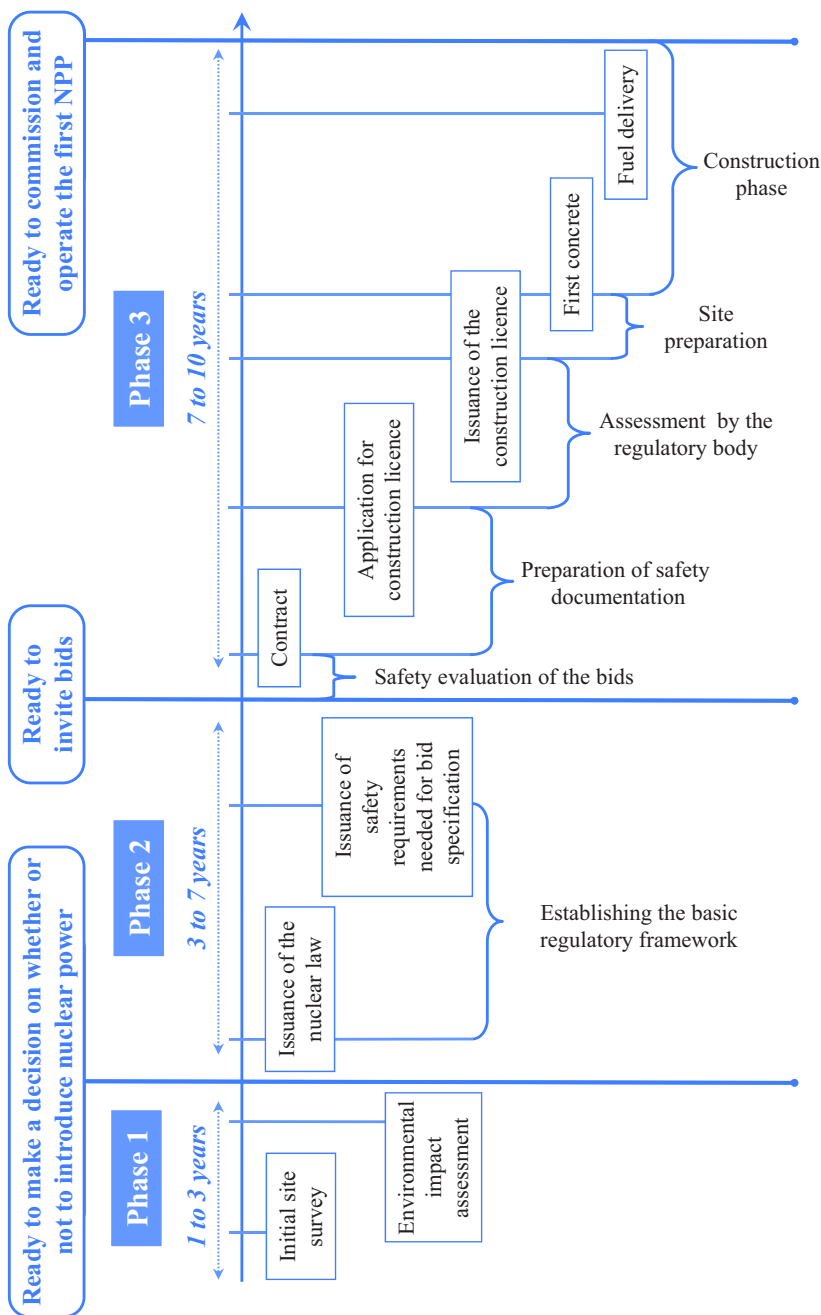


FIG. 3. Some steps important to the development of the safety infrastructure (indicative only, to be used with flexibility; see also Fig. 7 for siting).

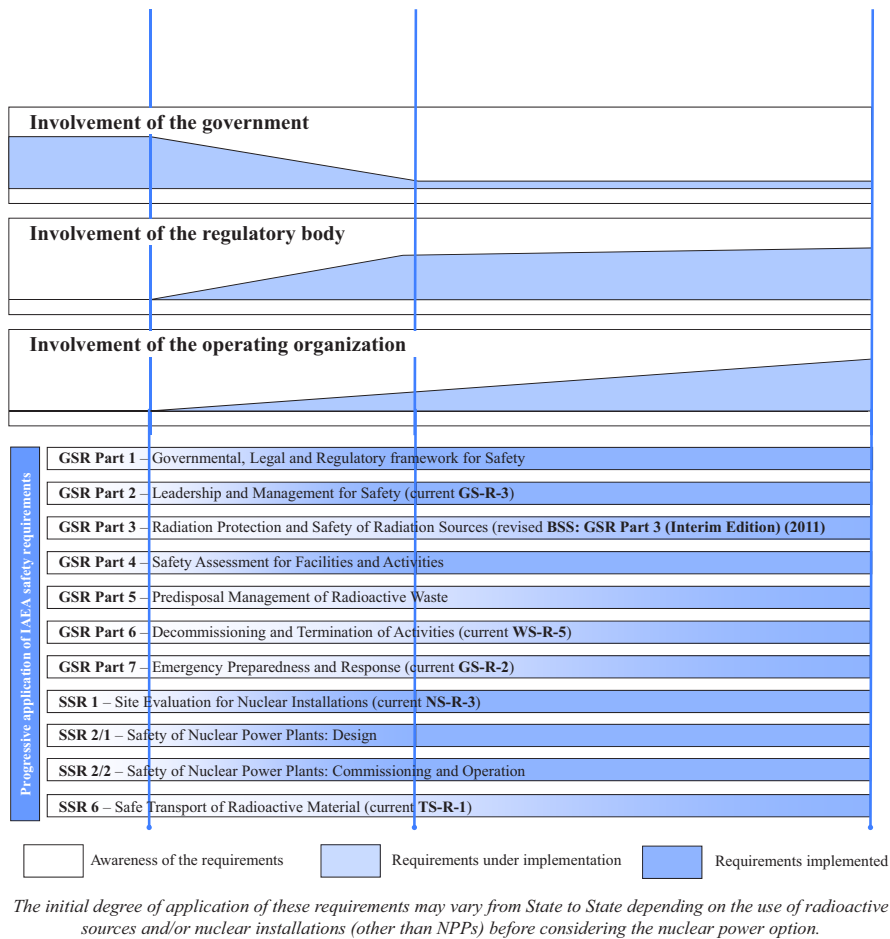


FIG. 4. Progressive involvement of the main organizations in a nuclear power programme and progressive application of the IAEA Safety Requirements (indicative only, to be used with flexibility).

Safety Guide includes consideration of the interface between nuclear safety and nuclear security. Further information on this issue can be found in the INSAG report on The Interface Between Safety and Security at Nuclear Power Plants [7].

1.24. The IAEA's statutory mandate concerns risks associated with ionizing radiation. Conventional risks such as risks associated with chemical hazards are not within the purpose and scope of this Safety Guide; however, they also have to be regulated by the State.

STRUCTURE

1.25. Sections 2 and 3 provide guidance on the development of a nuclear safety infrastructure in line with the IAEA safety standards during Phases 1, 2 and 3. Section 2 addresses the 'general safety requirements' of this infrastructure (elements 1–14), while Section 3 addresses the 'specific safety requirements' of the infrastructure (elements 15–20), in accordance with the structure of the IAEA Safety Standards Series (see Fig. 5). For each of the elements considered, this Safety Guide identifies the main actions that should be taken in Phases 1, 2 and 3, respectively, and also specifies the IAEA Safety Requirements to be complied with.

1.26. In the text, for each of the elements considered, numbered actions appear as 'should' statements, and then the following paragraphs provide the user with further background on, and the rationale for, these numbered actions.

1.27. This Safety Guide specifies, for each phase, the IAEA Safety Requirements publications that serve as a basis for the actions.

1.28. The appendix consists of a summary of all the actions (as 'should' statements) which should be taken in Phases 1, 2 and 3, respectively, as well as the bases for these actions.

1.29. The IAEA's web sites provide a comprehensive list of relevant IAEA Safety Requirements and Safety Guides, as well as other key safety related publications such as INSAG reports (<http://www-ns.iaea.org/standards>, <http://www-pub.iaea.org/books>).

	20 ELEMENTS OF THE SAFETY INFRASTRUCTURE	MAIN SUPPORTING IAEA SAFETY REQUIREMENTS IDENTIFIED	CORRESPONDING NUMBER IN THE LONG-TERM STRUCTURE
SECTION 2 General Safety Requirements	1 - National policy and strategy	GSR Part 1	GSR Part 1
	2 - Global nuclear safety regime		
	3 - Legal framework		
	4 - Regulatory framework		
	5 - Transparency and openness		
	6 - Funding and financing		
	7 - External support organizations and contractors		
	8 - Leadership and management for safety	GS-R-3	GSR Part 2
	9 - Human resources development		
	10 - Research for safety and regulatory purposes		
	11 - Radiation protection	Current BSS (GSR Part 3 (Interim) 2011)	GSR Part 3
	12 - Safety assessment	GSR Part 4	GSR Part 4
	13 - Safety of radioactive waste, spent fuel management and decommissioning	GSR Part 5 WS-R-5	GSR Part 5 GSR Part 6
	14 - Emergency preparedness and response	GS-R-2	GSR Part 7
SECTION 3 Specific Safety Requirements	15 - Operating organization	NS-R-2 (being revised)	SSR 2/2
	16 - Site survey, site selection and evaluation	NS-R-3	SSR 1
	17 - Design safety	NS-R-1 (being revised)	SSR 2/1
	18 - Preparation for commissioning	NS-R-2 (being revised)	SSR 2/2
	19 - Transport safety	TS-R-1	SSR 6
	20 - Interfaces with nuclear security	GSR Part 1	GSR Part 1

FIG. 5. Structure of Sections 2 and 3 of this Safety Guide, in accordance with the structure of the IAEA Safety Standards Series.

1.30. The IAEA web site provides a listing of current IAEA safety standards as well as downloadable files for all standards and information on IAEA safety standards being drafted or reviewed: <http://www-ns.iaea.org/downloads/standards/status.pdf>

1.31. The IAEA has set up a web site for this Safety Guide to provide users with hyperlinks to the applicable Safety Requirements (<http://www-ns.iaea.org/tech-areas/safety-infrastructure>).

2. IMPLEMENTING IAEA GENERAL SAFETY REQUIREMENTS FOR THE ESTABLISHMENT OF THE SAFETY INFRASTRUCTURE

ACTIONS 1–10: NATIONAL POLICY AND STRATEGY FOR SAFETY

General

2.1. A nuclear power programme is a major national undertaking requiring careful planning and preparation, and a major investment in time and human and financial resources. While nuclear power is not unique in this respect, it is considered to be different because of the safety issues associated with the possession and handling of nuclear material and the long term commitment to ensuring safety after the decision to embark on a nuclear power programme has been made.

2.2. Given the wide spectrum of issues to be considered and the implications and duration of the commitments associated with a nuclear power programme, the decision to embark on a nuclear power programme has to come from the government. The prime importance of safety has to be recognized and reflected in policy decisions as well as in the strategy adopted by the government.

2.3. Past experience shows that there are many possible ways to establish a nuclear power programme. States wishing to embark on a first nuclear power plant project may be at various levels of capability with regard to safety, ranging from no experience, to experience with laboratory scale nuclear facilities and industrial applications, the operation of research reactors, or handling of radioactive material in large amounts. In this Safety Guide, for the sake of generality, it is assumed that the State does not have an institution or organization that would be ready to assess the feasibility of the nuclear power option as part of a national energy policy and that could present its findings to the government's highest level decision makers.

2.4. From the earliest phase of the development of safety infrastructure, the prime responsibility for safety will rest with the prospective facility operating organization, and the government is required to establish an effective governmental, legal and regulatory framework to support a high level of safety [5]. The prime responsibility for safety cannot be delegated or outsourced [1]; it must be discharged by the operating organization through leadership, adequate funding, sufficient expertise and legal responsibility.

2.5. A State that is considering launching a nuclear power programme is likely to look for proven existing technologies rather than developing a specific new design. Nevertheless, the choice will be made from among various available technologies. Such a choice may be made at different times depending on the overall policy, but in any case, the policy should emphasize the effective transfer of competence in safety to the State. If there is a strategy of the State to establish an early partnership with a certain other State, the selection of a technology can take place in Phase 1 as part of the decision process to move forward with the nuclear option, or early in Phase 2. In such a case, the partnership between the State providing the technology and the State embarking on a nuclear power programme should include agreements at the governmental level to establish the framework for and objectives of such cooperation. An alternative strategy — the strategy that is described in this Safety Guide — would be first to develop a national knowledge base through a large network of international contacts during Phase 2, and then to open a bidding process.

2.6. The government will decide on the level of national participation in the nuclear power programme and the necessary resources to be allocated to develop the nuclear safety infrastructure. In any circumstance, a vigorous programme for the development of a national workforce with the required competence to manage the nuclear technology and to safely conduct nuclear activities is an essential requisite for a sustainable programme. This development programme for the workforce should be planned and progressively implemented through the three initial phases of the nuclear power programme.

Phase 1

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirement 1 of GSR Part 1 [5];
- Requirements 10 and 29 of GSR Part 3 [8];
- Requirement 2 of GSR Part 5 [9].

Action 1. The government should consider the necessary elements of a national policy and strategy for safety to meet the fundamental safety objective and the principles established in the IAEA Safety Fundamentals [1].

Action 2. The government should provide for the coordination of all activities to establish the safety infrastructure.

Action 3. The government should ensure that the status of the safety infrastructure in relevant areas is assessed and that radiological considerations are adequately taken into account.

Action 4. The government should take due account of the assessment of the elements of the safety infrastructure and of the fundamental principle of justification when making a decision on whether or not to introduce a nuclear power programme.

2.7. In a national policy and strategy for safety, the fundamental safety objective and the fundamental safety principles established in the IAEA Fundamental Safety Principles [1] apply:

- Principle 2 of the IAEA Fundamental Safety Principles [1], ‘Role of government’, states that “The government is responsible for the adoption within its national legal system of such legislation, regulations, and other standards and measures as may be necessary to fulfil all its national responsibilities and international obligations effectively...”.
- The national position should reflect an understanding of the principles expressed in the IAEA’s Fundamental Safety Principles [1], in particular Principle 4: Justification of facilities and activities, which states that “Facilities and activities that give rise to radiation risks must yield an overall benefit”. Therefore, a full and proper evaluation should be undertaken before deciding to introduce a nuclear power programme in the State. At this first stage, the assessment of the balance between risks and benefits may be of a general nature.

2.8. For the preparation of the information that the government needs as a basis for its decision and for the coordination of all the work that is needed to facilitate a knowledgeable decision regarding a prospective nuclear power programme, it may be appropriate for the government to appoint a project organization that is given an explicit governmental mandate.

2.9. The government should also take into account:

- Binding international instruments and other international instruments (see also paras 2.18–2.32 on the global nuclear safety regime);
- The necessary scope and elements of the governmental, legal and regulatory framework for safety (see also paras 2.33–2.47 on the legal framework and paras 2.48–2.83 on the regulatory framework);

- The need for and provision for a vigorous competence building programme and the associated human and financial resources (see also paras 2.158–2.177 on human resources development and paras 2.97–2.106 on funding and financing);
- The provisions and framework for research and development (see also paras 2.178–2.189 on research for safety and regulatory purposes);
- The promotion of leadership and management for safety, including safety culture (see also paras 2.142–2.157 on leadership and management for safety);
- The need for and provision for spent fuel management and radioactive waste management, including disposal of radioactive waste (see also paras 2.222–2.238 on safety of radioactive waste management, spent fuel management and decommissioning³); and
- Potential environmental, social and economic impacts of a prospective nuclear power programme.

2.10. Although the State may already have experience in the management of research reactors or radioactive sources, there are new activities that should be commenced in a timely manner, and that will require the corresponding resources (human, organizational and financial).

2.11. In most States, major projects are subject to environmental restrictions and their promoters have the obligation to demonstrate the impacts of their project (including the impacts of the different alternatives considered) by means of a document generally called the environmental impact assessment report. The authority to which such a report should be submitted is typically a ministry of the environment or an environmental authority. Interfaces, roles and coordination among other organizations involved in the environmental impact assessment should also be taken into consideration. For a nuclear power plant project, such a report is very broad and the radiological environmental impact analysis is only a part of the environmental impact assessment. Non-radiological impacts to be assessed typically include: significant environmental impacts on water, air, flora and fauna; land use, population aspects, residues and emissions (all types, i.e. water, air and soil pollution, noise, vibration, light, heat, radiation). This Safety Guide deals only with the radiological impacts, in accordance with the statutory mandate of the IAEA³. Principle 7 of the IAEA Fundamental Safety Principles [1] states that

³ Although non-radiological aspects of safety (e.g. industrial safety, fire safety) and environmental protection are not explicitly considered in this Safety Guide, States are expected to fulfil their international undertakings and obligations in relation to these.

“People and the environment, present and future, must be protected against radiation risks”. The radiological environmental impact analysis (which in most States constitutes one section of the environmental impact assessment) is further addressed in paras 2.190–2.201 on radiation protection and paras 3.24–3.48 on site survey and site evaluation. In the event that the State already has a regulatory body for radiation protection and nuclear safety, this body should contribute to the review of the environmental impact assessment in its field of responsibility.

2.12. Before making a knowledgeable decision regarding the introduction of a nuclear power programme, the government should ensure that the expected environmental impact is thoroughly understood, and that an adequate assessment of the State’s safety infrastructure and needs has been conducted. At the end of Phase 1, the government should be fully aware that embarking on a nuclear power programme implies a firm and long term commitment to maintaining activities that are necessary for ensuring safety.

Phase 2

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirement 1 of GSR Part 1 [5];
- Requirements 10 and 29 of GSR Part 3 [8];
- Requirement 2 of GSR Part 5 [9].

Action 5. The government should establish a clear national policy and strategy for meeting safety requirements in order to achieve the fundamental safety objective and to apply the fundamental safety principles established in the IAEA Safety Fundamentals [1].

Action 6. The government should establish a policy for knowledge transfer for ensuring safety by means of contracts and agreements with organizations in other States that may be involved in the nuclear power programme.

Action 7. The government should ensure identification of responsibilities and their progressive allocation to the relevant organizations involved in the development of the safety infrastructure.

Action 8. The government should ensure that all the necessary organizations and other elements of the safety infrastructure are developed efficiently and that their development is adequately coordinated.

2.13. After the State has decided to introduce a nuclear power programme, the implementation of activities begins in Phase 2. In Phase 2, the government gradually reduces its involvement, in parallel with the development of other organizations such as the regulatory body, the operating organization and relevant permanent structures within ministries. This transition should be carefully considered and prepared with a view to preventing any break in the effectiveness of the process and in the national commitment to nuclear safety. The crucial role of coordinating the development of the safety infrastructure among the various permanent organizations continues to be ensured by the government until all organizations and elements are in place and functioning, with a clear definition of roles and responsibilities.

2.14. The government should demonstrate a firm commitment to safety by providing its support and the necessary resources for the implementation of an effective safety infrastructure.

Phase 3

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirement 1 of GSR Part 1 [5];
- Requirements 10 and 29 of GSR Part 3 [8];
- Requirement 2 of GSR Part 5 [9].

Action 9. The government should continue to implement the national policy and strategy for safety.

Action 10. The government should ensure that the regulatory body and the operating organization are fulfilling their responsibilities.

2.15. The government should ensure that the coordination mechanisms put in place are efficient and effective, and should improve them as necessary.

2.16. Other actions to be taken by the government are described in the following sections of this Safety Guide.

ACTIONS 11–19: GLOBAL NUCLEAR SAFETY REGIME

General

2.17. A nuclear power programme in any State cannot be treated in isolation, owing to the potential transboundary effects of a radioactive release. A nuclear accident could have consequences anywhere through the impact on public opinion. States have a shared need for universal safe operation of nuclear facilities and safe conduct of activities. The national safety policy and the strategy adopted by the government should therefore take full benefit of effective participation in the global nuclear safety regime. However, the prime responsibility for safety rests within each State and with the licensed operators of nuclear facilities.

Phase 1

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

— Requirements 1 and 14 of GSR Part 1 [5].

Action 11. The government should prepare for participation in the global nuclear safety regime.

Action 12. The government should begin a dialogue with neighbouring States regarding its projects for establishing a nuclear power programme.

Action 13. The government and relevant organizations, if they already exist, should establish contact with organizations in other States and international organizations to seek advice on safety related matters.

2.18. Specific considerations should be given to neighbouring States whose interests could be affected by the State's nuclear power programme, both in normal operation and in the event of an accident. The government should implement a consultation mechanism that would allow neighbouring States to express their views and concerns. Such a process should be continued during all phases of development of the State's nuclear power programme.

2.19. International cooperation is an opportunity to share and benefit from the experience of States that have already implemented, or are also in the process of implementing, a nuclear power programme. In Phase 1, States embarking on the

development of a nuclear power programme will find it useful to establish contact with States that have advanced nuclear power programmes and with international organizations to seek advice on safety related matters, and to derive benefit from international operating experience and regulatory experience and from the dissemination of lessons learned. Liaising with other States with similar objectives for nuclear power programmes should also be considered.

2.20. The State should prepare for involvement in the global nuclear safety regime, which is promoted by the IAEA on the basis of the following elements:

- The international conventions that establish robust common principles and obligations for ensuring safety in the use of radiation, radioactive material and nuclear energy, and to provide an effective coordinated response to emergencies;
- Codes of conduct that promote good practices in the relevant operations;
- Internationally agreed IAEA safety standards that support the development of harmonized national safety requirements, guides and practices;
- International peer reviews of safety levels that aim for mutual learning by participating Member States;
- Knowledge networks and expert networks;
- Multinational and bilateral cooperation in safety matters that is aimed at enhancing safety by means of harmonized approaches and the increased quality and effectiveness of safety reviews and inspections.

2.21. In this phase, the government gives consideration to becoming party to international conventions and codes of conduct such as:

- The Convention on Nuclear Safety⁴ [10];
- The Convention on Early Notification of a Nuclear Accident [11];
- The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency [12];
- The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [13];
- The Convention on the Physical Protection of Nuclear Material [14];
- The Code of Conduct on the Safety and Security of Radioactive Sources [15].

⁴ The Convention on Nuclear Safety, which was developed to promote and harmonize nuclear safety, is a legally binding international agreement that was ratified by all States with operating nuclear power plants. The Convention sets up a system of national reporting and peer reviews to ensure that States are complying with their obligations to meet recognized international safety standards and to apply good practices.

Phase 2

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirements 1 and 14 of GSR Part 1 [5];
- Requirements 6.3–6.6 of GS-R-3 [16].

Action 14. All the relevant organizations should participate in the global nuclear safety regime.

Action 15. The State should become a party to the relevant international conventions, as identified in Phase 1.

Action 16. All relevant organizations should strengthen their cooperation on safety related matters with States with advanced nuclear power programmes.

2.22. One important consideration in the successive decision processes in a nuclear power programme is the interdependence of activities relating to nuclear power between all States. In Phase 2, activities that are required in the international agreements and conventions identified in Phase 1 should therefore be commenced. This will help to promote safety nationally and globally, as well as enhancing international confidence and trust. The consent of a State to be bound by international instruments may be expressed by means of signature, ratification, acceptance, approval or accession in accordance with the provisions of the respective instrument.

2.23. Activities and participation in the global nuclear safety regime that were identified and planned during Phase 1 should be progressively implemented by those parties who were identified and were assigned the responsibility to carry them out. The operating organization and the regulatory body participate, although for different reasons, in their respective international networks. An important part of international cooperation would be the exchange of construction experience and operating experience. The regulatory body should assess whether experience indicates that modifications are needed in the regulatory requirements or whether more attention will be given to certain safety issues in assessment and inspections. The operating organization should participate to be alerted to experience that may indicate the need for design changes or the reconsideration of operation or maintenance practices, so as to provide continued assurance of future safe operation.

2.24. Effective participation in international activities and networks promotes the transfer of knowledge on lessons learned and best practices from other States. It also facilitates the provision of support by States with advanced nuclear power programmes. Such support could include two way long term assignments of experts: whether consultants from other States coaching the developing organizations or experts sent to other States for on the job training.

2.25. Commitment to complying with the IAEA safety standards and to participation in international safety reviews and safety services on the basis of safety standards should be reaffirmed. Consideration should also be given to other international safety standards and to codes of conduct as well as to INSAG publications.

Phase 3

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirements 1 and 14 of GSR Part 1 [5];
- Requirements 6.3–6.6 of GS-R-3 [16];
- Requirement 24 of Ref. [17].

Action 17. All the relevant organizations should ensure continued participation in international activities and international networks for strengthening safety.

Action 18. The operating organization should implement a cooperation programme with the vendor and with other organizations operating nuclear power plants of the same type as that selected, for the purpose of strengthening safety.

Action 19. The regulatory body should implement a cooperation programme with the vendor State and with other regulatory bodies that have experience of oversight of nuclear power plants of the same type as that selected.

2.26. The State should participate in the review meetings of the relevant international conventions to which it has become a party.

2.27. The regulatory body, the operating organization and other relevant entities should strengthen their cooperation with their respective counterparts in other States and with international networks.

2.28. To gain feedback from regulatory bodies in other States, the regulatory body should extend its contacts, in particular through its participation in bilateral, multilateral and international cooperation on the subject of a nuclear power programme.

2.29. Assistance from the regulatory body of the supplier State, as well as from other regulatory bodies that have oversight experience with other nuclear power plants of the same type as that selected, including temporary assignments of staff, should be sought to the extent possible.

2.30. Exchange of results of safety reviews and joint inspections with regulatory bodies in other States having oversight experience with nuclear power plants of the type selected could be used for increasing the understanding of important safety issues.

2.31. The operating organization should establish professional cooperation arrangements with operating organizations in other States, as well as with international operator organizations such as the World Association of Nuclear Operators (WANO).

2.32. External support organizations, research organizations and academic bodies should also work in close cooperation with their counterparts in other States.

ACTIONS 20–23: LEGAL FRAMEWORK

General

2.33. Principle 2 of the IAEA's Fundamental Safety Principles [1], 'Role of government', states that "An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained."

2.34. The legal framework usually includes several levels of documents. The nuclear law itself typically does not contain detailed technical requirements. Instead it specifies the general rules and procedures for licensing nuclear facilities and the tasks and authorities of the parties involved in licensing and regulation. The technical safety requirements will usually be established by the regulatory body in the form of regulations and licence conditions.

Phase 1

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirements 1, 2, 3 and 4 of GSR Part 1 [5];
- Requirement 2 of GSR Part 3 [8];
- Requirement 1 of GSR Part 5 [9];
- Requirements 3.3 and 3.4 of WS-R-5 [18].

Action 20. The government should identify all necessary elements of a legal framework for the safety infrastructure, and should plan how to structure it and develop it.

Action 21. The government should consider the process that should be employed to license nuclear facilities in the later stages of the programme.

2.35. Establishing a nuclear power programme requires dedicated legislation that has not usually been enacted in a State when entering Phase 1. However, some of the needs for legislation may have been met in respect of other activities. The State should therefore perform a complete assessment of the need for legislation and a regulatory framework to support the safe operation and effective oversight and licensing of a nuclear power plant.

2.36. On the basis of such an assessment, the State should develop a plan to enhance its existing legal and regulatory framework to incorporate all elements. The IAEA's Handbook on Nuclear Law [19] provides detailed guidance on this subject.

2.37. A nuclear law, which should ensure transparency and should be clearly understandable, is prepared in Phase 1 so as to be enacted as a starting point of Phase 2. As established in GSR Part 1 [5], para. 2.5, a governmental, legal and regulatory framework for safety is required to set out the following:

- (1) Safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future (see also paras 2.190–2.201 on radiation protection);
- (2) The types of facilities and activities that are included in the scope (and that should be licensed in connection with nuclear power production);

- (3) The type of authorization⁵ that is required for the operation of facilities and the conduct of activities, in accordance with a graded approach;
- (4) The rationale for the authorization of new facilities and activities and the applicable decision making process;
- (5) Provision for the involvement of interested parties and for their input in decision making (see also paras 2.84–2.96 on transparency and openness);
- (6) Provision for assigning legal 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 (see also paras 3.1–3.23 on the operating organization);
- (7) The establishment of a regulatory body (see also paras 2.48–2.83 on the regulatory framework);
- (8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach (see also paras 2.202–2.221 on safety assessment);
- (9) The authority and responsibility of the regulatory body for promulgating (or preparing for enactment) regulations and preparing guidance for their implementation (see also paras 2.48–2.83 on the regulatory framework);
- (10) Provision for the inspection of facilities and activities and for the enforcement of regulations, in accordance with a graded approach (see also paras 2.48–2.83 on the regulatory framework);
- (11) Provision for appeal against decisions of the regulatory body;
- (12) Provision for preparedness for and response to a nuclear or radiological emergency (see also paras 2.239–2.250 on emergency preparedness and response);
- (13) Provision for the interface with nuclear security (see also paras 3.94–3.108 on interfaces with nuclear security);
- (14) Provision for the interface with the system of accounting for and control of nuclear material (this is not further addressed in this Safety Guide);
- (15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety (see also paras 2.158–2.177 on human resources development and paras 2.178–2.189 on research for safety and regulatory purposes);

⁵ Authorization to operate a facility or to conduct an activity may be granted by the regulatory body or by another governmental body to an operating organization or to a person. ‘Authorization’ includes approval, written permission, licensing, certification or registration (see Ref. [1]).

- (16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities (see also paras 2.222–2.238 on safety of radioactive waste management, spent fuel management and decommissioning, and paras 2.97–2.106 on funding and financing);
- (17) The criteria for release from regulatory control;
- (18) The specification of offences and the corresponding penalties;
- (19) Provision for controls on the import and export of nuclear material and radioactive material and for their tracking within and, to the extent possible, outside national boundaries, such as tracking of the authorized export of radioactive sources (this is not further addressed in this Safety Guide).

2.38. For drafters of legislation who are unfamiliar with nuclear law and nuclear technology, an option for consideration in preparing nuclear legislation is to apply models provided by the IAEA and other international organizations or the text of laws adopted by States with developed legal frameworks. This approach could be practicable and should be considered for a number of reasons. Firstly, it reduces the amount of new legal texts to be drafted. Secondly, it takes advantage of the technical or legal expertise of experienced organizations or States. Thirdly, in the case of incorporation of IAEA models, it can help a State to comply with the requirements of the IAEA and to receive IAEA technical assistance.

2.39. These advantages are accompanied by difficulties that should be given careful consideration, however. Firstly, there are concerns about whether and how international requirements or requirements of another State will fit into a State's legal structure. Secondly, standards or guidelines prepared elsewhere may contain provisions that are inconsistent with or contradictory to important features of a State's legal structure. Thirdly, translation might raise other concerns, since terms relating to nuclear energy that are derived from another language may be meaningless or confusing to persons expected to apply the national law or to comply with it. In addition, difficulties may arise from the fact that the external requirements (e.g. international instruments) may be subject to change, even on a regular basis.

2.40. There is a relationship between the development of nuclear legislation and the consideration of becoming party to the international conventions in the field of nuclear energy. The State should therefore ensure that the nuclear law is consistent and reflects the provisions of the relevant international instruments.

2.41. After preparation of a reasonably detailed initial draft, many governments have found it useful to subject the draft nuclear law to an independent review, to assess its adequacy and public acceptability.

2.42. To ensure consistency of legislation and to avoid conflicts and ambiguity in the application of nuclear law, the State should also identify correlated laws to be prepared or amended, both safety related and those not directly safety related. Such laws concern: radiation safety, industrial safety and fire safety, environmental protection, occupational health and safety, waste management, nuclear liability, criminal law enforcement, land use planning regulations, and international trade law and customs law, as relevant.

2.43. In Phase 1, the government should recognize that effective licensing requires a sound legal and governmental infrastructure, including a regulatory body with well defined responsibilities and functions. To conduct licensing effectively, the general process to be utilized should be considered and communicated to all interested parties as early as possible in the development of the nuclear power programme. This provides the applicant with the information that will be necessary to support licensing submissions, as well as information on the stages of development that will require licensing. Further information on this topic is given in Ref. [20].

Phase 2

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirements 1, 2, 3 and 4 of GSR Part 1 [5];
- Requirement 2 of GSR Part 3 [8];
- Requirement 1 of GSR Part 5 [9];
- Requirements 3.3 and 3.4 of WS-R-5 [18].

Action 22. The government should enact and implement the essential elements of the legal framework for the safety infrastructure.

2.44. During Phase 2, all essential legislation identified during the assessment process of Phase 1 should be enacted.

2.45. To ensure consistency of legislation, the State should also complement or amend the related laws identified in Phase 1.

Phase 3

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirements 1, 2, 3 and 4 of GSR Part 1 [5];
- Requirement 2 of GSR Part 3 [8];
- Requirement 1 of GSR Part 5 [9];
- Requirements 3.3 and 3.4 of WS-R-5 [18].

Action 23. The government should ensure that the legal framework for the safety infrastructure is fully in place and that the legislation is complied with by the relevant organizations.

2.46. In Phase 3, the role of the government is to ensure that the legal framework is fully in place, and that the legislation is implemented, complemented and amended, as appropriate.

2.47. Many States have established mechanisms for helping to determine whether legislation is being implemented in a manner consistent with its objectives. This can help to maintain confidence in the regulatory process. Periodic reports by regulatory bodies or audits conducted under an appropriate quality management system are examples in this regard.

ACTIONS 24–38: REGULATORY FRAMEWORK

General

2.48. Principle 2 of the IAEA's Fundamental Safety Principles [1], 'Role of government', states that "An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained."

2.49. In a nuclear power programme, the regulatory body should verify that site evaluation, design, construction, commissioning, operation and decommissioning comply with the relevant safety standards. The core functions of the regulatory body, as allocated in the legislation, include the following:

- Preparation of regulations and guides;
- Authorization of facilities and activities;
- Review and assessment of information relevant to safety;

- Inspection of facilities and activities;
- Enforcement of compliance with regulations and standards.

2.50. The regulatory body's responsibilities also include:

- Ensuring that emergency preparedness arrangements and emergency plans are in place to protect workers, the public and the environment;
- Establishing appropriate means of providing information to interested parties in a transparent manner;
- Promoting safety culture;
- Promoting the necessary coordination with other national and international bodies.

2.51. The regulatory structures and approaches currently in use vary significantly from one State to another. The approaches used in States with large nuclear power programmes may differ from those in States with small nuclear power programmes. Also, the approaches in States with a nuclear power plant vendor may differ from those in States that import nuclear power plants.

2.52. To be effective, the regulatory body should have adequate authority, independence, financial resources and technically competent staff. The regulatory body should make use of the services of external support organizations (see actions 61–71) in areas where it needs additional expertise. Requirements for an effective regulatory body are provided in GSR Part 1 [5], and the implementation of the requirements is supported by Safety Guides [21–25].

2.53. Development of human resources of the regulatory body and the development of its management system are addressed in paras 2.158–2.177 on human resources development and paras 2.142–2.157 on leadership and management of safety, respectively.

Phase 1

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirements 1, 3, 4, 7 and 11 of GSR Part 1 [5];
- Requirements 2 and 3 of GSR Part 3 [8];
- Requirement 1 of GSR Part 5 [9].

Action 24. The government should recognize the need for an effectively independent and competent regulatory body, and should consider the appropriate position of the regulatory body in the State's governmental and legal framework for safety.

Action 25. The government should seek advice from the regulatory body on radiation safety issues relating to a nuclear power programme.

Action 26. The government should identify the prospective senior managers of the regulatory body.

2.54. In Phase 1, there may already be a regulatory body for the regulation of radiation safety. In this case, consideration should be given to whether the scope of tasks of the existing regulatory body will be extended or whether a new regulatory body will be created. If different authorities are to coexist, then clarity of their respective roles and responsibilities should be ensured. In any case, emphasis should be given to assessing and understanding the appropriate position of the regulatory body in the governmental structure of the State.

2.55. The prospective senior manager of the regulatory body and other senior staff should be identified. These individuals should begin acquiring knowledge of nuclear regulatory matters.

2.56. The development of the regulatory framework involves maintaining a balance between prescriptive approaches and more flexible goal setting approaches. This balance might depend upon the State's legal system and regulatory approach. Since the approach chosen will have a major influence on the resources needed by the regulatory body, and the decision on the approach should be made in Phase 2, the persons expected to be in charge of the regulatory body should start learning and considering various regulatory approaches in Phase 1. A strategy is envisioned to determine which regulatory approach will be chosen.

2.57. IAEA Safety Standards Series No. GS-G-1.4, Documentation for Use in Regulating Nuclear Facilities [24], presents some advantages and disadvantages of different regulatory approaches and provides further guidance on this topic.

Phase 2

The following actions are recommended to be completed in this phase as a step towards the full implementation of all relevant IAEA Safety Requirements:

- Requirements 1, 3, 4, 7, 11, 16, 17, 18, 21, 22, 23, 24, 25, 26, 30 and 32 of GSR Part 1 [5];
- Requirements 2 and 3 of GSR Part 3 [8];
- Requirements 1 and 3 of GSR Part 5 [9];
- Requirements 3.5 and 3.6 of WS-R-5 [18];
- Requirement 3.7 of GS-R-3 [16].

Action 27. The government should establish an effectively independent regulatory body and should empower it with adequate legal authority, technical and managerial competence, and human and financial resources, to discharge its responsibilities in the nuclear power programme.

Action 28. The government should appoint senior managers and key experts to the regulatory body and should assign to them the responsibility for developing the organization.

Action 29. The regulatory body should consider the various regulatory approaches that are applied for nuclear power programmes of the same size, and should tentatively plan its approach, taking into account the State's legal and industrial practices and the guidance provided in the IAEA safety standards.

Action 30. The regulatory body should issue regulations and guides specifying the documentation and procedures necessary in the various steps of the licensing process and inspections to be conducted.

Action 31. The regulatory body should specify the safety requirements that should be known for the bidding process.

Action 32. The regulatory body should begin establishing a suitable working relationship with the operating organization and with international organizations.

2.58. The regulatory body's core functions should be clearly defined in the legislation, and as stated in GSR Part 1 [5]. Specific guidance to assist the

regulatory body in establishing its regulatory framework can be found in Safety Guides Nos GS-G-1.1 to GS-G-1.5 [21–25].

2.59. The regulatory body should be effectively independent of all entities — including parts of the government — that promote the development of the nuclear industry. The regulatory body should have the legal authority, technical competence and resources to fulfil its statutory obligation to regulate facilities and activities, and its regulatory decisions should be free from undue political and economic influence.

2.60. In establishing the regulatory body, a knowledgeable decision should be made on whether to expand the existing regulatory body or whether to create a new regulatory body. If the regulatory body consists of more than one authority, there should be formal arrangements to ensure that regulatory responsibilities and activities are clearly specified and coordinated, to avoid any omissions or unnecessary duplication and to avoid conflicting requirements being placed upon the operating organization.

2.61. The organizational structure and size of the regulatory body could be influenced by many factors, such as the number of authorities involved in the regulatory process, the legal system, the regulatory approach selected, and the role and capability of external support organizations.

2.62. The organization of the regulatory body, its structure and size, and the technical skills of staff, will change as the regulatory body goes through various stages in Phase 2, starting with its early organization and preparation of its regulatory framework to the stage where it is able to specify regulations and to make safety assessments as part of the licensing process. The regulatory body therefore develops competences in managing growth and change.

2.63. One of the first things that the regulatory body should consider before starting the recruitment of its staff is its future regulatory approach. The type of approach chosen can have a major impact on the necessary number and qualifications of the regulatory staff. Notwithstanding the approach chosen, an approach should be developed and enough staff should be recruited to cover all core competences necessary for understanding all relevant safety issues of the nuclear power programme. The regulatory approach also has implications for the need for external expert support for the regulatory body.

2.64. In Phase 2, before the State decides which reactor technology is going to be deployed, the regulatory body should be aware of the two main alternative

regulatory approaches: a prescriptive approach with a large number of regulations, or a performance, function and outcome oriented approach. Each regulatory approach has benefits and disadvantages associated with it, and there are also approaches that combine features of these two main alternatives. When a decision is made in Phase 3 on the reactor technology to be deployed, the regulatory body should be ready to adopt a regulatory approach that best suits the State's needs. The regulatory body should have its chosen approach approved by the government, since there will be resource implications. Specific features of these two alternatives are listed below:

- A *prescriptive regulatory approach* places a great deal of importance on the adequacy of the regulations for safety and requires detailed development. The regulations establish clear requirements and expectations for the regulatory body as well as for the operating organization, and thus can be used to promote systematic interaction between the regulatory body and other parties. The regulations could set detailed technical requirements, or could identify issues that the operating organization and its suppliers should address and present for assessment by the regulatory body. Specific technical requirements can then be taken from relevant international industrial standards (including nuclear specific standards) or industrial standards of other States, as agreed by the regulatory body at an early stage of the licensing process for nuclear power plants. Issuing detailed regulations places a high demand on the regulatory body's resources for their development and updating, which adds to the administrative burden.
- A *performance based regulatory approach* allows the operating organization more flexibility in determining how to meet the established safety goals and may require fewer, less detailed regulations. However, this approach requires the establishment of specific safety goals and targets. Verifying that appropriate measures to ensure safety have been identified by the operating organization may be difficult unless the regulatory body's staff, the staff of its external support organization and the staff of the operating organization all have a high level of professional competence and are able to interact to determine whether established safety objectives for each topic are met.

2.65. Besides the general alternatives just described, the approaches in different States vary with respect to the scope and depth of safety assessment and inspection. The scope of issues that are under regulatory control may include all structures, systems and components classified as safety relevant or may be limited to the most safety relevant parts only. The targets of the comprehensive and systematic regulatory control and inspections are specified in a deterministic